



# Substance Use Disorder PRIVACY RULES

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Business Assurance and Compliance  
Health and Human Services Agency  
County of San Diego  
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# DISCLAIMER



This slide deck is provided as an aide to help you manage your agency's privacy requirements. It remains the responsibility of your agency to ensure your program is aware of and adheres to all applicable laws, rules, regulations, and contractual requirements. This slide deck includes common topics but is not meant to be a comprehensive list of requirements nor to provide legal advice.

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# POTENTIAL PRIVACY CONSIDERATIONS



LIVE WELL  
SAN DIEGO

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# CONTRACT REQUIREMENTS



- Article 14 Language: ([Article 14](#))
- Substance Use Disorder DMC-ODS Agreement with DHCS:  
([DMC-ODS State Agreement](#))
- Services template requirements
- Statement of Work
- Substance Use Disorder Provider Operations Handbook  
(<https://www.optumsandiego.com/content/sandiego/en/county-staff---providers/dmc-ods.html>)

# EMPLOYER POLICIES & PROCEDURES



- Minimum Necessary
- Training
- Use and Disclosures
- Provision of NPP
- Safeguards
- Breach Notifications

Examples of Policies and Procedures:

[https://www.sandiegocounty.gov/content/sdc/hhsa/programs/sd/compliance\\_office/resources/privacy/policies\\_procedures.html](https://www.sandiegocounty.gov/content/sdc/hhsa/programs/sd/compliance_office/resources/privacy/policies_procedures.html)

# CODE OF ETHICS



- Employer Code of Ethics
- Professional Association, Certification and/or Licensing Board Code of Ethics

Examples of Codes of Ethics:

[Code of Ethics.pdf](#)

[HHSA: Code of Conduct](#)

# CLIENT REQUESTS



- Access to Records
- Amendments
- Accounting of Disclosure
- Requests for Restrictions
- Alternate Communications
- Authorizations/Disclosure Requests
- Privacy complaints/Non-retaliation

Examples of Client Requests Processes and Forms: ([Privacy Resources](#))



# STATUTES & REGULATIONS



- 42 CFR Part 2 – Confidentiality of Substance Use Disorder Patient Records (Part 2)
  - [2024-02544.pdf](#)
- 45 CFR Parts 160, 162, and 164 – Health Information Portability & Accountability Act (HIPAA)
  - [eCFR :: 45 CFR Part 160 -- General Administrative Requirements](#)
  - [eCFR :: 45 CFR Part 164 Subpart C -- Security Standards for the Protection of Electronic Protected Health Information](#)
- State Legislation
  - [California Code, HSC 11845.5.](#)

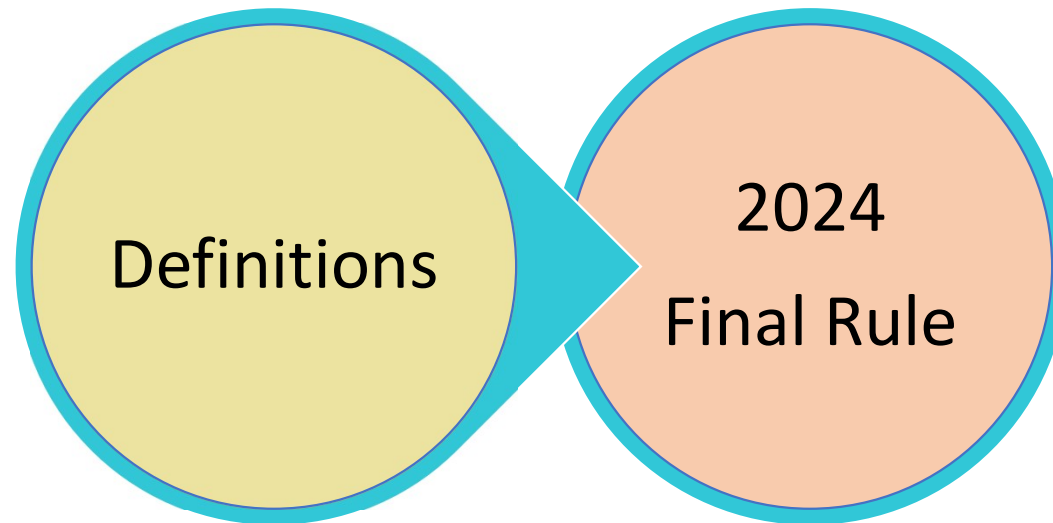
# STATUTES & REGULATIONS



## PART 2 VS. HIPAA - HIGHLIGHTS

	HIPAA	Part 2
Program Applicability	"Covered entities" (healthcare providers, health plans, healthcare clearinghouses) and Business Associates	SUD patient records from federally-assisted "Part 2 programs"
Data Applicability	"Protected Health Information"	Records identifying an individual as seeking or receiving SUD treatment
Purpose	...to ensure the integrity, confidentiality, and accessibility of PHI ...to provide individuals with rights to understand and control how their PHI is used	...to encourage people to seek SUD treatment and reduce stigma through enhanced confidentiality
Disclosures	Permits disclosures without patient authorization for treatment, payment and healthcare operations	Generally, requires patient consent for disclosures related to treatment, payment, and healthcare operations

# PART 2 DEEP DIVE



# PART 2 DEFINITIONS



- “Part 2 Records” include any patient identifying information created, received, or acquired by a “Part 2 Program”
- “A Part 2 Program” is an individual, entity, or an identified unit/personnel in a general medical facility, that “holds itself out” as providing diagnosis, treatment, or referral for treatment for SUD, and which is federally assisted.
- “Holds itself out” means any activity that would lead one to reasonably conclude that the Program provides SUD diagnosis, treatment, or referral

SAMHSA’s “Does Part 2 Apply to Me?”: <https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>

# PART 2 FINAL RULE OF 2024



Provision	What Changed?	Why Was This Changed?
<b>Single Consent</b>	Part 2 now allows for a single consent form for all treatment, payment and health care operations disclosures, including care coordination, instead of one consent form per entity/purpose. Allows HIPAA Covered Entities and Business Associates that receive records under this consent to redisclose the records in accordance with HIPAA regulations	To facilitate more efficient coordination of care and align more closely with HIPAA.
<b>Separate Consent Needed for Legal Proceedings</b>	Restricts the use of records and testimony in civil, criminal, administrative, and legislative proceedings against clients, without client consent or a court order.	To continue and strengthen Part II's purpose of encouraging individuals to seek and participate in SUD treatment without fear of legal consequences.
<b>Client Rights</b>	Part 2 clients now have the right to receive an accounting of disclosures and the right to request restrictions on their SUD records.	To afford SUD clients the same rights to their SUD information that clients have had under HIPAA.

[Part II Final Rule Fact Sheet](#)

# PART 2 FINAL RULE OF 2024



Provision	What Changed?	Why Was This Changed?
<b>Penalties</b>	Aligns Part 2 penalties with HIPAA by replacing criminal penalties currently in Part 2 with civil and criminal enforcement authorities that also apply to HIPAA violations.	To align administration of Part II more closely with HIPAA
<b>No Segregation of Records</b>	SUD records no longer have to be segregated or segmented from the rest of the medical record	To improve the coordination of care between all providers to a client when the client signs the consent. To reduce administrative burdens for providers.
<b>Protection of SUD Counseling Notes</b>	Creates a new definition for “SUD Counseling Notes” created by an SUD Counselor and maintained separately from the medical record. SUD Counseling Notes require specific consent from an individual and cannot be used or disclosed based on a broad TPO consent. This is analogous to protections in HIPAA for psychotherapy notes.	To provide greater protection to specific notes used by an SUD counselor to serve a client.
<b>Breach Notification</b>	Part II now includes the same requirements for breach notification as apply under HIPAA.	To align administration of Part II more closely with HIPAA

# PART 2 FINAL RULE OF 2024



Provision	What Changed?	Why Was This Changed?
<b>Safe Harbor</b>	Clarifies and strengthens the reasonable diligence steps that investigative agencies must follow to be eligible for the safe harbor: before requesting records, an investigative agency must look for a provider in SAMHSA's online treatment facility locator and check a provider's Patient Notice or HIPAA Notice of Privacy Practices to determine whether the provider is subject to Part 2.	To place more responsibility on the part of investigative agencies in determining which providers are subject to Part II and therefore, which records have greater protections.
<b>Disclosures to Public Health Authorities</b>	Permits disclosure of records without patient consent to public health authorities, provided that the records disclosed are de-identified according to the standards established in the HIPAA Privacy Rule	To improve Public Health response while continuing to provide protections to SUD clients.
<b>Notice of Privacy Practices</b>	Applies the same requirement to inform SUD clients of their rights as is required under HIPAA's Notice of Privacy Practices.	To inform SUD clients of the rights they have under Part II and to align Part II more closely with HIPAA.

## PART 2 RESOURCES



- SAMHSA FAQ and Fact Sheets on Part 2:
  - <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>
- ASAM et al.'s 'Closer Look at Part 2':
  - <https://www.asam.org/docs/default-source/advocacy/coe-phi-faqs-about-42-cfr-part-2.pdf>



# PROPOSED CHANGES TO HIPAA



HHS has issued a **Notice of Proposed Rule Making (NPRM)** to the HIPAA Security Rule to address the rapidly growing threat to cyber security and specifically the increase in cyber attacks targeting the health care system. [Federal Register :: HIPAA Security Rule To Strengthen the Cybersecurity of Electronic Protected Health Information](#)

The proposed rule would modify the HIPAA Security Rule to require covered entities and their business associates, to strengthen cybersecurity protections.

## Proposed changes include, but are not limited to:

Converts many standards from “addressable” to “required.”	Requires written documentation of all Security Rule policies, procedures, etc...
Requires IT asset inventory and a network map that illustrates the movement of ePHI through the entity’s information systems.	More robust and greater specificity in security risk analysis.
More robust and greater specificity in contingency planning.	Increased accountability to Covered Entities from Business Associates regarding the BA’s compliance with the Security Rule.

# OTHER PRIVACY DEVELOPMENTS



- **ONC's Cures Act Final Rule on Information Blocking**
  - <https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule>
- **CMS Interoperability and Patient Access Final Rule: [CMS Interoperability and Patient Access Final Rule \(CMS-9115-F\)](#)**
- **HIPAA Reproductive Health Final Rule: [Federal Register HIPAA Privacy Rule To Support Reproductive Health Care Privacy](#)**