



Substance Use Disorder PRIVACY RULES

Agency Compliance Office
Health and Human Services Agency
County of San Diego
January 2022



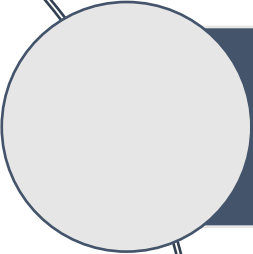
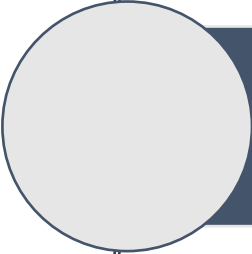
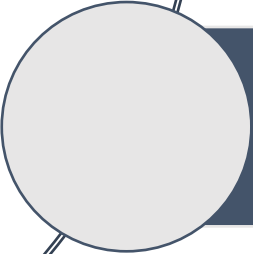
DISCLAIMER



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.

CONTENT



-  Potential Privacy Considerations
-  Part 2 Deep Dive
-  Other Privacy Developments

POTENTIAL PRIVACY CONSIDERATIONS



Contract
Requirements

Employer
Policies &
Procedures

Code of Ethics

Client
Requests

Statutes and
Regulations

CONTRACT REQUIREMENTS



- Article 14 Language
 - https://www.sandiegocounty.gov/content/sdc/hhsa/programs/sd/compliance_office/article_14.html
- Substance Use Disorder DMC-ODS Agreement with CA DHCS
 - https://www.sandiegocounty.gov/content/sdc/hhsa/programs/sd/compliance_office/article_14.html
- 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/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:

- https://www.sandiegocounty.gov/content/dam/sdc/hhsa/programs/sd/compliance/compliance-policies-and-procedures/code_of_conduct.pdf
- <https://www.sandiegocounty.gov/content/dam/sdc/cao/docs/elspstmt.pdf>

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:

https://www.sandiegocounty.gov/content/sdc/hhsa/programs/sd/compliance_office/privacy_policies_procedures.html

STATUTES & REGULATIONS



- 42 CFR Part 2 – Confidentiality of Substance Use Disorder Patient Records (Part 2)
 - <https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf#page=52>
- 45 CFR Parts 160, 162, and 164 – Health Information Portability & Accountability Act (HIPAA)
 - <http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/combined/hipaa-simplification-201303.pdf>
- State Legislation

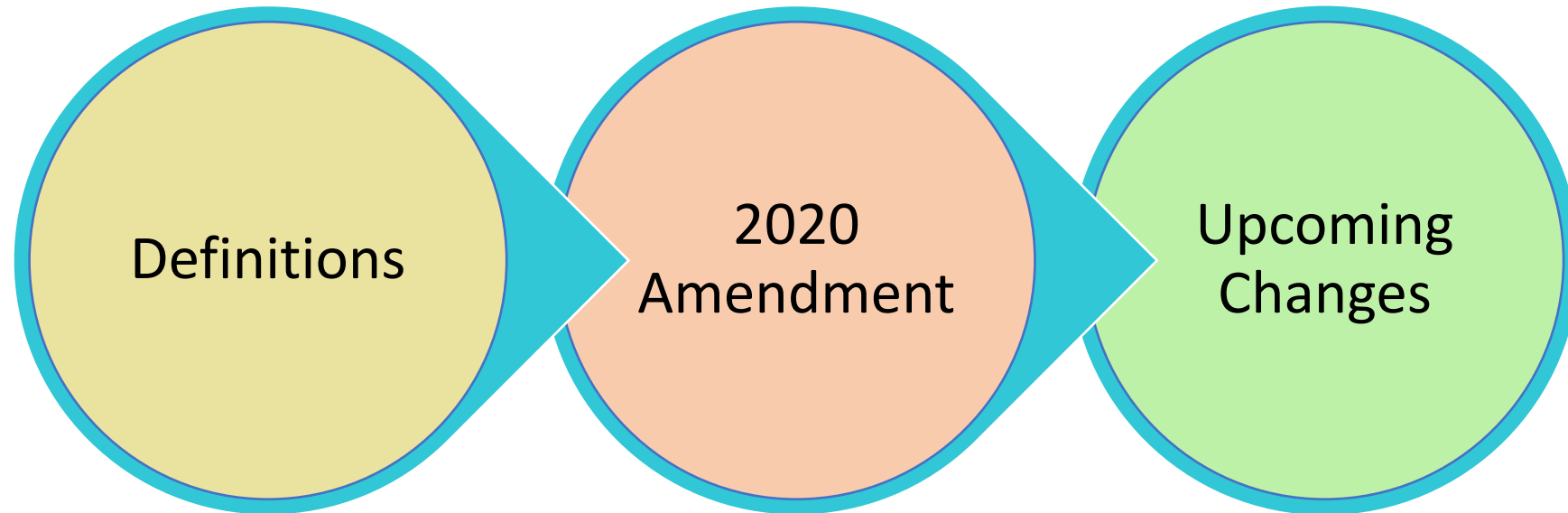
STATUTES & REGULATIONS



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 AMENDMENT IN 2020



Provision	What Changed?	Why Was This Changed?
Applicability and Re-Disclosure	Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records. Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.	To facilitate coordination of care activities by non-part-2 providers.
Disposition of Records	When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for “sanitizing” the device by deleting that message.	To ensure that the personal devices of employees will not need to be confiscated or destroyed, in order to sanitize in compliance with Part 2.
Consent Requirements	An SUD patient may consent to disclosure of the patient’s Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure.	To allow patients to apply for benefits and resources more easily, for example, when using online applications that do not identify a specific person as the recipient for a disclosure of Part 2 records.

PART 2 AMENDMENT IN 2020



Provision	What Changed?	Why Was This Changed?
Medical Emergencies	Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a “bona fide medical emergency,” for the purpose of disclosing SUD records without patient consent under Part 2.	To ensure clinically appropriate communications and access to SUD care, in the context of declared emergencies resulting from natural disasters.
Research	Disclosures for research under Part 2 are permitted by a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule (re: Research on Human Subjects).	To facilitate appropriate disclosures for research, by streamlining overlapping requirements under Part 2, the HIPAA Privacy Rule and the Common Rule.
Audit and Evaluation	Clarifies specific situations that fall within the scope of permissible disclosures for audits and/or program evaluation purposes.	To resolve current ambiguity under Part 2 about what activities are covered by the audit and evaluation provision.
Undercover Agents and Informants	Court-ordered placement of an undercover agent or informant within a Part 2 program is extended to a period of 12 months, and courts are authorized to further extend the period of placement through a new court order.	To address law enforcement concerns that the current policy is overly restrictive to some ongoing investigations of Part 2 programs.

PART 2 AMENDMENT IN 2020



Provision	What Changed?	Why Was This Changed?
Disclosures Permitted w/ Written Consent	Disclosures for the purpose of “payment and health care operations” are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and health care operations now specified under the regulatory provision.	In order to resolve lingering confusion under Part 2 about what activities count as “payment and health care operations,” the list of examples has been moved into the regulation text from the preamble, and expanded to include care coordination and case management activities.
Disclosures to Central Registries and PDMPs	<p>Non-OTP (opioid treatment program) and non-central registry treating providers are now eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program.</p> <p>OTPs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.</p>	To prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment.

* HHS also issued guidance related to staff’s use of personal email or cell phone to communicate with clients. Although HHS does not encourage patient communications through such personal devices, if an SUD patient sends an incidental message to an employee’s personal device, the employee may fulfill Part 2 sanitation requirements by deleting the message.

PART 2 AMENDMENT RESOURCES



- HHSA Compliance Office Tip Sheet:
 - [ACO Tip Sheet – 42 CFR Changes \(pdf\) \(optumsandiego.com\)](https://optumsandiego.com)
- 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>

UPCOMING CHANGES TO PART 2



- The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) amended Part 2 to more closely align with HIPAA in an effort to facilitate care coordination
- However, Part 2 has not (yet) been changed to include CARES Act requirements
 - SAMHSA's statement on the Part 2 Amendment Process/Status:
<https://www.samhsa.gov/newsroom/statements/2021/42-cfr-part-2-amendments-process>

UPCOMING CHANGES TO PART 2



- **Consent:**
 - Consent will still be required for most disclosure of SUD records
 - With a general consent, TPO sharing will be made consistent with HIPAA for TPO
- **Use of Records**
 - Generally will prohibit use of SUD records in court proceedings without a court order or patient consent
- **Anti-Discrimination Provisions**
 - Will prohibit discrimination based on information in protected SUD records
- **Enforcement**
 - Will change enforcement authority
 - Will adopt HIPAA fines and penalties
 - Will apply HIPAA breach notification rules

OTHER PRIVACY DEVELOPMENTS



- Patient Access to Records – HHS Right of Access Initiative
- 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
 - <https://www.cms.gov/about-cms/health-informatics-and-interoperability-group/faqs/faqs>
- HIPAA Proposed Rule to support individuals’ engagement, remove barriers to care coordination, and reduce regulatory burden
 - HHS Press Release: <https://public3.pagefreezer.com/content/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2020/12/10/hhs-proposes-modifications-hipaa-privacy-rule-empower-patients-improve-coordinated-care-reduce-regulatory-burdens.html>
- Various COVID federal/State emergency Orders providing temporary abeyance of some privacy rules to allow new care pathways