

UCI School of Pharmacy &
Pharmaceutical Sciences

Pharmacy Law and Ethics

Lecture / Week #5

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February 1, 2022

Controlled Substances Dispensing

Today's Topics

- Faxed prescriptions
- Emergency fills
- Prescription transfers
- Prescription labels
- Orders & reconciliation
- Drug storage
- Record keeping

Faxed prescriptions

	Fax OK	Requirement	Exceptions
Schedule 5 (Lyrice)	Fax OK	<ul style="list-style-type: none"> • Prescriber must manually sign • Use regular RX form for fax (or else "VOID" appears) 	
Schedule 4 (Ambien, tramadol)			
Schedule 3 (Xyrem, Fiorinal, Fioricet, Androderm, Marinol)			
Schedule 2 (opioids, stimulants)	FAX NOT OK (but as FYI only)	<ul style="list-style-type: none"> • Patient must hand in physical RX (to be verified against fax) * • Patient can NEVER fax any RX 	Faxed C2 is ok for SNF, intermediate care facility, hospice, home health agency**

Refills (HSC 11200)

- (a) No person shall dispense or refill a controlled substance prescription more than **six months** after the date thereof.
- (b) No prescription for a **Schedule III or IV substance** may be refilled more than **five times** and in an amount, for all refills of that prescription taken together, exceeding a **120-day supply**.
- (c) No prescription for a **Schedule II** substance may be refilled.

Refills without Prescriber Authorization (HSC 11201)

A prescription for a **controlled substance**, **except those appearing in schedule II**, may be **refilled without the prescriber's authorization** if the prescriber is unavailable to authorize the refill and if, in the *pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering*. The pharmacist shall refill only a **reasonable amount** sufficient to maintain the patient until the prescriber can be contacted. The pharmacist shall note on the reverse side of the prescription the date and quantity of the refill and that the prescriber was not available and the basis for his judgment to refill the prescription without the prescriber's authorization. The pharmacist shall inform the patient that the prescription was refilled without the prescriber's authorization, indicating that the prescriber was not available and that, in the pharmacist's professional judgment, failure to provide the drug might result in an immediate hazard to the patient's health and welfare or might result in intense suffering. The pharmacist shall inform the prescriber within a reasonable period of time. Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber.

The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

Refills of Controls (HSC 11166; HSC 11200)

	Expiration	Refill limit	PRN refills
Schedule 5 (Lyrica)	6 months from issue date	No refill limit but expires in 6 months	Not acceptable
Schedule 4 (Ambien, tramadol)	6 months from issue date	5 refills (or) 120 day supply (whichever is first)	Not acceptable
Schedule 3 (Xyrem, Fiorinal, Fioricet, Androderm, Marinol)	6 months from issue date		Not acceptable
Schedule 2 (opioids, stimulants)	6 months from issue date	ZERO REFILLS ALLOWED	No refills
Non controls	1 year from issue date	No refill limit	Acceptable

Emergency (Re)Fills

Drug	Quantity Limit	Notes
Non controls	No quantity limit	In the <u>pharmacist's judgment</u> , failure to refill the prescription might interrupt the patient's ongoing care; adverse effect on the patient's well-being
C3-C5	<ul style="list-style-type: none"> - Reasonable amount to cover emergency period - Note on reverse side of RX the date and quantity and MD not available and reason to refill 	
C2	<ul style="list-style-type: none"> - No refills (exceptions below) <u>EXCEPTIONS: Verbal C2 RX from Prescriber</u> - Exception #1: Minimum amount necessary to cover and Prescriber writes "Authorization for Emergency Dispensing" on original or emergency RX - Exception #2: Patient is resident of SNF, intermediate care facility, home health, hospice (HSC 11167.5) 	<ul style="list-style-type: none"> - Prescriber to provide original RX within 7 days (can be physical RX or e-script) - If not received, pharmacist must report to CA Bureau of Narcotic Enforcement within 144 hours (6 days) and report to local DEA office

Prescription Transfers

RX Transfers / Refills

Title 21, Code of Federal Regulations §1306.25 (paper RX)

- The transfer of original prescription information for a controlled substance listed in **Schedule III, IV, or V** for the purpose of **refill** dispensing is permissible between pharmacies on a **one-time** basis only
- However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization ("the CVS exception")

RX Transfers

Requirements

- The transfer must be communicated directly between **two licensed pharmacists**
- The transferring pharmacist must do the following:
 - Write the word “VOID” on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record
 - Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record
 - Record the date of the transfer and the name of the pharmacist transferring the information

Prescription Transfers: Non-Controlled Drugs

CCR § 1717(e)

- Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between **pharmacists** or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy
- The receiving pharmacist shall create a written prescription;
 - identifying it as a transferred prescription; and
 - record the date of transfer and the original prescription number

Prescription Transfers: Non-Controlled Drugs

When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer

- A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer
- Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division

Prescription Transfers: Non-Controlled Drugs

Information maintained by each pharmacy shall at least include:

- Identification of pharmacist(s) transferring information
- Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate
- Original date and last dispensing date
- Number of refills and date originally authorized
- Number of refills remaining but not dispensed
- Number of refills transferred

FAQs – Prescription Transfers

Can a Schedule II prescription be transferred? (Paper CII)

- No, pursuant to Health and Safety Code section 11158(a),
“...no controlled substance classified in Schedule II shall be dispensed without a prescription ...”
-- The Script, March 2013

BUT: Schedule II e-prescriptions are transferable between pharmacies!

- 2017: DEA received inquiries from pharmacists regarding the transfer of Schedule II electronic prescriptions (e-script)
- “an unfilled original EPCS [e-script] prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances”

Resources

- **Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling,**
<https://www.federalregister.gov/documents/2021/11/19/2021-24981/transfer-of-electronic-prescriptions-for-schedules-ii-v-controlled-substances-between-pharmacies-for>

BUT: Schedule II e-prescriptions are transferable between pharmacies!

The Drug Enforcement Administration (DEA) is proposing to amend its regulations to allow the **transfer** of **electronic prescriptions for schedule II-V** controlled substances between registered retail pharmacies for **initial filling on a one-time basis**. This amendment will specify the procedure that must be followed and the information that must be documented when transferring an electronic controlled substance prescription between DEA-registered retail pharmacies.

Resources

- **Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling**, <https://www.federalregister.gov/documents/2021/11/19/2021-24981/transfer-of-electronic-prescriptions-for-schedules-ii-v-controlled-substances-between-pharmacies-for>

DEA Re-direction Letter (2017)

- **Transferring unfilled schedule II-V EPCS :**

DEA understands the interest in being able to transfer from one pharmacy to another an unfilled EPCS for a schedule II-V controlled substance. DEA regulations do not specifically allow for the transfer of unfilled schedule II prescriptions in any form, and only specifically allow for the transfer of original information from schedule III-V prescriptions in any form for purposes of refill only. However, it is DEA's current policy that any **unfilled** EPCS for a schedule II-V controlled substance may be transferred to another pharmacy.

Knowledge check

Is it OK for a pharmacy technician to transfer a Schedule III, IV, or V controlled substance prescription to another pharmacy for refill purposes by simply faxing a copy of the computer-generated label to the other pharmacy?

No, section 1717(e) of Title 16, California Code of Regulations (16 CCR) and section 1306.25(b)(1) of the Title 21, Code of Federal Regulations (21 CFR) specify that only pharmacists may transfer and receive prescriptions. Under existing law, there is no authority for a prescription label to be used for the purpose of transferring a prescription.

-- The Script, March 2013

Knowledge check

Can an intern receive a transferred prescription?

Yes, an intern may perform all the functions of a pharmacist at the discretion and under the direct supervision and control of a pharmacist whose license is in good standing with the board (B&PC sections 4023.5 and 4114[a] and 16 CCR section 1726[a]).

Prescription Labels

Patient-Centered Labeling

1707.5 (a) Labels on drug containers dispensed to patients in California shall conform to the following format:

- Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12 point Sans Serif typeface, and listed in the following order:
- Name of the Patient
- Name of the Drug and Strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer
- The Directions for the use of the drug
- The Condition or Purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription
- For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1)
- The remaining required elements for the label specified in section 4076 of the business and professions code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface

VONS PHARMACY # 2188 (559) 438-1356
8949 N CEDAR AVE, FRESNO, CA 93720
JF / NA

Rx: 4040470 MD. NAME, DOCTOR

PATIENT NAME
ZOLPIDEM TARTRATE 5MG TABS
MFG: NORTHSTAR RX
TAKE ONE TABLET BY MOUTH
EVERY NIGHT AT BEDTIME AS
NEEDED FOR INSOMNIA

Qty: 30 Refills: 1 until 05/24/2012 Use before:
Generic for: AMBIEN 5MG TABS
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

TRANSACTION DATA SYSTEMS, INC.
1544 Purdue Avenue Los Angeles, CA 90025
407-614-0050

Rx 500001 Dr DOCTORS NAME 01/12/12
PATIENTS NAME
HYDROCHLOROTHIAZIDE 12.5 MG
Mfg: WATSON LABS
TAKE 1 TABLET BY MOUTH DAILY

Qty 30 Rfls left 0 Discard after: 01/11/13 RPh: TDS
oblong / white/teal S1: S2:

Orig. date 01/12/12

CAUTION: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

VCC - Pier View (760) 631-5000 ext 4111 English
818 Pier View Way Oceanside, CA 92054 ext 4112 Espanol

6186 DOCTORS NAME MD
RM 1/11/2012

PATIENT NAME
METFORMIN HCL 1,000 MG TABLET
GLENMARK PHARMA
Tome 1 tableta por boca dos veces al día
en la mañana y en la tarde con comida

3.00 REFILLS Qty 60 Drug Exp
film-coated, white, oblong tablet
SIDE 1: "G 45" SIDE 2: "1000"

CAUTION: FEDERAL LAW PROHIBITS TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM IT WAS PRESCRIBED.

COMMUNITY MEDICAL CENTER PHARMACY (619) 262-4373
610 GATEWAY CENTER WAY STE
SAN DIEGO, CA 92102

TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN PATIENT FOR WHOM PRESCRIBED IS PROHIBITED.

R 013-13013968 Refills Left: 6 1-24-12
until 08/14/12 12-28-11
PATIENT NAME Rph: LWH
Tech: MT

NEXIUM 20MG CAP Quantity: #30
ASTRAZENECA LP
TOME 1 CAPSULA ORALMENTE CADA DIA

NEXIUM 20 mg/AMETHYST/OBLONG
Dr. DOCTORS NAME
Discard After: DW: 8-15-11

Knowledge Check

A pharmacist receives a prescription for Ativan® 1 mg and elects to dispense a generic equivalent manufactured by S-G. Which of the following drug descriptions on the label would be legally CORRECT?

- A. "Generic Ativan 1 mg (S-G)"
- B. "Lorazepam 1 mg (S-G)"
- C. "Lorazepam 1 mg for Ativan"
- D. "Lorazepam 1 mg generic for Ativan"

Knowledge Check

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- D. "Lorazepam 1 mg generic for Ativan"

Translation

Translation

California Code of Regulations § 1707.5(d):

- Pharmacy must have policies and procedures (P&P) to help patients with limited English proficiency understand the information on the prescription label in the patient's language
- The Translation P&P must at least include:
 - the means of identifying the patient's language, and
 - the means of providing interpretive services in the patient's language

Translation

California Code of Regulations § 1707.5(d):

- Interpretive services must be available during all hours that the pharmacy is open, either
- in person by pharmacy staff, or
- by use of a third party interpretive service available by a phone that is located at or next to the pharmacy counter.

Translation

California Code of Regulations § 1707.6(c):

- Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:
- “Point to your language. Interpreter services will be provided to you upon request at no cost”

Point to your language.
Interpreter services will be provided to you upon request at no cost.

ARABIC	اختر لغتك. يتم تقديم خدمات الترجمة الفورية لك عند الطلب دون أي تكلفة.	Նշեք ձեր լեզուն: Թարգմանչի ծառայություններն անվճար կտրամադրվեն ձեզ՝ ըստ պահանջի:	ARMENIAN
CAMBODIAN	ចូរចង្អុលទៅកាន់ភាសារបស់អ្នក ។ មានផ្តល់សេវាកម្មបកប្រែភាសាដល់អ្នកតាមការស្នើសុំ ដោយឥតគិតថ្លៃ ។	廣州話 指向您的語言。 將根據您的要求免費為您提供翻譯服務。	CANTONESE
FARSI	زبان خود را مشخص کنید. خدمات ترجمه شفاهی بر حسب درخواست شما به صورت رایگان فراهم خواهد شد.	Taw rau koj yam lus. Kev pab cuam neeg txhais lus yuav muaj pub rau koj raws li kev thov yam tsis yuav nqi.	HAONG
KOREAN	언어를 지정해 주십시오. 요청 시 통역 서비스를 무료로 제공해 드립니다.	官話 指向您的語言。 將根據您的要求免費為您提供翻譯服務。	MANDARIN
RUSSIAN	Указать на ваш язык. Услуги переводчика будут бесплатно предоставлены Вам по требованию.	Indique su idioma. Se le proporcionarán servicios de intérprete sin costo si lo solicita.	SPANISH
TAGALOG	Ituro ang iyong wika. Ang serbisyo ng interpreter ay ibibigay sa iyo kapag hihilingin nang walang bayad.	Xin hãy chỉ vào ngôn ngữ của quý vị. Dịch vụ thông dịch sẽ được cung cấp cho quý vị miễn phí theo yêu cầu.	VIETNAMESE

 **BE AWARE AND TAKE CARE:**
Talk to your pharmacist!
CALIFORNIA STATE BOARD OF PHARMACY



Translation

This text shall be repeated in at least the following languages:

- Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese
- Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. . .
- The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance
- Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open
- The flyer or handout shall be at least 8 1/2 inches by 11 inches

Translation

- In the “Minutes of May 1-2, 2012 Public Board Meeting,” the Board of Pharmacy Executive Director, Virginia Herold, responded to a direct public query specifically on this point
- The question was asked “how the quality of oral interpretive services is being assessed”
- Ms. Herold responded that the Board was not in a position to evaluate the quality of the translation services, but that board inspectors would be inspecting merely for the availability of the service. Mr. Joshua Room, the Board’s legal counsel and Deputy Attorney General, further advised that there is no requirement in the law that the interpretive services meet a minimum standard. http://www.pharmacy.ca.gov/meetings/minutes/2012/12_may_bd.pdf
- Therefore liability to the pharmacist does not seem to flow from the quality of the interpretive service
- Rather, the Board’s sole concern focuses on the existence of one

Translation

BUT, liability could still potentially flow to the pharmacy if it were negligent in the hiring of that translation service

- I.e., if a reasonable prudent pharmacist would NOT have hired the same interpretative service that you did, then you could be held liable for negligently hiring that service
- Example:
 - Joe pharmacist, who only speaks English, hires “ABC Chinese Interpretation Services” for all of his Chinese-speaking patients
 - Joe has read horrible online reviews of this company, and heard from his fellow pharmacy friends & colleagues that ABC is unreliable and inaccurate in its translation
 - But Joe decides to ignore the warning signs and hires ABC anyway because the service is extremely cheap

What do you think? Is this legally appropriate? Does this meet the Board’s requirement? Does it meet another legal standard?

Record Keeping

Record Keeping Requirements

Two General Types of Daily Records:

- DRUG IN's
 - Invoices & Purchase Orders
 - Wholesale Purchases of Non-Controlled substance
 - Wholesale Purchases of C-III, IV, V substances
 - Wholesaler Purchases of C-II's (2-2-2 Order Forms)
- DRUG OUT's
 - Prescription/Rx Records
 - Rxs for Non-controlled substance + C-III, IV, V
 - Rxs for C-IIs
 - Proof of Pickup/Delivery
 - Proof of Consultation/Waiver

Record Keeping Requirements

CCR § 1715:

A completed **biennial** pharmacy self-assessment (by July 1 of every odd numbered year) is on file in the pharmacy and maintained for **3 years**

B&P §§ 4081, 4105, 4333:

All drug acquisition and disposition records (complete accountability) are maintained for at least **3 years**, including

Record Keeping Requirements

B&P §§ 4081, 4105, 4333: All drug acquisition and disposition records (complete accountability) are maintained for at least 3 years, including

- Prescription Records
- Purchase Invoices for All prescription drugs
- Biennial controlled substance inventory
- 2-2-2 DEA forms
- Power of Attorney for completion of DEA 2-2-2 forms
- Theft & Loss Reports (DEA form 106)
- Returns – Records documenting return of drugs to wholesaler or manufacturer
- Transfers - Record documenting transfers or sales to other pharmacies, licensees and prescribers

General Recordkeeping Requirements

Keep for at least:	Record
7 years	Hospital pharmacy chart order records for controlled substances
6 years	Patient HIPAA acknowledgement
6 years	Transaction info, history, statement for most Rx drugs per Drug Supply Chain Security Act
4 years	Cert of competition of CE (does not need to be on pharmacy premises)
3 years	Hospital pharmacy chart order records for NON-controls
3 years	Biennial Controlled Substances inventory
	Community or clinic pharmacy prescriptions
	CS inventory
	DEA forms 222, POA forms
	Purchase invoices for all RX drugs
	Self assessment forms
	Record documenting return of drugs to wholesaler/mfr
	Record documenting transfers/sales to other pharmacists, licenses, prescribers
	Theft and loss reports of controls (DEA form 106)
2 years	PSE, ephedrine sale logbooks
1 year	Patient medical profile (unless traveler, out of town, then don't need to keep profile) (1 year from last dispense)
1 year	Medication error report
	QA reports

General Recordkeeping Requirements

Action	Reporting Time Period
Change of pharmacist address or name	30 days (to Board)
Change of PIC	30 day (to Board)
Changes in pharmacy permit	30 days (to Board)
Theft/impairment of STAFF licensee	14 days (to Board)
Theft/loss of CONTROLLED drugs	DEA immediately (1 business day) Board within 14 days (employee theft/loss) Board within 30 days (other loss) Send Form 106 to DEA and Board
Bankruptcy	Immediately
Pharmacy Take Back Program	
Establish takeback program	30 days (to Board)
Discontinue takeback program	
Tampering with collection bin	14 days (to Board)
Theft of deposited drugs	
Tamper, theft, damage of removed liner	
Disclosure of service, location of each receptacle	Annually with facility license renewal

Pharmacist in Charge - Record Keeping

General	Self Assessment	Records
<ul style="list-style-type: none">• Strict liability• 2 pharmacies• 50 miles	<ul style="list-style-type: none">• Biennial (every odd # year) before July 1• New Self-assessment Form within 30 days of new permit• New Self-assessment Form when new PIC	<p>Keep Self-assessment Form in pharmacy for 3 years</p>

Record Keeping Requirements

B&P § 4081

- (a) All records . . . of sale, acquisition, or disposition of dangerous drugs . . . shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making . . .
- (b) The owner, officer, and partner of a pharmacy. . . shall be jointly responsible, with the pharmacist-in-charge . . . for maintaining the records . . .
- (c) The pharmacist-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge had no knowledge, or in which he or she did not knowingly participate.
- [i.e., Criminal Immunity, but not Civil or Regulatory]

Form 222

How a Pharmacy typically orders drugs from its wholesaler:

- Non-Controlled substance
- C-III, IV, V
- C-II

C-II by Paper: Form-222

C-II Electronically: via the Controlled Substance Ordering System (CSOS) – <http://www.deaecom.gov/>

BLANK DEA FORM-222 U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions			No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).										OMB APPROVAL No. 1117-0010			
TO: (Name of Supplier)										STREET ADDRESS						
CITY and STATE					DATE					TO BE FILLED IN BY SUPPLIER SUPPLIER'S DEA REGISTRATION No.						
LINE No.	TO BE FILLED IN BY PURCHASER															
	No. of Packages	Size of Package	Name of Item					National Drug Code					Packages Shipped	Date Shipped		
	1															
	2															
	3															
	4															
	5															
	6															
	7															
	8															
	9															
10																
<div> <div>LAST LINE COMPLETED</div> <div>(MUST BE 10 OR LESS)</div> </div>										SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT						
Date Issued					DEA Registration No.					Name and Address of Registrant						
Schedules																
Registered as a					No. of this Order Form											

DEA Form-222 (Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

DEA 222 Forms - Record Keeping Requirements

A DEA Form 222 is required for each distribution, purchase, or transfer of a schedule II controlled substance

- When ordering a C-II, the purchaser is responsible for filling in the # of packages, the size of the package, and the name of the item.
- Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney.
- When the items are received by the pharmacy, the pharmacist must document on the purchaser's copy (copy three) the actual # of packages received and the date received.
- Executed DEA Form 222 must be maintained separately from the pharmacy's other business records. (DEA Pharmacist's Manual p 22-23)

Record Keeping Requirements

CCR § 1718

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

CFR § 1304.11(c) – Taking Inventory Count

- After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years.
- The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.
- CII inventory: take every quarter (3 months via physical count)

CFR § 1304.04(h)	Inventory& Purchase Records	Prescription Records
C-II	Maintained <u>separately</u> from all other pharmacy records	<u>Paper</u> prescriptions in a <u>separate</u> prescription file
C-III, C-IV, C-V	Maintained either <u>separately</u> from all other records of the pharmacy, OR in such form that the info is <u>readily retrievable</u> from ordinary business records of the pharmacy	<p>Either:</p> <ul style="list-style-type: none"> • (1) in a <u>separate Rx file</u> for C-III, IV, and V only, or • (2) in such form that they are <u>readily retrievable</u> from the other prescription records of the pharmacy. <p>Rxs are deemed <u>readily retrievable</u> if the face of the Rx is stamped in red ink in the lower right corner with the letter "C" at least 1" high and filed either with the Schedules II's, or in the usual consecutively numbered prescription file for noncontrolled Rxs.</p> <p>But if pharmacy uses a computer that permits ID by Rx# and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the red "C" requirement is waived.</p>

Off Site Storage (CCR § 1707)

- Records stored off-site (only for pharmacies who have obtained waiver from the Board of Pharmacy to store records off-site) must be secure and retrievable within 2 business days.
- Records for non-controlled substances must be maintained on the licensed premises for at least 1 year from the date of dispensing. (onsite)
Records for controlled substances must be maintained on the licensed premises for at least 2 years from the date of dispensing (onsite).

Duty to Consult

1707.2. Duty to Consult – When must consultation be performed?

A pharmacist shall provide oral consultation to patient or patient's agent:

- upon request; or
- whenever the pharmacist deems it warranted in the exercise of professional judgment
- 1) In addition, a pharmacist shall provide oral consultation to patient or patient's agent:
- whenever the prescription drug has not previously been dispensed to a patient; [i.e., New Prescription] or
- whenever a prescription drug is not previously dispensed to a patient in same dosage form, strength or same written directions [i.e., Change in prescription]
- For a prescription drug shipped by mail, pharmacy shall ensure that patient receives written notice of his right to request consultation; and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record

1707.2. Duty to Consult – When must consultation be performed?

In addition, a pharmacist shall provide oral consultation to patient or patient's agent:

- whenever the prescription drug has not previously been dispensed to a patient; [i.e., New Prescription] or
- whenever a prescription drug is not previously dispensed to a patient in same dosage form, strength or same written directions [i.e., Change in prescription]

For a prescription drug shipped by mail, pharmacy shall ensure that patient receives written notice of his right to request consultation; and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record

1707.2. Duty to Consult

Legal Minimum:	When a Pharmacist Deems Necessary, per Professional Judgment:
<ol style="list-style-type: none">1. directions for use2. storage3. importance of compliance with directions4. precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.	<ol style="list-style-type: none">1. name and description of the medication;2. route of administration;3. dosage form;4. dosage;5. duration of drug therapy;6. any special directions for use and storage;7. precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;8. prescription refill information;9. therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;10. action to be taken in the event of a missed dose.

Rite Aid Pharmacy Pays \$500,000 for Failing to Consult with Patients

From The Script, Winter 2015 Rite Aid Pharmacy Pays \$500,000 for Failing to Consult with Patients (https://pharmacy.ca.gov/publications/15_winter_script.pdf)

The California State Board of Pharmacy reached a settlement agreement with Rite Aid pharmacy chain for \$498,250 in a consumer protection lawsuit for the failure of its pharmacists to consult with patients on new or changed prescriptions.

Winter 2015

BOARD OF PHARMACY

Rite Aid Pharmacy Pays \$500,000 for Failing to Consult with Patients



Weisser said studies have found that 46 percent of patients misunderstand one or more instruction on prescription labels.

“It’s important that patients understand the proper use of their medications. A pharmacist obtains four years of post-graduate, specialized education in pharmacy and is the last health care professional a patient typically sees before initiating drug therapy. A consultation helps minimize or avoid medication errors, screens for drug interactions and ensures better compliance with therapy,” Weisser said.

California’s Pharmacy Law regulation 1707.2, enforced by the Board of Pharmacy, requires that a pharmacist must provide oral consultation on all new prescriptions not previously dispensed to a patient whenever the dosage, strength

The California State Board of

When can a clerk or technician offer to consult?

What is the acceptable phrase for a pharmacy technician or clerk to say to a patient when there is a new prescription that requires consultation?

- There is no specific phrase in regulation for directing the patient regarding consultation with the pharmacist, but most importantly, the patient should not be asked whether he or she wishes consultation with the pharmacist. Instead, the clerk or pharmacy technician may simply direct the patient to the consulting area, and advise that “The pharmacist would like to talk to you about your prescription.” The patient can then accept or refuse the consultation.

-- The Script, March 2013

Knowledge Check

A pharmacist is NOT required to initiate patient consultation when

- a) the prescription is a refill, but the dose is changed.
- b) the customer refuses consultation.
- c) appropriate auxiliary labels have been attached.
- d) the patient does not speak English.

Questions?

Midterm Paper Assignment – Due 2/15/2022

- You were able to schedule part of your internship rotation at the pharmacy where you worked in high school. The owner and pharmacist-in-charge is on vacation and you are working with a part time pharmacist as your preceptor. You notice as your shift starts that the pharmacist is slurring his words and is a bit off balance when moving about the pharmacy. You can't tell for sure whether the pharmacist has been drinking alcohol before coming to work. You and the precepting pharmacist are on the same shift. The pharmacist goes back to take a nap in the second hour of the shift and leaves you, a pharmacy technician and two clerks working while he dozes in a chair in the back of the pharmacy. From the chair where he is napping he can see you and the rest of the staff if he opens his eyes or wakes up.
- You refill a number of prescriptions with the pharmacist sleeping nearby. A patient comes in with a new prescription and you need to fill and dispense it and provide counseling. You tell the pharmacist what you are going to do. In response, he opens one eye before closing it to continue his nap.
- What are the issues in this situation? What are the rules (i.e. laws and regulations) governing this situation? What are the applications of the rules to the facts of this situation? What conclusions do you come to (what will you do about the situation you are in). What are your ethical obligations, if any?
- Please address the prompts in the first person. Remember, you are the intern pharmacist and need to decide what your best course of action will be.

Midterm Paper Assignment

- The paper should be written in the **first person** since the questions all are posed as if the student is the pharmacy intern in question.
- The class should all use Grammarly prior to submission and submit it via Turnitin
- Format:
 - Microsoft Word document
 - Times New Roman 12 point font
 - Single spaced
 - One inch margins--top, bottom and sides
 - No indentation on paragraphs
 - One line separation between paragraphs
 - May use headings or bolded/underlined words for emphasis of important points
 - Two pages of text with bibliography
 - May include the bibliography on a third page
- Mid-term paper is to be submitted electronically via Canvas.
- The students should name the file with their first and last name and the question number each separated by a space (i.e. Jane.Doe#12).