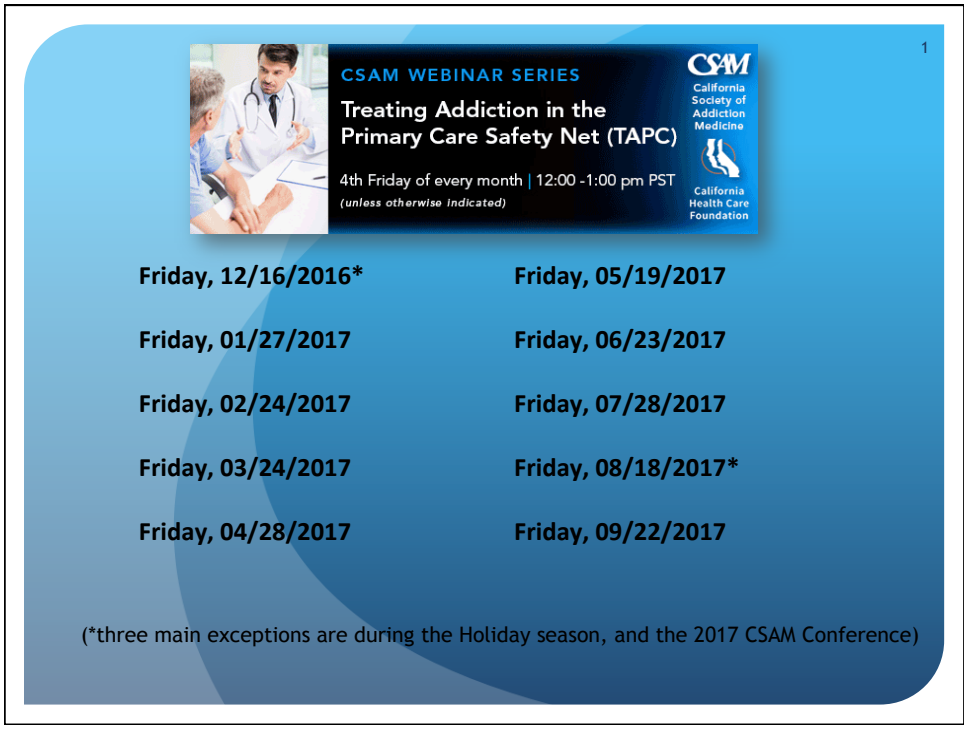
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CSAM WEBINAR SERIES
Treating Addiction in the Primary Care Safety Net (TAPC)
4th Friday of every month | 12:00 -1:00 pm PST
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California Society of Addiction Medicine
California Health Care Foundation
Friday, 12/16/2016*
Friday, 01/27/2017
Friday, 02/24/2017
Friday, 03/24/2017
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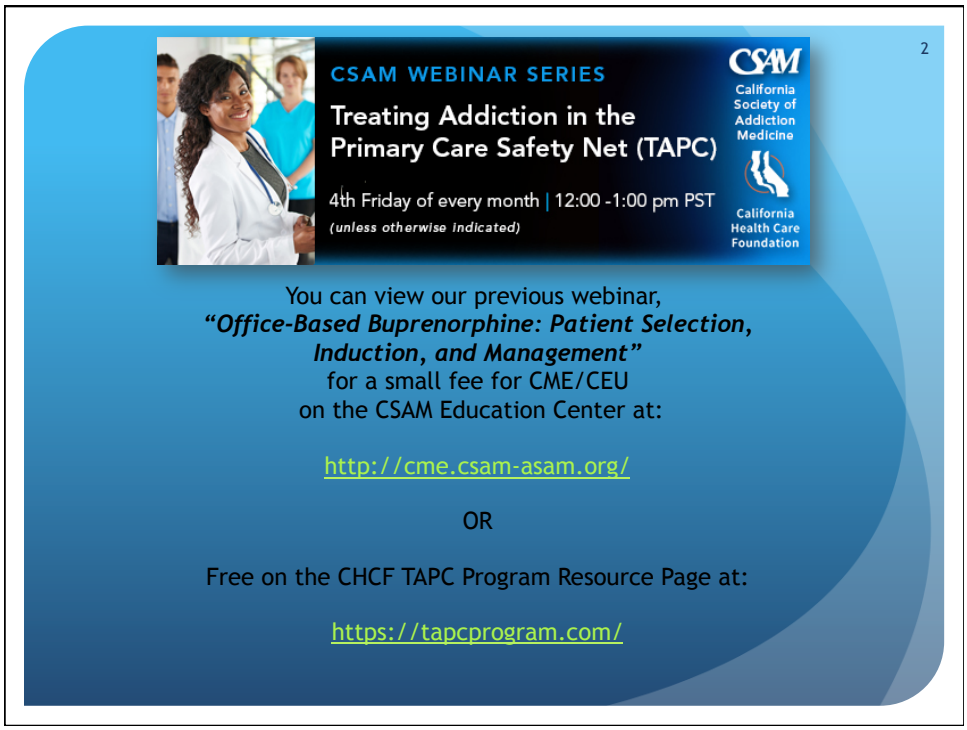
Friday, 05/19/2017
Friday, 06/23/2017
Friday, 07/28/2017
Friday, 08/18/2017*
Friday, 09/22/2017
(*three main exceptions are during the Holiday season, and the 2017 CSAM Conference)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You can view our previous webinar,
"Office-Based Buprenorphine: Patient Selection, Induction, and Management"
for a small fee for CME/CEU
on the CSAM Education Center at:
http://cme.csam-asam.org/
OR
Free on the CHCF TAPC Program Resource Page at:
https://tapcprogram.com/

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*Save the date!*

**Addiction Medicine State of the Art 2017**

**August 31 - September 3, 2017**

Hilton San Francisco Union Square


# Patient Confidentiality and Medication-Assisted Treatment in California Primary Care Settings

**David Kan, MD, DFASAM**
Private Practice
Medical Director of Bright Heart Health

**Harry Nelson, JD**
Founder and Managing Partner
Nelson Hardiman, LLP

CSAM Webinar Series:
Treating Addiction
in the Primary Care Safety Net (TAPC)
November 18, 2016

UCSF

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# Disclosure

*The speakers and planners of this webinar have no relevant financial relationships to disclose*

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The content of this webinar doesn't constitute legal advice. Please consult your legal counsel or compliance officer in designing your program

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# Overview

- Confidentiality
  - Federal Rules: HIPAA, 42 CFR part2
  - Translating this into primary care
  - How this might inform MAT program design in primary care.
  - SBIRT
  - Federal release of information
  - HIPPA vs. 42 CFR
  - Other things you need to know…

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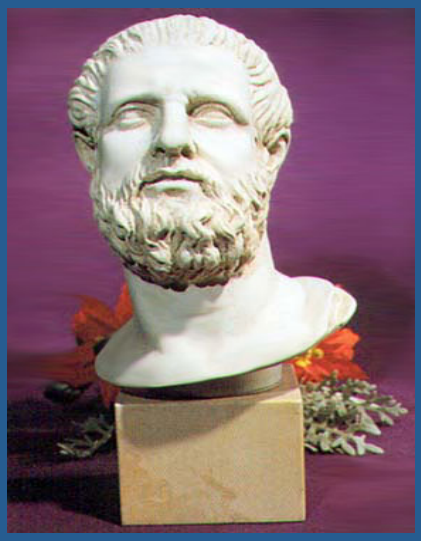
# Confidentiality



"Whatever, in connection with my professional practice or not, in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret."

Oath of Hippocrates
5th Century B.C.
(460-377 B.C.)

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# HIPAA: What you already know

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## The HIPAA in the Room 1996

- Governs protected health information
  - Electronic, Written, or Oral
- Who's Covered?
  - Health Plans, Providers
  - Health Care Clearinghouses
- Protected Health Information (PHI)
  - Governs: Access, transmission, tracks disclosure, & access to personally identifiable information
    - Diagnosis, treatment, billing

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# Confidentiality/Privilege

- COnfidentiality
  - –Clinician's Obligation to keep information secret
- PRivilege
  - –Patient's Right to bar information access

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## Confidentiality/Privilege Addiction Treatment

- Medical Information
  - – HIV/STDs
- Psychiatric Information
- Drug and Alcohol information
  - – Requires separate subpoena AND judges order
- Each has own levels of protection

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You are a primary care provider with an "X" waiver working in an FQHC and you are starting to offer buprenorphine-products to your patients you diagnose with DSM 5 opioid use disorder. Which is true?

A. Your services always activate 42 CFR part 2.
B. You services never activate 42 CFR part 2.
C. If 42 CFR is activated depends on factors determined by you and the system you work in.

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C. If 42 CFR is activated depends on factors determined by you and the system you work in.

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# 42 CFR Part 2: What you need to know

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## Federal Confidentiality Law 42 CFR § 2.12

- Applies if:
  1. Individual, program, or facility is federally assisted
     (tax exempt, federal funding, tax-deductible donations, medicare, provider holds a DEA license)

  AND

  2. ANY of three conditions are met
     i. Individual or program (other than a general medical care facility) ***holds itself out*** as providing addiction diagnosis, treatment or referral
     ii. Is a staff member at general medical facility whose ***identified, primary function*** is to provide addiction diagnosis, treatment or referral
     iii. Any unit at general medical facility ***holds itself out*** to provide addiction diagnosis, treatment or referral

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## Federal Confidentiality Law
## 42 CFR § 2.12

- If #1 and #2 is met, federal confidentiality laws apply
- Absent federal jurisdiction, state authority applies

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## 2016 Updates to 42 CFR Part 2

- General Medical Programs (GMP) or practices exempt BUT does apply to identified substance use disorder units within a GMP that diagnoses, treats, or refers for addiction treatment.
- Disclosures of information must be tracked and patients provided a list of disclosures upon request.
- Disclosure on ROI must be specified:
- What disorder, what treatment
- Who is recipient of disclosure

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Federal Register/Vol 81, No 26, pp 6988-7024

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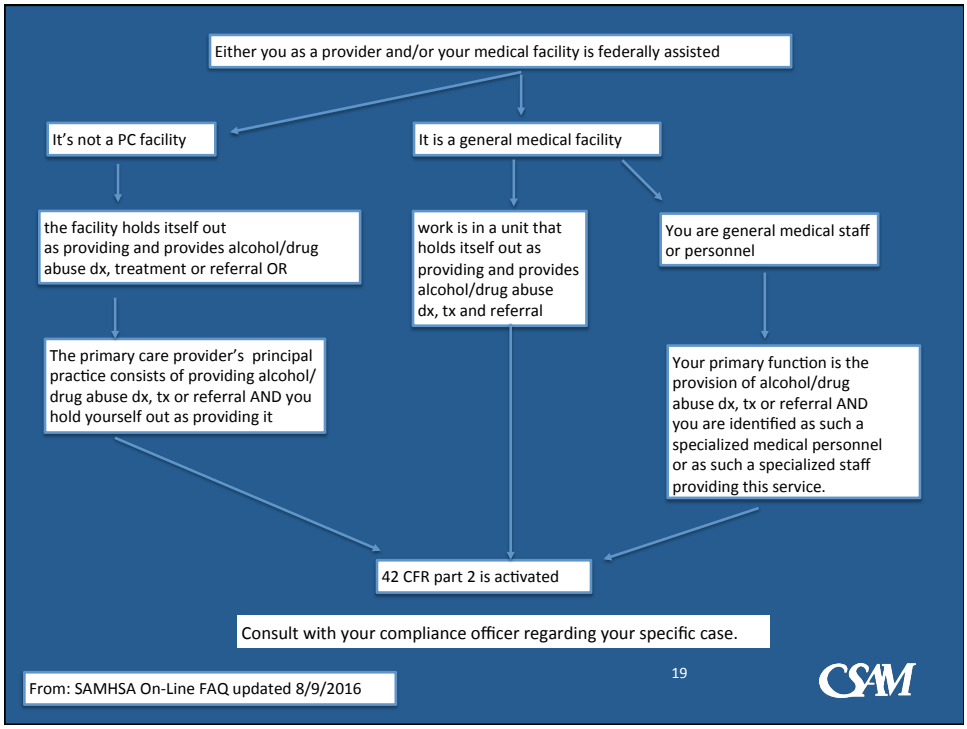
Either you as a provider and/or your medical facility is federally assisted
It's not a PC facility
It is a general medical facility
the facility holds itself out as providing and provides alcohol/drug abuse dx, treatment or referral OR
work is in a unit that holds itself out as providing and provides alcohol/drug abuse dx, tx and referral
You are general medical staff or personnel
The primary care provider's principal practice consists of providing alcohol/drug abuse dx, tx or referral AND you hold yourself out as providing it
Your primary function is the provision of alcohol/drug abuse dx, tx or referral AND you are identified as such a specialized medical personnel or as such a specialized staff providing this service.
42 CFR part 2 is activated
Consult with your compliance officer regarding your specific case.
From: SAMHSA On-Line FAQ updated 8/9/2016
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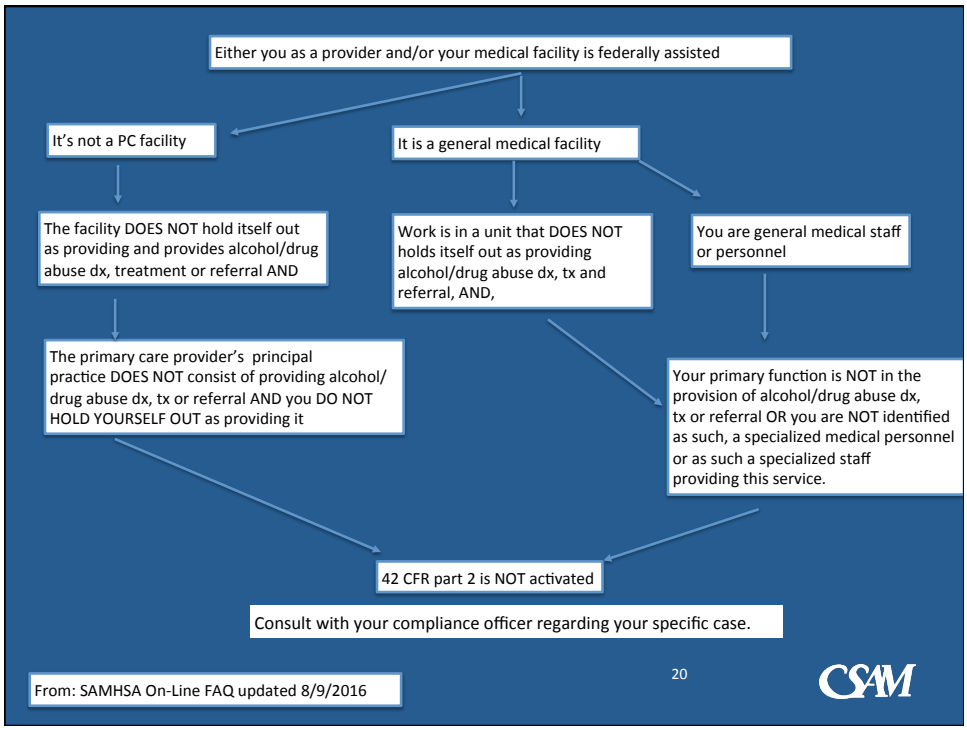
Either you as a provider and/or your medical facility is federally assisted
It's not a PC facility
It is a general medical facility
The facility DOES NOT hold itself out as providing and provides alcohol/drug abuse dx, treatment or referral AND
Work is in a unit that DOES NOT holds itself out as providing alcohol/drug abuse dx, tx and referral, AND,
You are general medical staff or personnel
The primary care provider's principal practice DOES NOT consist of providing alcohol/drug abuse dx, tx or referral AND you DO NOT HOLD YOURSELF OUT as providing it
Your primary function is NOT in the provision of alcohol/drug abuse dx, tx or referral OR you are NOT identified as such, a specialized medical personnel or as such a specialized staff providing this service.
42 CFR part 2 is NOT activated
Consult with your compliance officer regarding your specific case.
From: SAMHSA On-Line FAQ updated 8/9/2016
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## "Holds itself out" is not defined in the regulations but could mean:

- state licensing procedures
- advertising MAT services
- posting notices in the office
- certifications in addiction medicine
- listing yourself or your services in registries of MAT providers
- internet statements saying you provide MAT
- information presented to patients or their families
- or any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol/drug abuse dx, tx or referral.

From: SAMHSA On-Line FAQ revised 8/9/2016

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## How might this inform program design for MAT services if you would like to maintain a unified chart?

- no advertising, posters, brochures, or on-line promotions of MAT services
- no mention of MAT in phone services, answering machines, business cards, signage, names of units
- no groups identified as MAT groups
- no listing in registries
- staff introduce themselves by general title ( primary care provider, psychiatrist, social worker, case manager etc)

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## How might this inform program design for MAT services if you would like to maintain a unified chart? (cont)

- For staff that are trained as addiction counselors, consider cross-training them in a broader set of skills (possible examples: MI, mindfulness, relaxation techniques, vocational/educational or housing support, etc.) This might move them into a broader scope of practice such as behavioral medicine counselor.

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## You work in a FQHC that prides itself on providing whole-person care. Because of this you design a system to not "put out" in any way that you are providing MAT. How do you find patients?

A. Word of mouth
B. data mining in EHR
C. brochures/outreach promoting your general medical services at needle-exchange programs
D. Screen all patients for drugs/alcohol
E. all of the above…

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E. all of the above…

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## What about SBIRT?

Does it activate 42 CFR part 2 in primary care?

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## Screening and Brief Intervention and Referral to Treatment(SBIRT)

- If your provider or facility activates 42 CFR part 2, so does your SBIRT
- If neither your provider nor your facility activates 42 CFR part 2, then your SBIRT doesn't either.

From: SAMHSA On-Line FAQ up-dated 8/9/2016

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You are a primary care provider in an FQHC and a patient doing well in a nearby methadone maintenance clinic comes to you asking to be transitioned onto a buprenorphine product. The patient fills out a ROI for her/his pertinent records from the methadone clinic to be sent to you. When they arrive:

A. They can go in the general medical chart and require no "firewall".
B. They must be kept behind 42 CFR part 2 "firewall" in the EHR.
C. I don't know.

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You are a primary care provider in an FQHC and a patient doing well in a nearby methadone maintenance clinic comes to you asking to be transitioned onto a buprenorphine product. The patient fills out a ROI for her/his pertinent records from the methadone clinic to be sent to you. When they arrive:

A. They can go in the general medical chart and require no "firewall".
B. They must be kept behind 42 CFR part 2 "firewall" in the EHR.
C. I don't know.

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## Contrasting HIPAA and Title 42 Requirements

| HIPAA | Title 42 |
|---|---|
| –Notices of Privacy Practices enables "TPO" disclosures without patient consent | -Disclosure prohibited without patient consent |
| –Patient personal representative "stands in patient's shoes" | -Patient rights delegated only by court appointment of legal guardian |
| –No Limitations on Re-Disclosure | -Prohibition on re-disclosure |
| –Minimum necessary standard | -No disclosures except as needed to carry out purpose of disclosure |
| -Significant patient record access rights | -Significant provider discretion in sharing records |

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## Contrasting HIPAA and Title 42, continued

| HIPAA | Title 42 |
| --- | --- |
| –Disclosure to other treatment providers OK without consent for any treatment and to family (location, pt condition) in emergency | -Disclosure to *other treatment providers* without consent only in medical emergency |
| –Disclosure to public health authorities for disease control or exposed individuals permitted | -Disclosure to public health authorities for disease control or exposed individuals requires authorization or court order |
| -Liberal authorization standard for use by law enforcement with subpoena, with court order, or as required by law | -Limited power for court-ordered authorized release (exceptions for child abuse/neglect and crime on premises) |

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## Federal Confidentiality (42 CFR)

- Consent Form
  - Name of program or person permitted to make disclosure
  - Name or title of individual or organization receiving disclosure
  - Name of Patient
  - Purpose of disclosure
  - How much and what kind of information
  - Patient Signature
  - Date of Signature
  - Statement that consent is subject to revocation at any time to the extent that the program has already acted on it
  - Expiration date, event, or condition

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## Federal Confidentiality (42 CFR)

- Consent required when purpose of disclosure is *not* for "treatment, payment, or health care operation."
- Patients must receive copy of consent.
- Program must retain record of consent for six years from expiration date.

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## Federal Confidentiality Exceptions

- Crimes on program premises or against program personnel
- Child Abuse Reporting
  - Reporting of viewing of child pornography (in CA) as of January 1, 2016
- Medical Emergencies
  - Information limited to medical emergency
- Subpoenas and court-ordered
  - Patient must sign consent to respond to subpoena unless court order issued

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## Federal Confidentiality

- Qualified Service Organizations
  - Business associate agreement needed
- Accreditation Bodies (Joint Commission)
  - Considered extension of program
- Research
  - Even more rules

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## Resolving HIPAA/Title 42 Tensions

- Different Focus
  - HIPAA – Enacted 1996 with focus on privacy implications of EHR adoption
  - Title 42 – Enacted 1975 with focus on not deterring addiction treatment based on feat of criminal prosecution.
- Last Updated?
  - HIPAA – significant revisions via HITECH Act in 2010. Final Rule implemented September 2012
  - Last substantive updated 1987. February 2016 notice of proposed revisions.
- Ahead? Significant regulatory reconciliation needed to facilitate behavioral health integration, care coordination, and EHR patient data management and exchange

From: SAMHSA On-Line FAQ revised 8/9/2016

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## Planning Considerations in Federal Compliance

- HIPAA and Title 42 enforcement activity still limited - focusing primarily on investigating complaints and damage caused by breaches – increasing enforcement over time
- Indications are that most healthcare organizations still have work to do on process and training
- HIPAA compliance requirements provide framework that can be revised/ augmented to address heightened requirements
  - Appointment/Monitoring and Oversight by Privacy Officer and a Security Officer
  - Annual workforce training
  - Develop/update policies and procedures
  - Perform and document risk analysis
    - Ensure appropriate IT security safeguards are in place
    - Evaluate potential threats
    - Deploy appropriate hardware/software
  - Prepare for breach response/reporting and audit for breaches

From: SAMHSA On-Line FAQ revised 8/9/2016

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## Don't forget compliance with state law

- Federal laws establish the floor, not the ceiling, on privacy and data security requirements
- California state law gives rise to private right of action (*i.e.* lawsuits) in contrast to the lack of private standing to enforce federal law:
  - California Confidentiality of Medical Information Act (CMIA) establishes a $1,000 per violation penalty for failing to manage medical records in a manner that preserves their confidentiality
  - SB 1386 (Civil Code §§ 1798.29, 1798.82, 1798.84): any business that owns electronic data with "personal information" is required to disclose any breach of security to CA resident
- Less technical – primary focus is on breach reporting and response - readiness

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## Other things you should have in mind around regulations:

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- 42 CFR is in the process of being further revision, so stay tuned.
- Follow DEA requirements for buprenorphine record-keeping.
- Until C.A.R.A. is activated, for any evaluation of buprenorphine refill or dose change, the patient must see or speak with the x wavered doctor

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## CURES: CA Senate Bill No. 482 ( approved 9/27/16)

- Before prescribing schedule II-IV drugs, health care practitioners must consult CURES no earlier than 24 hours or one business day before and, if on chronic rx, at least q 4 months (unless exempt)
- Exemptions: pharmacists, veterinarians, if pt is in hospice care, pt admitted to a medical or surgical facility and meds for use on premises of the facility and doesn't exceed 5 day supply, E.R visit if supply doesn't exceed 5 days.
- At initiation of dosing, if the provider is exempt, they must check CURES before subsequently prescribing it and thereafter at least every 4 months if on chronic rx.

For full information please review the text of the bill at: leginfo.legislature.ca.gov

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## Special thanks to

Michael Barack, CSAM
Olma O'Neill, CSAM

Tammy Fisher, CCI
Susannah Brouwer, CCI

Jean Marsters, MD

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## Selected Resources

- In CA SB 482:
  https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB482
- On SAMHSA Confidentiality FAQ page:
  http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs
- Confidentiality Regulations FAQs | SAMHSA
  http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs
- Medical Insurance Exchange of California (good practice guidelines)
  http://www.miec.com/default.aspx?tabid=8
- Medical Board of California (laws governing practice of medicine in California)
  http://www.mbc.ca.gov/About_Us/Laws/laws_guide.pdf
- 42 CFR Part 2
  - A good summary of changes
    **http://www.cbhda.org/wp-content/uploads/2016/02/42-CFR-vk_v2.pdf**
  - **Text of 2016 Update**
    **https://www.federalregister.gov/articles/2016/02/09/2016-01841/confidentiality-of-substance-use-disorder-patient-records**
- Fine Print: Rules for Exchanging Behavioral Health Information in California
  http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/PDF%20F/PDF%20FinePrintExchangingBehavioral.pdf

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