



BE AWARE & TAKE CARE:
Talk to your pharmacist!

The Script

CALIFORNIA BOARD OF PHARMACY

Board of Pharmacy will hold open forum on pharmacy manpower

Today's technology and automation are evolving at an increasingly rapid rate, and the state requirements for pharmacy practice have not kept pace—resulting in critical pharmacist shortages in many areas of the state and country. To discuss these and other issues and assure that California consumers have access to quality pharmacists' care, the Board of Pharmacy will hold an open forum on September 16, 1999. The forum will be from 9 a.m. to 3 p.m. at 400 R Street, Suite 1030 (First Floor Hearing Room), in Sacramento.

Among the topics to be discussed are:

- ❖ reciprocity of pharmacist licensure between California and other states
- ❖ alteration of the pharmacist/technician ratio
- ❖ direction of pharmacists to patient care functions (consultation, dosage form modifications, profile review functions) and use of auxiliary personnel for non-discretionary tasks
- ❖ pharmacists' control over working conditions
- ❖ automation issues—central refill, pharmacist practice outside a pharmacy

The Board encourages all interested parties to attend or provide written comments, especially those pharmacists who interact with patients on a day-to-day basis. Those wishing to present information at this forum should contact the Board office in advance so that adequate time can be scheduled for each speaker. Please be prepared to discuss possible solutions to the pharmacy manpower issue, including the pharmacist shortage and ways that technology can be utilized and pharmacy practice expanded to ensure the best patient care.

*Thank you for your interest.
Richard Mazzoni, R.Ph.
President, Board of Pharmacy*

Buyer Beware! Drugs purchased outside the U.S. may have problems

More and more we hear individuals expressing excitement over their ability to buy drugs more cheaply in Mexico. However, as with most things that seem to be too good to be true, this apparent serendipity has many downsides that must be considered: (1) what is the quality of the drugs purchased, (2) are the purchased drugs labeled correctly, and (3) how well trained are the personnel of the pharmacies?

Quality of drugs

Before a drug is approved and allowed for sale in this country, the Food and Drug Administration (FDA) investigates to determine whether the drug's benefits outweigh its negative aspects. However, since even an approved drug may not be totally harmless, and may cause adverse effects or other complications when taken with other medications, a prescription is required.

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President's Message

by **Richard Mazzoni, R.Ph.**
President, California Board of Pharmacy

Recently, the media has focused on a number of health-related events and issues, one of which relates to aging baby boomers (those born 1946–1964). This large population segment is expected to consume more healthcare services and

products than any generation that has gone before and has caused the media to feature numerous health and lifestyle stories.

Consider just a few examples of recent media issues: Y2K's impact on the prescription drug supply chain, prescription errors, and the "smuggling" by patients of drugs from other countries.

So, what does media attention have to do with the everyday practice of pharmacy in your particular situation? My impression is that these trends point out very clearly that we pharmacists are no longer mere purveyors of a product, but that we must be providers of information. Effective communication with your patients is critical to their proper use of medication and the avoidance of adverse drug events. The appropriate use of

automation and ancillary personnel is a very effective means to move the pharmacist from the routine dispensing activity to the much more important patient interaction activity. Your patients need your input on the events affecting their health; they need answers to the questions that the media generates about the proper (and improper) use of medications.

For example, the effect of Y2K on the supply chain of prescription medication is a concern to some people. But, according to a recent article from the National Association of Chain Drug Stores, "Focus group consumers see the local pharmacist as the primary Y2K advisor for their prescriptions." Spending a few moments reassuring your patients about the continued availability of their medications can go a long way towards preventing a perceived problem from becoming a real problem.

Resolve each day to spend more time with your patients. Take the initiative to address their concerns and questions. Little slices of time spent with patients can have enormous impact on their well-being and quality of life.

Board of Pharmacy wins another national award!

On May 12, 1999, the California State Board of Pharmacy was presented with the Paul G. Rogers/NCPIC Medication Communicators Award by the National Council for Patient Information and Education in Washington, DC. This award (in the governmental agency category) was presented to the Board for (1) its outstanding leadership in the development, production, and dissemination of educational public service—a large portion of which was achieved through commercial media programming designed to enhance consumers' understanding of the value of high quality communication about medicines and (2) its development and advancement of public policy to support improved medicine communication. Central to qualifying for this award was the Board's ingenuity in creating partnerships with the media, profession, and industry for the successful implementation of a highly visible consumer education program with minimal cost to the Board's revenues.

In 1995, the Board, under the direction of its Public Communication and Education Committee, adopted and implemented an ambitious five-year strategic plan to encourage Californians to

become better informed about medications they take and assure that pharmacists take a proactive role in communicating with and providing drug information to patients. Before funding became available in 1997, the Board creatively partnered with private entities to implement its public education program.

One of the first major elements of the Board's program was the adoption of a logo that represented its commitment to pharmacist consultation with the patient—two communicating faces silhouetted on the sides of a mortar and pestle to represent the pharmacist's role as communicator and dispenser of information as well as medication. An additional part of the Board logo is the slogan, "Be Aware & Take Care...Talk to your pharmacist!"

The Board next launched a separate educational campaign to provide "Get the Answers" information leaflets (containing questions patients should ask pharmacists about their medication) for distribution directly to patients by pharmacists with each prescription filled, and one California pharmacy chain reproduced the pamphlet in a statewide newspaper advertisement. It is estimated that more than 3 million consumers were exposed to the leaflet's message.

Also in 1995, the Board initiated its still ongoing statewide information campaign by cosponsoring with the consumer/health reporters of local television stations "Talk to a Pharmacist" media

Buyer Beware!*Continued from Page 1*

The FDA also regulates drug manufacturing quality standards to ensure that:

- The manufacturing plant is clean and appropriate.
- A particular manufacturing plant is capable of manufacturing the specific drug in question, not just drugs in general.
- A particular drug is manufactured according to approved methods that guarantee its potency.
- There are no contaminants or manufacturing errors in the process.
- The drug container is appropriately labeled and that the labeling accurately reflects the effects of the drug on the patient and includes possible adverse effects and cautions or warnings.

Drugs in Mexico are sold only in the manufacturer's unopened containers with no dosage directions. Because the drugs and their containers may look the same as those purchased in this country, tourists may assume that they are receiving FDA-approved American drugs when, in fact, the label and/or the drugs may be counterfeit.

Four types of drugs are available in Mexico:

1. FDA-approved drugs exported from the U.S. to Mexico.
2. Drugs manufactured by American companies in Mexico, labeled in Spanish, and intended for sale in Mexico. Even though these drugs are manufactured by either American or well-known pharmaceutical companies, manufacturing plants in Mexico are regulated by the Mexican government, not the FDA.
3. Drugs manufactured by Mexican companies, labeled in Spanish, and regulated by the Mexican government.
4. Foreign generics—drugs manufactured in countries other than the U.S. or Mexico. These drugs are of totally unknown quality and could have any of the following characteristics:
 - Sub-potency—so little actual drug in the tablet that the drug would be ineffective.
 - Super-potency—so much more drug in the tablet than the label indicates that the tablet could be potentially harmful to the patient.
 - The wrong drug in the container—the drug in the container is different from that stated on the label.
 - No drug in the container—there are tablets in the container, but no actual drug of any kind in the tablet.

Because of the uncertainty about the actual contents of many prescription drugs available in foreign countries, it is dangerous to purchase or ingest them. Doing so could even be fatal for patients with chronic conditions such as diabetes, heart conditions, or high blood pressure.

In this country, thanks to the diligence of the FDA and the accuracy of manufacturing, we have the luxury of assuming that the drugs we take will do what the literature says they will do. The drugs themselves have been tested extensively, and the methods for their manufacture have been tested and are sound.

Proper labeling of prescription drugs

In California, pharmacists are required to dispense drugs in containers labeled with specific instructions for the patient, and the pharmacy retains the original prescription document. However, in Mexico, the drugs by law are sold only in the manufacturer's original container, with no patient-specific use directions on it. The patient is allowed to keep the original prescription—and is forced to rely on it for directions. If the prescription is written in Spanish, the non-Spanish-speaking patient would have difficulty knowing exactly how to take the medication. Even prescriptions written in English can be very confusing for the patient because of illegibility, abbreviations, etc. Consequently, labeling of the prescription container is **vital** to the patient's health and safety.

Pharmacy personnel

In Mexico, unlike in California, a pharmacist is not required to be present in the pharmacy at all times. Often, the person in charge of a Mexican pharmacy may be the equivalent of a pharmacy technician or may not even have that much training. In those instances, there is no professional in the pharmacy to provide patient care—no one to evaluate drug interactions or provide consultation or advice to the patient. Further, if a patient is taking drugs purchased in Mexico, the patient's physician in the U.S. may not know what medication the patient is taking, or the patient may have an adverse reaction to the drug, and the emergency room personnel would not know exactly what the patient is taking. Additionally, if a patient's condition worsens after taking drugs purchased in Mexico, it can't be known immediately whether the condition is caused by a disease progression or a problem with the drug.

The requirement for a prescription mandates that a physician, and in most cases a pharmacist, continually monitor and weigh the benefits of the drug for the patient against the adverse effects of that therapy. Pharmacists in California are required by law to consult with patients about their medication. However, drugs obtained in a foreign country are not monitored for drug effectiveness, adverse effects, or drug interactions.

Advise your patients:

Fill your prescriptions at a pharmacy on *this* side of the border.

President's Council on Year 2000 Conversion

On June 14, 1999, a press conference was held in Washington DC to provide information to consumers on the pharmaceutical industry's Y2K readiness and the availability of prescription drugs in the beginning months of the year 2000. One of the speakers was John A. Koskinen, Assistant to the President and Chair, President's Council on Year 2000 Conversion. Mr. Koskinen's press release is below, followed by the answers to questions patients are most likely to ask about medication availability into Y2K.

Press Release:

Prescription drugs are an important part of everyday life for millions of Americans. For a vast number of patients, regular medication is critical to overall health and well being. In recent months, attention has focused increasingly on how the Y2K computer problem could affect the consistent supply of prescription drugs.

Last month, the President's Council on Year 2000 Conversion convened a meeting of industry representatives to examine the Y2K readiness of the pharmaceutical supply system. More than 90 participants, representing manufacturers, wholesalers, distributors, retailers, hospitals, doctors, health maintenance organizations, insurance companies, and patient advocate organizations, reviewed how the pharmaceutical supply system operates and efforts by all system participants to ensure that it is equipped to handle the Y2K transition. Also participating were the Department of Veterans Affairs, the Department of Health and Human Services, the Department of Defense, and the Food and Drug Administration. A working group was formed to develop the guidance announced today that consumers and other system participants can follow to help assure a continued adequate supply of pharmaceuticals for the date change.

The Council agrees that consumers and other participants can be assured a continued supply of medications for the date change by refilling prescriptions when they have a 5-7 day supply of medication remaining. Consumers should know it is clear that companies within the system are taking very seriously their responsibility to patients by testing critical computer systems and refining contingency plans. In addition, the pharmaceutical supply system typically operates with a 90-day inventory and, as a matter of course, maintains readiness for emergency situations that may occur.

No one can guarantee that every system will function smoothly as the country makes the transition to the Year 2000. But with continued progress on remediation and contingency planning and responsible actions by all participants, Americans can be assured a continued supply of prescription drugs while moving into the new millennium.

Answers to Questions Patients Are Likely to Ask About Their Medications and Y2K

The following is based on information provided by the Department of Veterans Affairs, a participant of the President's Council on Year 2000 Conversion.

Q. What is Y2K?

A. The year 2000 (Y2K) technology problem was created in the early days of computers when computer memory was expensive and scarce. Instead of using a four-digit code for each year, a two-digit code was used. When the year 2000 arrives, programs coded with two-digit year codes will not be able to distinguish between the years 2000 and 1900. This may cause computers to malfunction. However, federal, state, and local governments, banks and retail businesses, telecommunications, transportation, health care, and other groups affected by this problem have been working to resolve it.

Q. What is being done so that I will not have difficulty getting my prescription filled during the first few weeks of 2000?

A. Government agencies and organizations within the pharmaceutical industry supply system (including manufacturers,

group purchasers, distributors, pharmacies, mail order pharmacies, hospitals, physicians, pharmacists, patient advocates, and insurers) have been working closely together to prepare for the year 2000 date change and its potential impact on the supply of pharmaceuticals. The President's Council on Year 2000 Conversion, in conjunction with the Veterans Health Administration, hosted a Roundtable event on May 17, 1999, convening 90 pharmaceutical industry supply system representatives to ensure that open communication lines exist throughout the supply system and that contingency plans have been developed to ensure multiple paths of distribution for pharmaceuticals. The Roundtable attendees worked closely with the government to draft guidelines for patients when preparing for the year 2000. Substantial progress has been made, and government and industry are confident that the pharmaceutical supply system should continue to function normally into the year 2000.

See Y2K Q&A, Next Page

Y2K Q&A

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Q. What guidelines do the government and pharmaceutical industry representatives that participated in the May 17 Roundtable recommend for patients?

A. Both government and pharmaceutical industry representatives feel that it is advisable to refill your medication when you have a 5- to 7-day supply remaining—as you would normally do.

Q. Will I be able to get enough of my medications?

A. The year 2000 should not affect your ability to receive your normal dose of medications. Local pharmacists should have access to a substantial supply of pharmaceuticals. The industry typically operates with a 90-day supply in the distribution system among manufacturers, distributors, and pharmacies. If you have questions about your individual supply, it is recommended that you speak with your physician or pharmacist.

Q. Do I need to have additional supplies of my prescription medications on hand?

A. It is advisable to get a normal refill of your medication when you have a 5- to 7- day supply of medication remaining. The supply system is resilient and can correct issues that might arise within 5 to 7 days. As a result of the substantial supply of pharmaceuticals that already exist within the supply system, it is unnecessary for you to obtain additional supplies of your prescription medications in anticipation of Y2K. If you regularly refill your prescriptions 5 to 7 days before running out, you should not have any problems with your supply.

Q. Where do I go for the most accurate information about supplies of my medication?

A. If you have any questions about the supply of your specific medications, we recommend that you speak with your local pharmacist or doctor. Additionally, some pharmaceutical manufacturers have information about their specific systems on the Internet.

Q. Who, besides my pharmacist and the manufacturer, is involved in providing medications to patients?

A. Your prescription medications flow through a very efficient and extensive supply system. The supply system starts with manufacturers and distributors of the raw materials that make up the final drug product. It flows to the pharmaceutical manufacturer, who uses the raw materials to make the drugs you need. Drug wholesalers and distributors move the pharmaceuticals from manufacturers to your pharmacy. Finally, the drug product is delivered to you. Companies involved throughout the supply system have been working very hard to ensure that Y2K has minimal impact on the drug supply. It is important to note

that the supply system is a complex web of manufacturers, distributors, retailers, and providers, and not a chain that is easily broken.

Q. What are drug manufacturers doing to address Y2K issues?

A. A drug manufacturers' report in April 1999 revealed that 100 percent of the companies surveyed—including nearly all of the top 20 research-based pharmaceutical firms—have Y2K and emergency response plans in place to assure that the supply of medicines to patients continues without interruption.

Q. Is it true that the majority of raw materials used in manufacturing pharmaceuticals come from outside the U.S.? Does this make the supply more vulnerable to Y2K issues?

A. Most pharmaceutical companies manufacture their products here in the U.S., and the majority of the raw materials used comes from the U.S. Pharmaceutical manufacturers have been working with all of their suppliers, both domestic and overseas, to ensure that their supply of raw materials is uninterrupted. In many cases, manufacturers have brought in extra materials for use in the event of minor disruptions from overseas suppliers.

Q. I have heard that Y2K issues may create problems in the databases that contain patients' medical information, such as past allergic reactions and adverse drug reactions. What is being done to prevent such problems?

A. Word-processing documents, spreadsheets, databases, and systems that check for allergies, duplicate medications, and drug interactions are being reviewed. Existing systems are being corrected or replaced with Y2K-compliant hardware, software, programs, and files. Also, many medical records are retained on paper—and therefore are not affected by computer problems.

Q. Is there a backup plan if something fails at the turn of the century?

A. Government and those organizations involved in the production of prescription and nonprescription medicines have backup plans in place and are continuing to work together to further enhance contingency planning throughout the supply system. Pharmaceutical companies already had well-developed emergency response plans in place before Y2K became an issue. These companies have a great deal of experience utilizing these plans to cope with product demands following hurricanes, fires, earthquakes, and other disasters. In the unlikely event of a disruption, each element of the supply chain will work together to ensure your continued care.

Pharmacists and wholesalers must be alert to orders for OTCs that could be used for methamphetamine production

The Board of Pharmacy, the Medical Board, the Drug Enforcement Administration (DEA), and the state's Bureau of Narcotic Enforcement (BNE), all are working together to curtail the increasing use of ephedrine, pseudoephedrine, and phenylpropanolamine for illicit laboratory production of methamphetamine and methcathinone. They are reminding pharmacists, pharmacies, and wholesalers to be aware of and report excessive sales of these products, whether OTC or wholesale.

The reason for the increased use of OTC products in the illicit production of methamphetamine is, of course, the extremely lucrative returns for street sales. For example, one lb. of pseudoephedrine could produce up to 1 lb. of methamphetamine, with a street value of \$7,000–\$10,000.

Because of the growing problems of illicit methamphetamine production, the Comprehensive Methamphetamine Control Act of 1996 established both recordkeeping and reporting requirements:

Records—A record must be kept of all transactions involving ephedrine, ephedrine combination products, and products containing pseudoephedrine and propanolamine in amounts above the threshold levels set by the DEA. The threshold for single ingredient ephedrine is any transaction of any size (the prescription document can be the record of disposition for single ingredient ephedrine). The threshold for the other drugs mentioned is 24 grams per transaction. Section 1310.06 of the Code of Federal Regulations (CFR) details specifically the records that must be maintained by anyone selling these products (including pharmacies), even though some are over-the-counter medications.

Reports—Section 1310.05 of the CFR mandates that each person shall report to the Special Agent in Charge of the DEA Diversion Office in his or her local area any transaction involving an extraordinary quantity of these chemicals, any uncommon method of payment or delivery, any excessive loss, or any other unusual circumstances surrounding any transaction with these products. This notification should be by telephone and be followed within 15 days by a written report. If the DEA has previously identified suspect purchases and/or buyers for the pharmacist or wholesaler, he or she may not complete transactions with those identified persons without previously notifying the DEA and obtaining approval for the transaction.

When determining whether an order for the discussed drugs may be for illicit production, review the following:

Suspicious ordering methods (While the following information seems most pertinent to wholesalers, pharmacies, too, should be alert for OTC orders in inordinate amounts):

- Intended use does not make sense (e.g., 1,000 tablets to treat a cold; 1,000 tablets for friends who have allergies; a donation to be used for colds).

- Successive purchases below the drug amount threshold by one or more individuals.
- Change in ordering pattern by an established customer.
- Vague, false, or suspicious address or telephone number, etc.
- No references or refusal to furnish references.
- New customer.
- Unable to correctly pronounce the chemical name.
- Unable to explain proper use of the chemical.
- If for industrial use, the buyer does not know his or her own industry.
- Buyer travels a long distance to buy the drug.
- Unusual quantities and combinations of chemicals.
- Individual quantities exceed regulatory thresholds.
- Communications are not done in a professional business manner (phone, mail, etc.).
- Customer provides little or no background information—cannot verify business.

Suspicious payment methods:

- Does not use a personal or business check.
- Pays by cashier's check, money order, large sums of cash, or means other than normal for a business transaction.

Suspicious delivery or transportation methods:

- Wants to pay cash and pick up from the wholesaler, not have the drug delivered.
- Wants delivery to a post office box, mini-locker, or other unusual location.
- An established customer wants delivery to an address different from the usual delivery address at home or business.
- Unusual requests regarding shipping, labeling, or packaging.
- A freight forwarder will pick up the merchandise with no further destination listed other than the freight forwarder.

The DEA and the other agencies are actively prosecuting, both administratively and criminally, all cases of nonreported excessive sales of these drugs. Federal and state agencies are cooperating in this effort, and all instances of violation are being reported to the DEA for referral to the U.S. Attorney General's Office. It is important to note that compliance failure due to lack of knowledge is not considered a defense.

In conclusion, carefully review sections 11100 through 11105 of the Health & Safety Code, and 21 CFR 1310, and be alert to anything out of the ordinary, as well as to any evasiveness or inability to provide information about the buyer's own health or industry. Things that don't make sense are good reasons to suspect diversion!

Wins national award

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events encouraging consumers to come to selected sites to talk to pharmacists about their medications. Additionally, information brochures in five languages were available to consumers who attended. Approximately 15 million viewers saw reports of the events on TV, and some 3,300 consumers attended the 13 events.

More recently, on January 23, 1999, the Board cosponsored a "Talk to a Pharmacist/Free Diabetes Screening" event with students from all four California schools of pharmacy. The event (covered by KTLA-TV in Los Angeles, KCRA-TV in Stockton, and KCBS-AM in San Francisco—reaching approximately 399,000 viewers and 178,400 listeners) was held in five pharmacies throughout the state, provided screening to approximately 900 people, and referred 84 to physicians for further testing and diagnosis.

The Board's consumer health education newspaper columns are published in Spanish as well as English, with a readership of approximately 24 million. In addition, the Board has broadcast radio public service announcement messages in both English and Spanish, reaching approximately 13 million listeners.

To help pharmacists become aware of health issues of interest to consumers, the Board published the first three of a series of *Health Notes* monographs: "Pain Management," "Women's Health," and "Pharmacist Involvement in Anticoagulant Therapy: How Patients Benefit." Each publication was disseminated to approximately 50,000 pharmacists, pharmacies, other health care professionals, and consumers.

A major contribution to the advancement of public policy to support improved medicine communication was the Board's Summit of Health Care Payers and Providers on April 23, 1998. The Board coordinated the summit to include the United States Department of Health and Human Services, the State of California Health and Welfare Agency, and the California State Board of Pharmacy. Payer attendees of the summit were

Are you sure you have the right drug? Better look again!

With so many look- and sound-alike drugs, it is very easy to misread a written prescription or read it correctly, but select the wrong drug from the shelf. The following is a good example of drugs that could be easily misread or confused:

CELEBREX™ (*celecoxib capsules*)—manufactured by Searle and indicated for osteoarthritis and adult rheumatoid arthritis.

CELEXA™ (*citalopram hydrobromide tablets*)—manufactured by Forest Laboratories and indicated for major depression.

CEREBYX® (*fosphenytoin sodium injection*)—manufactured by Parke-Davis and indicated for the prevention and treatment of seizures.

Note: Although Cerebyx is an injectable agent, confusion could occur with Dilantin® (phenytoin sodium) when switching from IV to oral phenytoin sodium therapy. Like Celebrex, Dilantin has a 100-mg capsule formulation.

When filling a prescription or dispensing one of these products, remember to check the name (brand and generic), dosage form, and strength to better ensure that the proper medication is getting to each patient. **Whenever possible, check the indication directly with the patient, and offer counseling on proper use.**

This information was provided by the National Community Pharmacist Association (formerly NARD).

encouraged to develop partnerships with providers to focus on cost-effective pharmaceutical care and patient compliance. (The summit generated interest nationwide and subsequently was featured in the May/June issue of *APhA's Pharmacy Today*.) A follow-up template or guide, *Making the Case*, was developed and distributed to all boards of pharmacy and pharmacy associations to encourage those agencies to plan their own summits.

The Board provides leadership through its participation in the National Association of Boards of Pharmacy (NABP) Bureau of Voluntary Compliance to develop a model public education program for other state boards of pharmacy. The Board also contributed to the advancement of public

policy to support improved medicine communication when the NABP, in 1995 at its 91st annual meeting in Dallas, adopted resolution # 91-5-95, entitled, "Public Awareness of Pharmacists' Responsibilities." California proposed this resolution and demonstrated how to implement it with limited funds and a lot of commitment.

Moreover, two years ago, the Board's public education program received another honor, the "Fred T. Mahaffey" award—an award presented by the NABP to a state pharmacy board for demonstrating outstanding leadership in protecting the public.

The Board of Pharmacy is very proud of the Public Communication and Education Committee's accomplishments!

Update of State and Federal Laws on Oral/ Electronic Transmission and Fractionation of Schedule II Controlled Substances Rxs

Because of substantial amendments to California laws governing the transmission of Schedule II prescriptions, a few federal changes, and the continuing inconsistencies between federal and state provisions, the following comparison and reconciliation of federal and state laws is provided.

As a starting point, it is essential to remember that when a federal statute or regulation is in conflict with a state statute or regulation governing Schedule II prescriptions, **the more restrictive of the two provisions controls**. In other words, if federal law permits something and California law prohibits it, it is prohibited; if California law permits something and federal law prohibits it, it is prohibited. Similarly, if federal law requires that something be done and California does not, it is still required and, again, the reverse is also true.

The following information and table were constructed to illustrate and clarify the similarities and differences between federal and state laws.

Faxing prescriptions

State law defines electronic transmission prescriptions as including both image and data prescriptions:

- ✓ An electronic **image** transmission prescription is any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber.
- ✓ An electronic **data** transmission order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

In contrast, the **federal** regulations governing controlled substances recognize the facsimile transmission of prescriptions, *but do not recognize electronic data transmission of prescriptions*.

The two major factors contributing to the differences between state and federal laws and regulations are the triplicate prescription requirements in California and the federal prohibition of oral (except in an emergency) and electronic data transmission (in all cases) of Schedule II controlled substances prescriptions.

Exceptions to the Triplicate Requirement for Schedule II Prescriptions

In general, a written triplicate prescription must be issued by the prescriber before a pharmacy can fill an order for a Schedule II controlled substance. The existence of the electronic reporting system for Schedule II prescriptions has not changed this requirement. The only exceptions are as follows:

- ✓ **For an emergency:** In this case, a pharmacist may dispense only that amount necessary to meet the emergency, which the Drug Enforcement Administration (DEA) defines as no more than a 72-hour supply (up to a 7-day supply for an institutionalized patient). A faxed prescription may also be used, in which case the original prescription must be received before the controlled substances are dispensed to the patient. The pharmacist must reduce an oral prescription to writing before dispensing the controlled substances to the patient. The prescriber must provide a triplicate prescription,

in the usual form, by the seventh day following the transmission of the original order (a postmark by the seventh day following transmission satisfies this requirement). The pharmacist must promptly notify both the Bureau of Narcotic Enforcement (BNE) and the DEA if the prescriber fails to do so and must make a record of the physician's failure to comply and of the pharmacy's having notified the BNE.

- ✓ **For a resident of a skilled nursing facility (SNF) or intermediate care facility (ICF):** In this case, a pharmacist may dispense a Schedule II controlled substance based on a faxed prescription from the prescriber (California law would permit an oral or electronic data transmission, but federal law permits neither in this situation). The pharmacist must reduce the faxed prescription to writing on a pharmacy-generated triplicate prescription form (this refers to a form issued by the BNE, not to the DEA's triplicate order form). The person receiving the controlled substance at the SNF or ICF must sign the original of the pharmacy-generated triplicate prescription. The faxed copy of the prescription and the appropriate copy of the pharmacy-generated triplicate prescription must be maintained as the pharmacy's prescription record. The pharmacy must obtain a copy of any original signed order from the facility.
- ✓ **For a patient of a home health agency providing hospice care:** In this case, a pharmacist may also dispense a Schedule II controlled substance based on a faxed prescription from the prescriber. The pharmacy must then follow the procedures described above for a Schedule II prescription for a patient of a SNF or ICF and must also note on the prescription that the patient is a hospice patient. To be eligible for this exception, the hospice must be either certified by Medicare or licensed by the State of California to provide hospice care.

Note that federal law would also permit the use of a faxed prescription for any patient for a Schedule II narcotic by infusion (or injection), but California has no parallel provision, so such faxed prescriptions are not permitted in California.

Federal	State
Faxing a prescription for a Schedule II controlled substance	
21 CFR 1306.11(a) Except as indicated below, a Schedule II prescription may be faxed from the prescriber to the pharmacy, but the controlled substance may not be dispensed until after the pharmacist obtains the original written, signed prescription.	There is no similar provision in state law. Note that in California, a Schedule II prescription must be written on a triplicate prescription form.
Emergencies	
21 CFR 1306.11(d) In an emergency, a pharmacist may dispense up to a 72-hour supply of a Schedule II controlled substance, based on an oral prescription. The pharmacist must reduce the prescription to writing. The prescriber must provide a written prescription to the pharmacy for the controlled substance within seven days; the pharmacy must notify the DEA if the prescriber fails to do so. The written prescription must show the words “Authorization for Emergency Dispensing” and the date of the original oral order.	H&SC 11167 In an emergency, a pharmacist may dispense a Schedule II controlled substance on a prescription transmitted orally or electronically by the prescriber. The pharmacist must reduce the prescription to writing. The prescriber must supply a written triplicate prescription for the controlled substance within seven days (or postmarked by the seventh day) following the transmission of the original order. The pharmacy must notify the BNE within 144 hours of the prescriber’s failure to supply the written triplicate, and make a record of having done so.
Patients of long term care facilities	
21 CFR 1306.11(f) For a resident of a long term care facility (LTC), a pharmacist may dispense a Schedule II controlled substance, based on a faxed prescription from the prescriber. The faxed copy of the prescription may serve as the original written prescription.	H&SC 11167.5 For a resident of a skilled nursing facility (SNF) or intermediate care facility (ICF), a pharmacist may dispense a Schedule II controlled substance, based on a prescription transmitted orally or electronically from the prescriber. The pharmacist must reduce the prescription to writing on a pharmacy-generated triplicate prescription form. The person receiving the controlled substance at the SNF or ICF must sign the pharmacy-generated triplicate prescription. The pharmacy must obtain a copy of any original signed order from the facility.
For home infusion pharmacies—injectable Schedule II narcotics	
21 CFR 1306.11(e) A home infusion pharmacy may dispense a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, based on a faxed prescription from the prescriber. The fax will serve as the original written prescription.	There is no parallel provision in state law.
Hospice patients	
21 CFR 1306.11(g) A pharmacy may dispense a Schedule II narcotic prescription, based on a fax of the original prescription, for a patient residing in a hospice certified by Medicare or licensed by the state. The practitioner or practitioner’s agent shall note on the prescription that the patient is a hospice patient.	H&SC 11167.5 For a patient of a licensed home health agency providing hospice care, a pharmacist may dispense a Schedule II controlled substance on a prescription transmitted orally or electronically from the prescriber. The pharmacist must reduce the prescription to writing on a pharmacy-generated triplicate prescription form. The person receiving the controlled substance at the home health agency providing hospice care must sign the pharmacy-generated prescription. The pharmacy must obtain a copy of any original signed order from the facility. Note: The federal DEA considers the use of pharmacy-generated triplicate prescriptions as the original written prescriptions to be in violation of federal law.
Terminally ill patients	
There is no parallel provision for terminally ill patients under federal law; however, the process authorized by the state for terminally ill patients would meet the basic federal requirements for any Schedule II prescription.	H&SC 11159.2 A prescription for a terminally ill patient may be issued using an ordinary written prescription form, provided the prescription is signed and dated by the prescriber and contains the name of the drug, the quantity prescribed, and directions for its use—all of which must be written in ink or indelible pencil, all in the prescriber’s handwriting. Other required information need not be in the prescriber’s handwriting. The prescription must contain the words “11159.2 exemption” to indicate the physician’s certification that the patient is terminally ill. Where the certification is technically in error (but not missing), the pharmacist may fill the prescription if he or she has personal knowledge that the patient is terminally ill and if the pharmacist returns the prescription to the prescriber for correction within 72 hours. “Terminally ill” in this context refers to a patient who, in the reasonable medical judgment of the prescriber, is suffering from an illness that is incurable and irreversible and that the illness will, if it follows its normal course, bring about the patient’s death within one year. It also means that the prescriber’s treatment is primarily for the control of pain, symptom management, or both, rather than for cure of the illness.

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Federal	State
Chart orders for hospital patients	
Federal law has no provision that is directly parallel to the state's provision.	H&SC 11159 An order for use by a patient in a licensed hospital is exempt from all requirements for controlled substances but must be in writing on the patient's record. The order must be signed by the prescriber, dated, and shall state the name and quantity of the controlled substances ordered and the quantity actually administered. The record must be maintained by the hospital for seven years.
Partial filling: drugs unavailable	
21 CFR 1306.13(a) A Schedule II prescription may be partially filled if the pharmacist is unable to supply the full quantity. The pharmacist must make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. No further quantity may be supplied beyond 72 hours without a new prescription. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber.	There is no similar provision in state law.
Partial filling: long term care facility or terminally ill patients	
21 CFR 1306.13(b) A Schedule II prescription written for a patient in an Long Term Care Facility (LTCF) or for a patient diagnosed as terminally ill may be partially filled. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." For each partial filling, the pharmacist must record on the prescription the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. The fractionated Schedule II prescription may be valid for a period not to exceed 60 days from the issue date unless terminated sooner by the discontinuance of medication.	16 CCR 1745 A triplicate prescription for a Schedule II controlled substance written for an inpatient of a SNF or for a terminally ill patient may be partially filled. The prescription must be tendered and at least partially filled within seven days following the date of issue. The pharmacist must record the date and amount of each partial filling and the initials of the pharmacist dispensing the prescription. No portion of the prescription may be dispensed more than 30 days from the prescription's date of issuance. Regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription. The original triplicate prescription must be forwarded to the Department of Justice at the end of the month in which the prescription has been completely filled or in which the prescription had been canceled by death of the patient or otherwise, whichever comes first.

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Note also that while California law permits the use of a chart order for a Schedule II controlled substance for an inpatient of a licensed hospital, federal law does not contain a parallel exemption from the requirement of a written prescription, signed and dated by the prescriber in ink or indelible pencil.

- ✓ **For terminally ill patients:** A prescription for a Schedule II controlled substance for a terminally ill patient may be dispensed, based on a written prescription that is signed and dated by the prescriber and contains the name of the drug, the quantity prescribed, and directions for its use—all of which must be written wholly in ink or indelible pencil in the prescriber's handwriting. The prescription must also contain the certification "11159.2 exemption" to indicate the prescription is exempt from the triplicate requirement. The pharmacist may fill the prescription despite an error in the certification if he or she personally knows of the patient's terminal illness and returns the prescription to the prescriber for correction within 72 hours.

For purposes of this provision, "terminally ill" means a patient who, in the prescriber's reasonable medical judgment, is suffering from an illness that is incurable and irreversible, and whose illness will, in the prescriber's reasonable medical judgment, bring about the patient's death within one year if the illness follows its normal course. In addition, the treatment being provided by the practitioner prescribing a Schedule II controlled substance pursuant to this exemption must be primarily for control of pain, symptom management, or both, rather than for cure of the illness.

- ✓ **Fractionation (Partial Filling) of Schedule II Prescriptions:** A written triplicate prescription for a Schedule II controlled substance may be *partially filled* for any patient if the pharmacist is unable to supply the full quantity. The pharmacist must make a notation of the quantity supplied on the face of the written triplicate prescription. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. No further quantity may be supplied beyond 72 hours without a new written triplicate prescription. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber.

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Any triplicate prescription for a Schedule II controlled substance written for an inpatient of a SNF or for a terminally ill patient may be partially filled. The triplicate prescription must be tendered and at least partially filled within seven days following the date of issue. On the original triplicate prescription, the pharmacist must record the date and amount of each partial filling, the remaining quantity authorized to be dispensed, and the initials of the pharmacist dispensing the prescriptions. No portion of the prescription may be dispensed more than 30 days from the prescription's date of issue, and regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

The original triplicate prescription must be forwarded to the Department of Justice at the end of the month in which the prescription has been completely filled, or in which the prescription has been canceled by death of the patient or otherwise, whichever comes first. The prescription can no longer be partially filled once the original triplicate prescription has been forwarded to the Department of Justice.

If the prescription is a pharmacy-generated triplicate prescription for a resident of a SNF or ICF, or a patient of a home health agency providing hospice care, and the triplicate prescription is being partially filled, the original of the pharmacy-generated triplicate prescription must be signed by the person receiving the controlled substance at the SNF or ICF (or the person receiving the narcotic at the home health agency providing hospice care) with each partial filling.

Pharmacy Board meetings are open to the public

In accordance with its strategic plan, the Board has formed committees to address issues related to meeting the plan's objectives. To share the various committee goals, activities, and accomplishments with the public, a portion of each Board meeting will be devoted to one of the committees and open for public comment.

The October 20-21, 1999, Board (and Legislation and Regulation Committee) meeting will be held in Sacramento at 400 R Street, First Floor Hearing Room.

On January 26-27, 2000, the Board (and Public Communication and Education Committee) meeting will be held in Orange County, but no site has been selected.

All interested parties are encouraged to participate in these meetings. If you cannot present your comments in person, your written comments will be reviewed and considered if received at the Board office at least seven days prior to the meeting. Comments may also be mailed or faxed to the Board at (916) 327-6308.

Agendas with meeting times and locations may be obtained by calling the Board at (916) 445-5014.



Board elects new officers and welcomes a new public member

At its May 1999 meeting in San Diego, the Board of Pharmacy elected new officers: Richard Mazzoni, R.Ph., *President*; Robert Elnsner, Public Member, *Vice President*; and Caleb Zia, Public Member, *Treasurer*.

Another change to the Board included the departure of Public Member Ken Tait. The Board acknowledges Mr. Tait's dedication and commitment and thanks him for his many contributions to Board policy.

While saying goodbye to Mr. Tait, the Board wishes to welcome his replacement, Public Member Andrea Zinder, who was appointed to the Board on May 14, 1999, by Speaker of the Assembly, Antonio R. Villaraigosa. A graduate of Cornell University, Ms. Zinder presently serves as executive assistant to the president of the United Food and Commercial Workers International Union Local 324 in Orange County. In that capacity, her primary responsibility has



been to negotiate collective bargaining agreements for members represented by the union, including the pharmacy contracts for Rite Aid, Sav On, and the food stores. Ms. Zinder also serves as liaison for the local's professional division members (pharmacists) and writes a column for its bimonthly newspaper.

This newsletter is published by the
California State Board of Pharmacy
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400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
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BOARD MEMBERS

Richard Mazzoni, R.Ph., *President*
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Has your name or address changed?

Section 4100 of the Business and Professions Code requires all holders of personal Board-issued licenses (pharmacists, interns, pharmacy technicians and exemptees) to report name or address changes to the Board within 30 days of the change. Such changes must be mailed or faxed to the Board.

When notifying the Board of a change in your name, please include the following:

A copy of legal documentation (marriage license, divorce decree, or legal name change) of your name change or

Copies of your driver license **and** Social Security card (both reflecting the new name).

For address changes, please include your full name, license number, old address, and new address. **Your “address of record” is accessible to the public, pursuant to the Information Practices Act and the Public Records Act.** If you choose to use a post office box or business address as your address of record, section 1704 of the Business and Professions Code requires you to also provide your residence address.

Please mail or fax all change information to:

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
FAX: (916) 327-6308