ORANGE COUNTY BAR ASSOCIATION

HEALTH CARE LAW SECTION WEBINAR

Controlled Substance Law Refresher for Attorneys Advising Healthcare Professionals

Thursday, May 28, 2020

A Controlled Substance Law Refresher for Attorneys Advising Healthcare Professionals

OCBA Health Law Section

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Objectives

- At the conclusion of this talk, the participant will be able to articulate
  - The statutory and regulatory framework for controlled substances
  - Their healthcare clients' legal responsibilities when prescribing, ordering or dispensing controlled substances
  - Medication Assisted Therapy options for physicians with opioid dependent patients
  - Mandatory use of CURES and the exceptions
  - Red flags indicating prescription drug abuse at prescriber, pharmacy and patient levels
  - Basic components of electronic prescribing
  - Additional requirements for e-prescribing controlled substances
  - The DEA's "lose your registration" approach to the opioid crisis

Controlled Substances

Federal law

- Drug Abuse Prevention And Control Act of 1970, better known as the Controlled Substances Act (21 USC § 801-971)
  - Divides all drugs of abuse into five categories (Schedules I - V)

California law

- California Uniform Controlled Substances Act. (Health and Safety Code sections 11000-11651)

Why controlled substance regulation?

- Potential for abuse
- Results in more stringent regulatory control than other dangerous drugs
- To assure the drugs are produced and distributed through proper channels
- To assure the drug(s) are used for the proper medical indication/condition

Criteria used to determine a drug's schedule:

- Actual or relative potential for abuse
- Scientific evidence of the drug's pharmacologic effect
- State of current scientific knowledge regarding the drug or related substances
- History and current patterns of abuse
- Scope, duration and significance of abuse
- Risk, if any, public health
- Psychic or physiological dependence liability
- Whether it is an immediate precursor of a substance already controlled

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Controlled Substances

- Schedule I
  - Drug has a high potential abuse but no accepted and safe medical use:
    - *Hallucinogens* such as peyote, mescaline, cannabis and derivatives, LSD
    - Derivatives of opium not scheduled elsewhere (e.g., heroin)
    - Derivatives of coca plant not scheduled elsewhere (e.g., cocaine base)
    - CNS depressants not scheduled elsewhere (e.g., methaqualone)

Schedule II controlled substances

- High abuse potential but recognized as having safe and effective medical use
  - Opioids: morphine, meperidine, methadone, tincture of opium, hydrocodone, oxycodone, fentanyl, sufentanyl, codeine
  - Stimulants: Amphetamines, cocaine HCl
  - Short-half-life barbiturates: secobarbital, amobarbital

- Schedule III controlled substances
  - Recognized as safe and effective with declining potential for abuse
    - Compounds of certain Schedule II drugs with another (non-controlled substance) ingredient
      - Examples: acetaminophen or aspirin with codeine, milk of bismuth with tincture of opium, butalbital with aspirin and caffeine
    - Buprenorphine
    - Anabolic steroids
    - Dronabinol

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Controlled Substances

- Schedule IV controlled substances
  - Safe and effective with relatively little potential for abuse
  - Partial opiate agonists
    - Pentazocine
    - Tramadol
  - Depressants and tranquilizers, certain muscle relaxants
    - Benzodiazepines (diazepam, alprazolam, midazolam, etc.)
    - Zolpidem
    - Eszopiclone
    - Meprobamate, carisoprodol
    - Long-half-life barbiturates
      - phenobarbital, mephobarbital

Controlled Substances

Schedule V controlled substances

Safe and effective with very little potential for abuse

- Lomotil® (containing diphenoxylate)
- Lyrica ® (pregabalin)
- Codeine (low dose), when combined with another non-scheduled medication
  - Robitussin-AC ®

Activities subject to the CSA

- Manufacturing
- Distributing (and reverse distributing)
- Prescribing
- Dispensing (Schedules II – V)
- Research with any controlled substance
- Conducting a narcotic treatment program using *any narcotic* in Schedule II-V
- Conducting chemical analyses of controlled substances
- Importing/Exporting

Prescription Drug Abuse is on the Rise

An increasing percentage of drugs involved in overdoses come from prescriptions, many of which are dispensed by retail pharmacies

- Explosion of pill mills
- Increased “doctor shopping” by patients

Congress has put pressure on FDA and DEA to combat prescription drug abuse

California legislature has put pressure on prescribers and dispensers to combat prescription drug abuse

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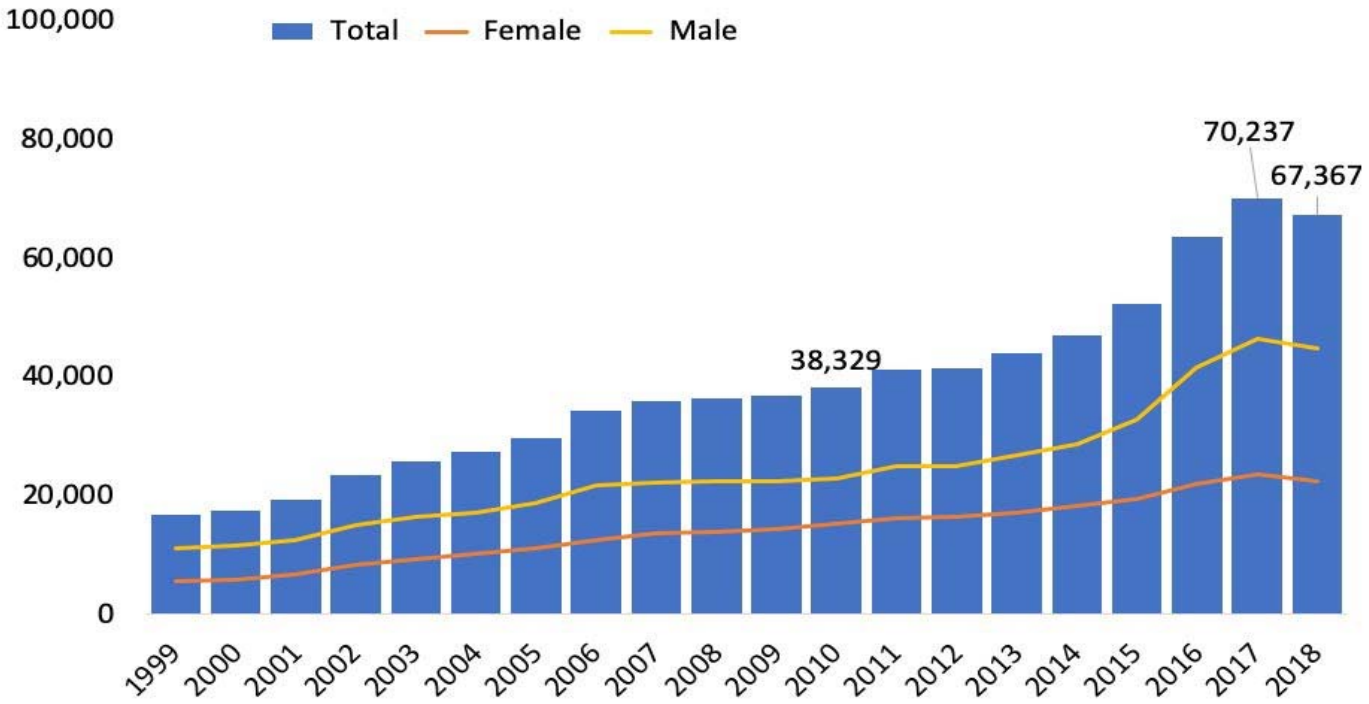
National Drug Overdose Deaths
Number Among All Ages, by Gender, 1999-2018



Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2018 on CDC WONDER Online Database, released January, 2019

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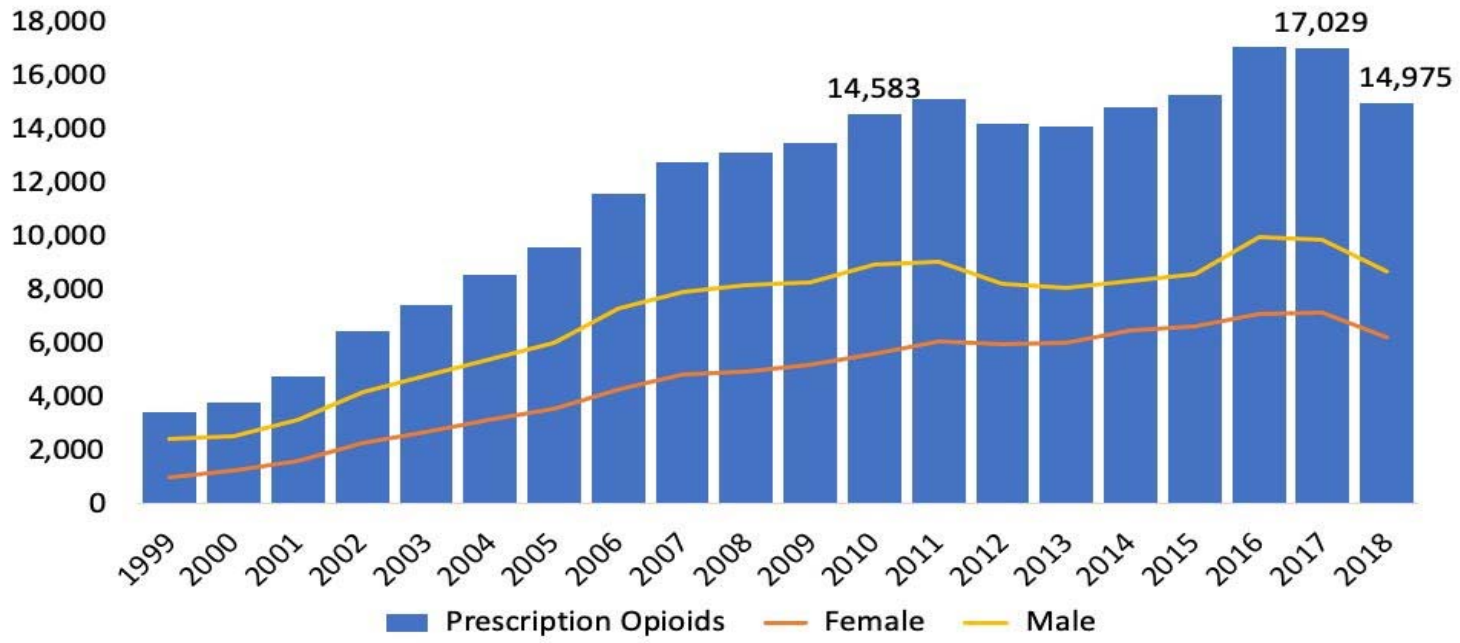
National Drug Overdose Deaths Involving Prescription Opioids, Number Among All Ages, 1999-2018



Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2018 on CDC WONDER Online Database, released January, 2019

California Relative Deaths from All Drugs vs All Opioids

Year	Deaths from All Drugs	Deaths from All Opioids	Opioid:All Deaths
2006	9.52	4.08	43%
2007	10.6	4.55	43%
2008	10.5	4.87	46%
2009	10.9	5.33	49%
2010	10.8	5.11	47%
2011	10.9	5.03	46%
2012	10.6	4.5	43%
2013	11.5	5.03	44%
2014	11.7	5.22	45%
2015	11.3	5.09	45%
2016	11.4	5.20	46%
2017	11.8	5.55	47%
2018	11.9	6.14	52%

https://www.americashealthrankings.org/explore/annual/measure/Drugdeaths/state/CA/
https://skylab.cdph.ca.gov/ODdash/

Medication Assisted Therapy (MAT)

There are only five federally registered opioid treatment programs in Orange County

- These typically use methadone replacement therapy

What about community physicians?

- They are prohibited from prescribing methadone or any other opioid for maintaining or tapering an addict.

However, under the Drug Addiction Treatment Act (“DATA”), qualifying physicians* may obtain a special DEA waiver and will be authorized to conduct maintenance and detoxification treatment using specifically approved schedule III, IV, or V narcotic medications

- Such physicians conduct “Medication Assisted Treatment” programs

*as of 2018, Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and other mid-level practitioners already registered with the DEA may also qualify for the DATA waiver

Medication Assisted Therapy (MAT)

Qualifying practitioners must satisfy *one of the following* two conditions to treat 100 patients in their first year:

- The physician holds a *board certification in addiction medicine or addiction psychiatry* by the American Board of Preventive Medicine or the American Board of Psychiatry and Neurology; *or*
- the practitioner *provides medication-assisted treatment (MAT) in a "qualified practice setting."* A qualified practice setting is a practice setting that:
  - provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;
  - provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
  - uses health information technology systems such as electronic health records;
  - is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law; and
  - accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or federal health benefits.

Medication Assisted Therapy (MAT)

Medicated-Assisted Treatment (MAT) is the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders.

- *More physicians and mid-level practitioners obtaining the DATA waiver allowing them to conduct office-based MAT could result in many more resources in the OC community to treat Opioid Use Disorder!*
- *DEA's proposed pending relaxation of telemedicine rule will also make telemedicine an option in treating opioid use disorder to geographically underserved areas*

https://www.samhsa.gov/medication-assisted-treatment

Monitoring Prescription Drug Use

Prescription Drug Monitoring Programs (PDMPs) collect data from records of controlled substance dispensing *from any provider*

- California's program is called CURES (Controlled Substance Utilization Review and Evaluation System)
  - Currently, only collects data for Schedule II – IV drugs
    - This was a problem, because there are Schedule V drugs being abused and "the street" knows there is no surveillance on these drugs

  Starting January 1, 2021, CURES submissions will include Schedule V drugs and dispensing must be reported to CURES no later than one business day (currently seven days)
- DOJ *may* develop an interstate data exchange with other PDMPs (not implemented to date)

Ref: HSC § 11165

Monitoring Prescription Drug Use

Why do prescribing clinicians hate CURES?

- *Workflow*
  - *Must stop working in Electronic Medical Record (EMR) or e-prescribing system to open a browser and connect to CURES*
  - *Must log into CURES*
  - *Must specify the patient*

Help is on the way!

- *HSC § 11165.1 required the CA Department of Justice to provide an Application Program Interface (API) available so that EMRs, e-prescribing systems and Pharmacy Information Systems can integrate CURES queries into these applications.*
  - *This will make the workflows for clinicians much easier and encourages checking of CURES reports, since they are integrated into the EMR or other clinical systems!*

Prescribing Controlled Substances

HSC §11165.1(a)(1)(A)(i) *requires prescribers to be registered* in CURES

HSC § 11165.4 *requires prescribers to check a patient's CURES profile* prior to prescribing Schedule II – IV* drugs to a *patient the first time*

- "First time" means the first time a provider intends to prescribe a controlled substance to a patient under his/her care
- Must run the CURES report no earlier than 24 hours (or one business day) before prescribing
  - If CURES check not done, prescriber must document why he/she was unable to do so
- Prescribers may now run a CURES report for all prescriptions attributed in CURES to him/her (new!)
  - May be unpleasantly surprised to find records not from prescriber that are attributed to him/her

*adds schedule V to requirement starting July 1, 2021

Prescribing Controlled Substances

- Each covered *Medi-Cal provider shall check the prescription drug history of a covered individual being treated by the covered provider through [CURES] before prescribing to such individual a controlled substance*; and in the case that a provider is not able to conduct such a check despite a good faith effort by such provider, requires the provider to document in the patient's record why the provider was unable to conduct the check.
- *Medicare Part D controlled substance prescriptions must be e-prescribed beginning January 1, 2021*, with limited exceptions including technical limitations, or where the prescriber determines that it is impractical for patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved.

42 U.S.C. § 1396w-3a,42 U.S.C. § 1395w-104(e)

Changes for Providers Who Prescribe

- Prescribing/furnishing clinicians now *required to take mandatory continuing education course in the management and risks of addiction* associated with the use of Schedule II drugs.
- Prescribing/furnishing clinicians *must counsel minor patients (or their parents/legal guardians) about risks of addiction and overdose*

BPC § 741

Changes for Providers Who Prescribe

Physician prescribers may now prescribe dangerous drugs without a physical examination and only reviewing a patient self-screening tool or questionnaire

- "An appropriate prior examination *does not require a synchronous interaction between the patient and the licensee* and can be achieved through the use of telehealth, *including, but not limited to, a self-screening tool or a questionnaire*, provided that the licensee complies with the appropriate standard of care"

- Online prescribing (with no *in-person* meeting) of controlled substances is still prohibited by federal law, but DEA is working on a special registration for providers who then can prescribe without an in-person meeting

2. BPC § 2242(a), 21 USC § 829(e)(2)(B)(i)

Prescribing Controlled Substances

21 CFR § 1306.05 – a controlled substance prescription must contain the following:

- Date of issuance
- Name and address of patient
- Drug name, strength, dosage form, and quantity
- Directions for use
- Number of refills, if any
- Prescriber name, address, DEA number, and signature

These are the facial requirements – but more is needed!

California Secure prescription form (HSC § 11161.5)

- Obtained from approved private printing companies
- May be ordered in any quantity
- May be ordered in any format
  - individual, group, institutional
  - for one or multiple drugs
- Must be serialized
- Need not be multi-copy (prescribers choice)
- Must have security features

PROBLEM: Bogus forms were proliferating!

AB 1753 (2018), limits authorized printers to no more than three, and adds additional auditing features to the prescription

All the issues with these forms will be obviated by upcoming requirements to prescribe controlled substances electronically

Multiple prescriptions on one form

Allowed, but form must be designed for multiple prescriptions, and must also state "prescription is void if the number of controlled substances prescribed is not noted"

- Can use for non-controlled drug prescriptions or prescriptions for both controlled and non-controlled drugs, but not filling in the number of drugs prescribed, whether controlled substances or not, voids all prescriptions on the form.

NB: Board of Pharmacy inspectors were citing pharmacies for filling legitimate prescriptions but where the number of drugs prescribed weren't filled in! The fact none of the drugs were controlled is irrelevant, in the view of BoP.

Use of Security Prescription forms:

- A controlled substance prescription *must be signed and dated by the prescriber*
  - *But, if prescription is generated by computer, the date may be printed by the computer*
  - All other information required on the prescription may be written or printed by the prescriber's agent

Pharmacists' authority to make changes to Schedule II prescriptions upon consultation with prescriber

- Board of Pharmacy concluded that the pharmacist is acting as an agent of the prescriber after speaking with prescriber and therefore can call and make any *appropriate* changes
  - Changes that can't be made upon oral consultation with prescriber:
    - Date
    - Drug
    - Prescriber's signature

Prescribing Controlled Substances

Prescribers must offer a prescription for naloxone or another opioid reversal drug to a patient when:

- the prescribed opioid dosage is equal to or more than 90 morphine milligram equivalents per day, or
- an opioid is prescribed within a year from the date a prescription for benzodiazepine has been dispensed to the patient, or
- the patient has increased risk for overdose (e.g., history of overdose, history of substance use disorder, or returning to a high dose of opioid medication to which the patient is no longer tolerant).

Additionally, *prescribers must provide education on overdose prevention and the use of naloxone* or another opioid reversal drug *to the patient or one or more persons designated by the patient, or for a patient who is a minor, to the minor's parent or guardian*

BPC § 740, 741

Prescribing Controlled Substances

- Exceptions to the HSC § 11165.4 requirement to check a patient's CURES profile prior to prescribing Schedule II – IV* drugs to a patient the first time:
  - Patients registered or admitted to hospitals, or any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility if the drug is administered *while the patient is in the facility*
  - Emergency Room prescriptions for no more than a seven day supply
  - Patients in hospitals, or any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility undergoing a surgical procedure, for a supply of five days or less
  - Hospice patients
  - *Where specified technical limitations preclude use of CURES*

*adds schedule V to requirement starting July 1, 2021

Beyond the Technical Requirements – The New Reality

Merely complying with technical prescription requirements of the regulations is NOT sufficient!!

- A controlled substance prescription “must be issued for a ***legitimate medical purpose*** by an individual practitioner acting in the usual course of his professional practice.” (21 CFR § 1306.04(a))
- For a controlled substance prescription to be valid, it must meet the technical requirements AND must have been written for a legitimate medical purpose
- A pharmacist has a “corresponding responsibility” along with the prescriber to ensure prescriptions are for a legitimate medical purpose

Beyond the Technical Requirements – The New Reality

"The pharmacist is the 'drug expert' in the healthcare delivery system and is well equipped to review a prescription to determine if it is legitimate.

If more pharmacists questioned the validity of prescriptions issued by rogue pain clinic physicians and refused to fill the prescriptions based upon their professional judgment, diversion would be significantly decreased.

The exercise of their 'corresponding responsibility', in many instances, is an opportunity for pharmacists to save lives."

- Statement by Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA, made at the Senate Caucus on International Narcotic Control, July 18, 2012

"Last Line of Defense"

DEA now considers the pharmacist to be the "last line of defense" against prescription drug prescribing abuse

Are they now the controlled substance police in addition to being clinicians?

- Some pharmacists will not fill prescriptions for pain medications unless the patient has an established history with the pharmacy
- Some pharmacists will not accept pain medication prescriptions written by emergency room doctors
- Some pharmacists are refusing to fill prescriptions written by certain doctors

Controlled Substance Prescription Red Flags

- Large portion of prescriptions for controlled substances issued by one prescriber
- Large portion of prescriptions from prescriber(s) located unreasonable distance from pharmacy
- Large portion of patients receiving controlled substances from a pharmacy
- Large percentage of prescriptions paid for in cash
- Patient uses street slang (purple drank, Ts and blues)
- Patient travels long distances from residence to reach prescriber or pharmacy
- Individual has prescriptions for controlled substances from multiple doctors
- Patient has prescriptions for large quantity or large doses of controlled substances
- Patient receives more than one controlled substance that treat the same indications
- Patient seeks early refills

Controlled Substance Prescription Red Flags

- Patient prescribed an opiate, a benzodiazepine, and carisopridol (“cocktail,” also known as the “holy trinity”)
- Patients who travel in groups to pharmacy
- Patient profile or CURES reveals patient is receiving controlled substances from multiple prescribers at the same time
- Cash payments for prescriptions (especially in combination with other red flags
- Prescribed drug inconsistent with prescriber’s area of practice (e.g., fentanyl from dentist)
- Lack of individualized dosing
- Relying solely on prescriber’s representation that prescription is legitimate
- Action against prescriber by state boards or law enforcement

Resolving Red Flags (aka CYA): What DEA tells pharmacists to do

- *Talk to the patient* –question them if they are from out of the area
- *Contact the prescriber*
  - Document all communications with the prescriber
- Talk with other pharmacists in your area
- Use CURES
- Use your instincts
- Refuse to fill the prescription
  - But always return a written prescription to patient!

Controlled Substance Prescriptions: Resentful Physicians

"The appropriateness of a prescription is *purely a medical decision* in the purview of the treating prescriber.

Invading the patient-physician relationship and/or questioning the judgment or rationale of the prescriber perverts DEA regulations.

Pharmacists *under no circumstance* should be required to confirm the appropriateness of a prescription.

Routine calls to verify prescriptions are unwarranted and *are an inappropriate interference with the practice of medicine."*

-American Medical Association (AMA) proposed committee resolutions in response to pharmacists routinely calling prescribers to verify the legitimacy of pain medications, May 2013

More Resentful Physicians

“While proper prescribing and dispensing of controlled substances must be encouraged, California Medical Association (CMA) is concerned with … administrative burdens and re-diagnosing by pharmacists arising from the inconsistent application and implementation of this policy. CMA has confirmed … that this policy is being implemented throughout California and nationwide.”

“If you or your patients have difficulties filling prescriptions for controlled substances at any pharmacy in California, please report problems to CMA's Center for Legal Affairs…”

http://www.cmanet.org/news/detail/?article=walgreens-refuses-to-fill-some-controlled

e-Prescribing

Electronic prescribing (e-prescribing) is an effective method of improving the clarity of prescribing information conveyed to the dispensing pharmacist

e-prescribing applications are increasingly integrated with the prescriber's Electronic Health Record (EHR), clinical decision support, and prescription benefit management (PBM) organization formulary data

The ability to compare the prospective medication against the patient's problem list, allergies, and list of active medications gives the prescriber the opportunity to be informed of potential medication related problems and modify the prescription as appropriate

The use of computerized clinical decision support tools in EHRs can optimize prescribing by "making it easy to do the right thing and hard to do the wrong thing."

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e-Prescribing becomes mandatory!

Starting January 1, 2022:

- California prescribers must *have the capability to issue an electronic data transmission prescription* on behalf of a patient *and to transmit* that electronic data transmission prescription to a pharmacy selected by the patient
- Pharmacies, pharmacists, or others who dispense or furnish a prescription shall *have the capability to receive an electronic data transmission prescription* on behalf of a patient.

- But remember, *all Medicare Part D controlled substance prescriptions must be e-prescribed beginning January 1, 2021!*

Basic components of e-Prescribing

e-prescribing Originating System (the Prescriber's)

- Stand-alone or integrated into an Electronic Health Record (EHR)
- May also allow printing of prescription forms

Intermediary (typically "cloud based")

- Receives prescription from originating system
- Converts data format between prescribing and pharmacy systems for compatibility and forwards to receiving pharmacy system
- Provides pharmacy-to-prescriber communication specific to e-prescription

e-prescribing Receiving System (the Pharmacy's)

- Receives prescription from Intermediary and places into a work queue
- Pharmacist reviews queue, can process and dispense from queue

Systems must provide for electronic communication from the pharmacy to the prescriber (e.g., for refill requests)

DEA Final Rule on e-Prescriptions for Controlled Substances

Originating system, intermediary, and receiving pharmacy systems each need to be certified as meeting DEA requirements:

- To ensure the person ordering the prescription is authorized to do so
- To ensure the prescriber cannot repudiate an e-prescription
- To ensure the prescription record throughout its storage in the e-Presciber's system, transmission, and receiving pharmacy system cannot alter any data related to the prescription

Prescriber System Requirements

Most EHRs and standalone e-prescribing systems require the clinician to sign in using a user name and password

In order to e-prescribe controlled substances, the systems must in addition:

- Provide authentication
  - Any two of:
    - “Something you know”
    - “something you have”
    - “something you are”
- Provide access control to ensure only authorized prescribers are allowed to do so

Prescribers ***must* be counseled to never provide login and authentication method to anyone. Not even their most trusted staff members!**

DEA Final Rule on e-Prescriptions for Controlled Substances

Prescriber authentication

- “Something you know”
  - Passwords
- “Something you have”
  - Token with rolling random number display used as a “key” to be entered into the system
  - COMMON: Cell phone or that receives a numeric “key” to be entered into the system
- “Something you are”
  - Biometric reader (retina, fingerprint, others approved by DEA)

Intermediary

- An *intermediary* means “any technology system that receives and transmits an electronic prescription between the practitioner and the pharmacy.” 21 CFR §1300.03
- Most electronic prescriptions are routed from the electronic prescription or EHR application through intermediaries, which convert prescription data between systems so that the receiving pharmacy application can correctly import the data
  - (DEA-required) contents of a prescription shall not be altered during transmission between the practitioner and pharmacy.
  - Any change to the content during transmission, including truncation or removal of data, will render the electronic prescription invalid
  - If intermediary cannot transmit the controlled substance prescription eRx to the pharmacy, the intermediary must notify the practitioner.
  - eRx data may be *converted* from one software version to another between the electronic prescription application and the pharmacy application; conversion includes altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data.

21 CFR §1311.170

DEA Final Rule on e-Prescriptions for Controlled Substances

Pharmacy

- The (DEA-required) contents of a prescription may be changed after receipt at the pharmacy, subject to the same laws and regulations that apply to paper prescriptions
  - This isn't saying the received e-prescription record itself can be modified; the original form must always be retrievable.
  - Pharmacy works with a copy of the actual received e-prescription
- Pharmacy application service providers must back up files daily.
- HIPAA applies to all PHI within pharmacy systems, with its own requirements for privacy, data integrity, and security

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Other e-prescribing requirements for controlled substances

For Prescribers and Pharmacies

- Once a prescription is created electronically, all records must be retained electronically
- Under federal law, retention of all records for minimum of two years
- Under California law, retention of controlled substance prescriptions and dispensing information must be retained for a minimum of three years

DEA Enforcement is Intense

DEA "death penalty" (besides potential criminal prosecution)

- Revocation of DEA registration of:
  - Wholesalers
  - Pharmacies
  - Prescribers
  - Hospitals
- Loss of DEA registration effectively shuts down wholesalers, pharmacies and hospitals
- Loss of DEA registration *severely curtails prescribers' ability to operate or practice*

California has a “rap sheet”

California sends this to pharmacies by email semi-monthly: Pursuant to Health and Safety Code section 11161.7(b), the Board of Pharmacy is distributing this list of prescribers whose authority to prescribe controlled substances has been restricted by the Medical Board of California. The board is making this information available to prevent the dispensing of prescriptions for controlled substances issued by restricted prescribers.

License	Last Name	First Name	Middle Name	Name Suffix	City	County	Effective Date	Description
A97083	ABDALAH	EHAB	FAROUK		GLENDALE	MARICOPA	11/30/2018	SHALL NOT ORDER, PRESCRIBE, DISPENSE, ADMINISTER, FURNISH, OR POSSESS ANY CONTROLLED SUBSTANCES, EXCEPT THOSE DRUGS LISTED IN SCHEDULES I, IV AND V.
C43166	ABRAMOWITZ	JOSEPH	MICHAEL		SAN DIEGO	SAN DIEGO	1/2/2020	SHALL NOT ORDER, PRESCRIBE, DISPENSE, ADMINISTER, FURNISH, OR POSSESS ANY CONTROLLED SUBSTANCES LISTED IN SCHEDULES I, II AND III.

These data *may* automatically populate in pharmacy and Medical Staff Office systems, meaning almost real-time ability for a pharmacy or hospital to take appropriate measures to prevent prescribing/ordering controlled substances. A pharmacy can now theoretically be held administratively liable for filling controlled substance prescriptions of providers listed, since the Board of Pharmacy is now regularly sending these data.

DEA Actions Against Registrants

In order to suspend or revoke a DEA registration, the Attorney General must prove one of the following factors:

- That registrant materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;
- That registrant was convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(cont'd)

DEA Actions Against Registrants

In order to suspend or revoke a DEA registration, the Attorney General must prove one of the following factors (cont'd):

- That registrant had a state license or registration suspended, revoked or denied by competent state authority and is no longer authorized by state law to engage in the manufacturing, distribution or dispensing of controlled substances or list I chemicals, or has had the suspension, revocation, or denial of his registration recommended by competent state authority;
- That registrant committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or
- That registrant was excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42. 21 USC § 823.

DEA Actions Against Registrants

DEA is very slow in adjudicating registration suspension or revocation

- A 2014 OIG report cited extreme delays in adjudication for suspensions, revocations and denials of registration.[1]

But DEA can, in "emergency" situations the Attorney General can suspend any registration *simultaneously* with instituting proceedings where there is an "imminent danger to the public health or safety." [2]

It is almost never a good idea to voluntarily surrender DEA registration when action is taken against the registrant

- Delays in resolving after surrender will cause registrant difficulty in continuing practice, reputational injury and so forth
- Registrant can continue to prescribe/dispense until final adjudication

Always advise clients to exercise their due process rights and request a hearing

1. The Drug Enforcement Administration's Adjudication of Registrant Actions (May 2014), at https://oig.justice.gov/reports/2014/e1403.pdf
2. 21 USC § 823(d)

Questions????

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