



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person: Patricia Harris
(916) 445-5014

ENFORCEMENT COMMITTEE MEETING

September 13, 2005

9:30 a.m. – 12:30 p.m.

**Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Director A & B
Burbank, CA 91505-1019
(818) 843-6000**

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Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER

9:30 a.m.

- A. Discussion Regarding the Importation of Prescription Drugs
- B. Proposed Revisions to the Disciplinary Guidelines (16 CCR § 1760)
- C. Proposed Self-Assessment form for Wholesalers
- D. Review of Citation and Fine Program
- E. Legibility of Prescriptions
- F. Clarification from the DEA of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances
- G. New Labeling Requirements – Physical Description of the Dispensed Medication (Effective January 1, 2006)
- H. Implementation of SB 1307 (Chapter 857, Statutes of 2004) Relating to Wholesalers
- I. Adjournment

12:30 p.m.

Committee materials will be available on the board's website by September 7, 2005

AGENDA ITEM A

State of California

Department of Consumer Affairs

Memorandum

To: Enforcement Committee

Date: September 6, 2005

From: Patricia F. Harris 
Executive Officer

Subject: **Importation of Prescription Drugs**

This is a standing agenda item for the meetings of the Board and the Enforcement Committee. Attached are various articles that have appeared since the last board meeting.

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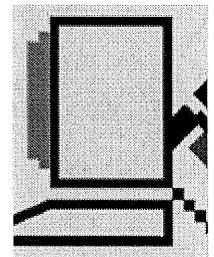
- [Overview](#)
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October 2005

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Prescription drugs: The facts about Canada

Even though the practice is illegal, Americans in droves have been importing prescription drugs from Canada. Last year, an estimated 2 million U.S. citizens spent \$800 million on medicines purchased from Canadian pharmacies by fax, phone, or Web site. That's 33 percent more than in 2003. A long list of states and cities, including Kansas, Illinois, Minnesota, Missouri, New Hampshire, Wisconsin, Boston, and Portland, Maine, have set up programs to help residents and employees import Canadian drugs priced on average 25 to 50 percent below those on the U.S. market.



Canada's distribution and systems are less foster counter

Illustration by Bob

Related information

- [HMOs vs. PPOs 9/05](#)
- [Recalls](#)
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What's happening is controversial. The U.S. Food and Drug Administration stands foursquare against imports, arguing that it cannot ensure they are safe. Many Americans, however, believe that buying from Canada, a familiar next-door neighbor, is no more dangerous than picking up a prescription at a local drugstore. Almost 70 percent of the 1,400 people surveyed by the Henry J. Kaiser Family Foundation and the Harvard School of Public Health in November 2004 said allowing citizens to order drugs from Canada would make medicines more affordable without sacrificing safety or quality.

Here's the reality of the government's arguments against buying from Canada:

Canadian drugs are not as safe as U.S. drugs. False. The FDA maintains that "many obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs, are, in fact, of unknown quality." Furthermore, FDA officials have expressed the concern that news of product recalls issued in Canada may not reach U.S. consumers.

But Canada's manufacturing and regulatory system is comparable to that of the U.S., according to an October 2003 study by the state of Illinois' Office of Special Advocate for Prescription Drugs. The study's FDA critics counter, moreover, that the agency cannot entirely ensure the safety of drugs manufactured in the U.S.

The Illinois study also concluded that Canada's pricing and distribution system is less likely to foster the drug counterfeiting that concerns the FDA. Drugs in the U.S. typically move through multiple vendors (manufacturers, wholesalers, repackagers, retailers, second repackage) before reaching the patient. In Canada, medications are dispensed mainly in typical doses and shipped in sealed packages directly from manufacturer to pharmacy. In a June 2004 report, the U.S. Government Accountability Office said that all of the prescription drugs it ordered from Canadian Internet pharmacies contained the proper chemical compositions, were shipped in accordance with special handling requirements, and arrived undamaged.

In addition, if a recall is issued for a drug sold in Canada, Canadian pharmacies are required to alert all consumers who purchased the affected lot, regardless of where they live. "This is a recall policy that has been in place in industrialized countries for decades," says Andy Trachtenberg, president of the Canadian International Pharmacy Association (CIPA), an industry group that certifies Canadian pharmacies.

Canadian drugs are not always cheaper. True. To see how much consumers can expect to save by buying from Canadian pharmacies, we asked PharmacyChecker.com, a group that evaluates online pharmacies, to compare drug prices from its highest-rated Canadian and U.S. Web sites. (See [Brand name vs. generic costs](#).) When we compared the lowest prices of known brand-name drugs from both Canadian and U.S. sources, the Canadian pharmacies saved consumers between \$72 and \$226 per prescription (including shipping charges). Such savings are cheaper in Canada in large part because its federal Patented Medicine Review Board has the authority to limit prices that it deems to be excessive.

But in a similar comparison, a U.S. site had the best prices for the five most prescribed generic drugs. Because generic drugs cost less, the savings are less: from \$7 to \$31 per prescription. "The larger, more competitive generic market in the U.S. helps keep prices down," says Robert McGinnis, the FDA's director of pharmacy affairs.

You could get arrested. True but unlikely. Ordering prescriptions from Canadian Web sites violates the Federal Food, Drug, and Cosmetic Act, which generally makes it a crime for anyone other than the original manufacturer to import a drug, even if it was first manufactured in Canada.

So far, however, the FDA has focused its enforcement efforts only on those who engage in large-scale drug importation. One example: RxDepot, an Oklahoma prescription drug service that was forced to shut down in 2003. But there are currently no plans to charge consumers. McGinnis says that the FDA is allowed to exercise enforcement discretion, and it's not our policy to go after individuals.

Many Internet sites are not legitimate pharmacies. True but avoidable. CIPA warns that many Web sites selling medications have been created to lure U.S. consumers seeking cheap prices. Patients who order from such sites run the risk of receiving medications that are subpotent, improperly handled, or counterfeit. Furthermore, the FDA says some Web sites may not disclose that a drug they sell you is obtained from an overseas supplier. "You may be sent a drug that originated in Australia, Great Britain, or Pakistan," says McGinnis. "We don't know anything about the strength, quality, or purity of those medications."

Patients, however, can avoid such problems by ordering only from pharmacies that have been thoroughly scrutinized by CIPA. To display a CIPA seal on its Web site, an online pharmacy must have a valid Canadian license, submit to a quarterly on-site inspection, and keep personal information confidential in compliance with PIPEDA, the Canadian privacy act similar to the Health Insurance Portability and Accountability Act, or HIPAA, in the U.S.

The online pharmacy must also require you to submit a valid prescription and medical history to check for possible drug interactions. And CIPA members must let you know in advance if they are supplying you with a medication from another country so you have the right to refuse. Find a list of the 37 Canadian pharmacies with CIPA seals at www.ciparx.ca/cipa_pharmacies.html.

Another source of information about online pharmacies is PharmacyChecker.com, whose verification process is similar to CIPA's. It also provides prices and customer feedback.

WHAT TO DO

The flow of prescription drugs from Canada may not last forever. Ujjal Dosanjh, the Canadian Health Minister, proposed on June 29 that a new supply network be established to keep the nation's drugs and that bulk shipments to the U.S. be stopped if the system detects a shortage. In addition, he proposed a requirement that "an established patient-practitioner relationship" should exist before a physician may prescribe any medications. Whether or not that means that U.S. citizens will have to meet face-to-face with a Canadian doctor before they can purchase drugs will not be determined until sometime this fall, when the minister plans to introduce legislation.

But whatever happens, you should take the following steps before ordering:

- Check Consumer Reports Best Buy Drugs (www.CRBestBuyDrugs.org) to learn about drug options, including generics and over-the-counter drugs, that could save you money.

- Ask your doctor to prescribe generic drugs, which cost much less than brand-name drugs. Remember to buy them in the U.S., where they are generally cheaper than in Canada.
- If you need a high-priced, brand-name drug, check with the Partnership for Prescriber Assistance (www.pparx.com; 888-477-2669), which lets you find out in one step whether you are eligible for any of the 275 programs that offer cost savings to consumers.
- If ordering from Canada is the only way you can afford the medication you need, go to PharmacyChecker.com for recommendations of approved outlets, and look for the CIPA logo to protect yourself.

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Texas Places Prescription Drug Reimportation Law on Hold To Allow Time for Review of Federal Complaint
[Sep 01, 2005]

Texas has placed on hold a new state law that will allow residents to purchase less-expensive medications from Canada to allow state attorneys time to review a complaint from the federal government that the measure violates a federal law related to prescription drug imports, the *Houston Chronicle* reports. The Texas law, part of a broader measure scheduled to take effect on Thursday, will require the Texas State Board of Pharmacy to provide information on a Web site to help state residents purchase prescription drugs from as many as 10 Canadian pharmacies. In addition, the law will require the board to inspect the pharmacies to ensure that they meet Canadian and U.S. safety standards. Acting FDA Associate Commissioner Randall Lutter prompted the review of the legislation with a letter to Gov. Rick Perry (R) that raised concerns about potential safety risks. Lutter also wrote that the federal Food, Drug and Cosmetic Act supersedes the law (Robison, *Houston Chronicle*, 8/31). In response to the letter, the board asked state Attorney General Greg Abbott (R) to review the legality of the Texas law. Gay Dodson, executive director and secretary of the state pharmacy board, said that the board does not plan to take action on the law until Abbott issues an opinion. The inspection of the Canadian pharmacies required under the law "is not equivalent to licensure," but "the procedure ... would be equivalent to the board condoning, if not promoting, these Canadian pharmacies shipping prescription drugs into Texas," Dodson wrote in a letter to Abbott (*AP/Fort Worth Star-Telegram*, 8/31). State Rep. Scott Hochberg (D), who sponsored the Texas law, said that the measure does not violate federal law. He said, "States clearly have the right and responsibility to protect the health and safety of their residents, and Texas has a compelling interest to inspect Canadian pharmacies as long as they continue to solicit drug sales to Texans" (*Houston Chronicle*, 8/31).

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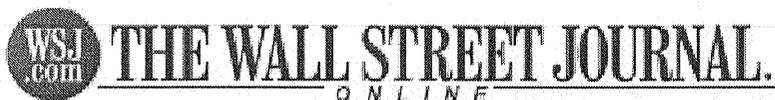
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Health Care Marketplace

NPR's 'Talk of the Nation' Discusses Health Savings Accounts
[Sep 01, 2005]

NPR's "[Talk of the Nation](#)" on Tuesday included a discussion of health savings accounts, a "relatively new alternative" that some employers have begun to offer to encourage employees to "assume more responsibility" for health care costs (Conan, "Talk of the Nation," NPR, 8/30). Under the 2003 Medicare law, HSAs are



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August 30, 2005

PAGE ONE

Tangled Web
**For Entrepreneur,
Online Drug Sales
Meant Fast Profits**

**Mr. Kolowich Smuggled Pills
From Mexico, Then India;
A Big Hit With Viagra**

FBI Gets Clues From a Laptop

By **HEATHER WON TESORIERO**
Staff Reporter of THE WALL STREET JOURNAL
August 30, 2005; Page A1

Browsing the Internet on Halloween night in 1998, Mark Kolowich read that Viagra was difficult to get in Great Britain while the government decided whether to pay for it. The owner of a struggling San Diego picture-frame business smelled a new commercial opportunity.



Mark Kolowich

Barbara.

In a couple of weeks, Mr. Kolowich says, he had procured the anti-impotence pills from Tijuana, Mexico, where they could easily be obtained without a prescription. He started selling the pills to United Kingdom buyers on a rudimentary Web site, which later became known as WorldExpressRx.com. Within five years, Mr. Kolowich was selling a wide array of prescription drugs to thousands of customers around the world. By one U.S. government estimate, he made as much as \$7 million, but he says he made much more.

Eventually, Mr. Kolowich was arrested for importing and selling counterfeit drugs, mail fraud and money laundering. In April 2004, he pleaded guilty to all four counts and is now serving a 51-month prison term at the low-security Federal Correctional Institution in Lompoc, Calif., near Santa

Barbara. But for years, he was able to evade investigators from the Food and Drug Administration, border officials from U.S. Immigration and Customs Enforcement and the Federal Bureau of Investigation. The 45-year-old Mr. Kolowich agreed recently to discuss in detail his commercial operations, and how he was able to stay one step ahead of the law for so long. In a four-hour interview -- clad in prison khakis, 40 pounds lighter than when he was living the high life, sitting in plastic chairs in the prison's visitors lounge -- he offered a rare look into the rapidly expanding, often shady, sector of online pharmaceutical sales.

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Though Viagra and other anti-impotence remedies are available with a prescription at legitimate pharmacies, there's a thriving online market for these drugs, where customers can obtain the pills anonymously and with ease. But online pharmacies are largely unregulated and unmonitored by health authorities. In many cases, site operators such as Mr. Kolowich are unlicensed to sell or prescribe prescription medications. Since October 1999, the FDA's Office of Criminal Investigations has made about 180 Internet drug arrests, most of which have resulted in convictions.

PILL SALES

• Fake-Drug Sites Keep a Step Ahead¹
08/10/04

New sites are constantly sprouting up. Like Mr. Kolowich, criminals set up online drug sites because they're inexpensive to create and hard to shut down. Counterfeit supplies are widely available and easy to smuggle. Drug makers consider other versions of their patent-protected drugs to be counterfeit. **Pfizer** Inc.'s Viagra patent is valid in the U.S. until March 2012.

There are "tens of thousands of URLs, which lead back to thousands of online pharmacies," according to Michael Allison, chairman and chief executive officer of ICG Inc., a Princeton, N.J., firm that investigates fraudulent Internet activity for companies. ICG estimates that 80% of drugs sold online are considered counterfeit by drug manufacturers, although others in the industry caution that such figures are hard to prove.

Mr. Kolowich remembers a life as the youngest of eight children in a rich, roving family. He says he spent some of his childhood aboard an 82-foot yacht in the Caribbean and attended a British boarding school. One of his sisters confirms this account. Mr. Kolowich's father was an entrepreneur who made a fortune selling a trucking business. He says his father, now deceased, also served 30 days in prison for tax evasion.

Job to Job

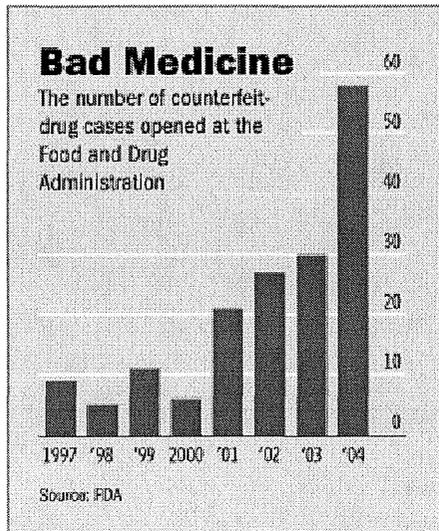
Mr. Kolowich never went to college. He never graduated from high school. He says he passed a high-school equivalency exam back in the U.S. and then hopscotched from job to job, including as an overnight federal-funds trader and as an airline ticketing agent. He never held a position for long.

Then came the Halloween inspiration. Mr. Kolowich taught himself how to build a Web site from a few books on e-commerce. Recalling his days at the British boarding school, he sprinkled the site with words such as "chemist" and "fortnight." He figured out how to use aboveboard businesses to his advantage.

He opened a bank account with the First Bank of Beverly Hills, listing his business as selling "health supplements." The bank sold its merchant-accounts unit in June 2001. First Bank of Beverly Hills Chief Executive and President Joseph W. Kiley, who wasn't with the bank when Mr. Kolowich said he did business with it, said he wasn't aware of this particular case.

Since he initially targeted British customers, Mr. Kolowich procured London-based telephone numbers from j2 Global Communications Inc., a company that sells phone numbers for more than 1,300 cities around the world. Customers would think they were calling England, while Mr. Kolowich and his employees would take the calls in California, according to the criminal complaint filed by the government.

Christine Brodeur, a spokeswoman for j2 Global, confirmed that Mr. Kolowich had an account, and said the company reserves the right to terminate service if it determines a customer is acting illegally. She says the company wasn't contacted by law enforcement regarding Mr. Kolowich.



In the first week his Web site was live, Mr. Kolowich says, he got 40 orders. He drove to Tijuana to buy what he says were Pfizer-made Viagra pills from a pharmacy, smuggling them back to San Diego in his Lexus. Mr. Kolowich says he was able to make bulk purchases without a prescription from a local Tijuana pharmacy. He had no license to prescribe or sell prescription drugs.

As business picked up in the first few months of 1999, Mr. Kolowich grew savvy about getting past border-patrol protocol. He says he stuffed the pills under the seat and floor mats -- every place but the trunk. A spokesman for U.S. Customs and Border Protection says that "every car, every person does undergo some level of inspection." But he adds that the high volume means "the officer has precious few seconds" sometimes for the inspection.

In his first year, Mr. Kolowich says, he had revenue of \$985,000 from his Viagra sales. He then diversified, selling what he says were also real versions of weight-loss drug Xenical, painkiller Celebrex and hair-loss drug Propecia, bought in Mexico at pharmacies. Law-enforcement agents say that the drugs Mr. Kolowich sold were tested and though they contained some active ingredient, they weren't manufactured by pharmaceutical companies that had patented them.

Mr. Kolowich hired three employees for customer service and filling orders, and merged several sites he had built into one: WorldExpressRx.com. A growing number of U.S. customers, particularly those with college-campus mailing addresses, bought from the site. In his second year, he says, he brought in revenue of \$3 million.

In early 2001, Mr. Kolowich got a big break when he read an article online about "generic Viagra" made by the Indian drug company Ranbaxy Laboratories Ltd., under the name Caverta. In the past, India hasn't recognized U.S. pharmaceutical patents, spawning a thriving industry in knockoff drugs.

Mr. Kolowich says he and a friend flew first class to Mumbai. Carrying \$40,000 in cash, he says, he met with people at Ranbaxy who politely told him that the drug wasn't for export. But he says someone at the company gave him the name of a local wholesaler whom he met six hours later. He won't identify his tipster. A spokesman for Ranbaxy, informed of Mr. Kolowich's account, declined to comment on it and would only say, "Ranbaxy abides by all local laws, rules and regulations in all countries where it has operations."

Mr. Kolowich says he paid cash to the local wholesaler at 48 cents a pill -- well below the \$7 a pill he was paying in Mexico. Online, he charged \$13 a pill for his Mexican supply. Viagra sells for about \$10 a pill when purchased through legitimate outlets. Back in the U.S., he planned to sell Ranbaxy's Caverta pills for \$6.50 each, a 1,200% markup. He bought 80,000. The pills were red triangles, as opposed to Viagra's blue diamonds. He jammed them into two large suitcases.

Mr. Kolowich encountered some unexpected resistance on his India trip. It took him several weeks to negotiate the supply deal. The cash payment, he says, "was a red flag" to the wholesaler, who photocopied every U.S. bill he had brought and asked for a "one-page due diligence" document about his creditors. He passed himself off as a doctor, saying he had an online pharmacy on the side.

Then in Mexico City, on the way back to San Diego from India, customs officials opened his bag. When they discovered his Caverta pills, Mr. Kolowich says, he was swarmed by security. He showed them a business card from a Tijuana pharmacy. Because he couldn't communicate well in Spanish, Mr. Kolowich says, he engaged in charades to explain that the drugs were for impotence. He says some men took a small sample of the pills, disappeared for a while, and let him proceed after they returned. He then drove the drugs over the border to San Diego.

Gabriela Deffis Ramos, a spokeswoman for Mexican customs, said customs didn't have a record of the incident.

About that time, Mr. Kolowich says, he received six months' notice from the First Bank of Beverly Hills saying it would be terminating his account. According to the bank's Mr. Kiley, many banks were getting suspicious about online businesses after there were a number of high-profile scams. Banks had started requiring these businesses to carry high minimum balances, charging high fees for all transactions -- and sometimes cutting them off.

Mr. Kolowich quickly adjusted. He got Deutsche Bank in Munich and Bank of Montreal in Vancouver to take his accounts. Spokesmen for Deutsche Bank and Bank of Montreal declined to comment on the case. Realizing that other online pharmacies had similar banking difficulties, he set up a new business to help them out, according to law-enforcement agents. He would allow other online druggists to become "affiliates" of WorldExpressRx.com, and would then manage their accounts for them. He'd charge them a transaction fee as low as 5%, a big savings for the pharmacists paying up to 9% at mainstream banks. Mr. Kolowich says he invested \$200,000 in software to handle the new financial side of his operation, and took in daily revenue on it of \$50,000 to \$60,000.

The drug side of the business was expanding sharply as well. He says the India supply line expanded and became the major source for his business, which advertised the Caverta pills as "generic Viagra." He made a second trip to India and sent a friend on a third, but eventually, he had his Indian drugs shipped to Mexico, and hired someone to smuggle them over the border. He says he paid about \$1 million to people in Mexico for smuggling. A federal investigation later uncovered letters and wire transfers from an Indian-based company requesting Mr. Kolowich pick up his shipment in Mexico.

He had plenty of money left over to enjoy a lavish lifestyle. According to law-enforcement agents familiar with the case, he drove a leased Porsche with the license plate "BLU PIL." He says he drank \$3,000 bottles of Bordeaux wine and fed a cocaine habit. "My whole life I always wanted to come up with an idea that would succeed, and here it was working," says Mr. Kolowich.

'Mark, It's Just Europe'

All the time his business expanded, Mr. Kolowich says, he wrestled with what he was doing. He was thrilled by a business success at last, but knew he was breaking the law. "I think I've unleashed a lion, the Internet's booming...I think I've got something pretty unique," he recalls feeling. "But I'm also doing something highly illegal." Mr. Kolowich had no license to sell or

import prescription drugs. Further, he didn't report income from his business. He told himself it was OK: "My inner voice said, 'Mark, it's just Europe.' "

When he expanded beyond Europe, and into the U.S., he still felt he was performing a service for his clients, an argument he stresses repeatedly in the prison interview. His customers, he says, frequently thanked him via email and phone calls. And he says that he never crossed the line to selling controlled substances, which he described as "dangerous drugs." Still, drugs sold without a prescription can pose serious health risks. For instance, patients taking nitrate-containing drugs such as heart medications shouldn't take Viagra, since the combination could cause a dangerous drop in blood pressure, according to a Pfizer spokesman.

In the fall of 2003, Mr. Kolowich told his girlfriend, Odette Pidermann, currently serving an 18-month sentence for crimes related to WorldExpressRx.com, he was getting out of the business by New Year's. In an interview last February before she began her prison sentence, Ms. Pidermann, who pleaded guilty to charges of conspiracy and mail fraud, said that she was drawn into the activities because of her relationship with Mr. Kolowich.

But "Jan. 1 came and went," he says, and instead of quitting, he only dove deeper into the illegal pharmaceutical world. Rather than just selling pills he purchased, he began negotiating a deal to manufacture his own knockoff pills in Mexico, according to the U.S. attorney's office in San Diego.

Mr. Kolowich's fate took a turn when a former employee of his firm happened to pawn a laptop. Law-enforcement agents familiar with the case say a person hired by the pawn shop to do the routine cleaning of the computer's hard drive notified authorities after discovering images of pills and other WorldExpressRx.com documents. That triggered an FBI investigation. According to the criminal complaint, law-enforcement agents also made several undercover purchases from Mr. Kolowich's site.

On March 22, 2004, Mr. Kolowich and his girlfriend landed at the San Diego International Airport, back from a ski vacation at a luxury resort in western Canada. Authorities trailed him as he got off the plane and walked through the airport. They arrested him and his girlfriend at the baggage carousel. They didn't resist.

"After the initial shock," says Mr. Kolowich, "it was a big relief."

Write to Heather Won Tesoriero at heather.tesoriero@wsj.com²

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Prescription Drugs | 10 Canadian Pharmacies Apply to Nevada for Licenses To Sell Prescription Drugs to State Residents [Aug 24, 2005]

Ten Canadian pharmacies have submitted applications to the [Nevada State Board of Pharmacy](#) seeking licenses to sell prescriptions drugs to state residents, officials said on Monday, the [AP/Nevada Appeal](#) reports (Bosshart, [AP/Nevada Appeal](#), 8/23). Friday was the deadline to submit applications and a \$500 filing fee. Louis Ling, general counsel for the pharmacy board, said he had expected no more than three applications (Ryan, [Las Vegas Sun](#), 8/23). Under a state law that took effect July 1, Nevada residents will be able to purchase a 90-day supply of some medications from Canadian pharmacies through a state-run Web site ([Kaiser Daily Health Policy Report](#), 6/22). The pharmacy board will review the applications at its Sept. 7 and Sept. 8 meetings. Ling and a pharmacy inspector will conduct on-site inspections of the approved pharmacies during the week of Sept. 19. Consumers should be able to order drugs from licensed pharmacies through the Web site by the end of September, Ling said ([AP/Nevada Appeal](#), 8/23). The site will include links to the pharmacies' Web sites and provide information on how to order prescriptions from the pharmacies. State residents will be able to fax their prescription to the Canadian pharmacies to be filled. Keith Macdonald, executive director of the pharmacy board, said consumers could save up to 40% by buying reimported prescription drugs, but he also noted that generics usually cost the same in Canada as in the U.S. ([Las Vegas Sun](#), 8/23).

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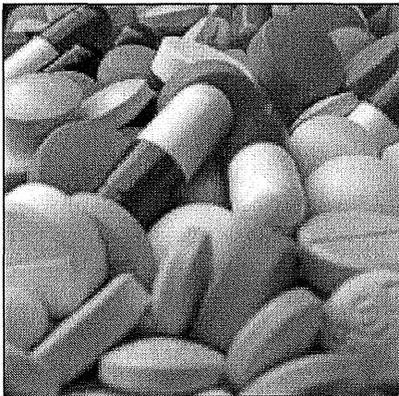
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HEALTH

A long-distance pharmacy

By Kelly Hartog August 21, 2005



Nathan Jacobson, founder of MagenDavidMeds.com, says that as long as medication prices in the U.S. remain unregulated, customers will seek pharmaceuticals abroad. Israel, he says, can provide them safely and efficiently.

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Magen David Meds

As pharmaceutical prices within the United States continue to climb, many North Americans are turning to foreign countries to purchase their prescription medications at more affordable prices.

Some physically cross the border to buy them in Canada, while others are looking further afield to purchase their medications from online pharmacies.

Based at the Weizmann Science Park in Rehovot, MagenDavidMeds is providing Israeli medications at prices up to 70% lower than in the US, which does not regulate pharmaceutical pricing.

The company, which bears no relation to Israel's ambulance rescue service Magen David Adom, has been in operation for almost two years, and is the first Israeli-based online pharmacy network to provide prescription drugs to US residents.

It is the brainchild of 50-year-old entrepreneur Nathan Jacobson, who holds joint Israeli/Canadian citizenship. According to Jacobson, by the end of its first year in operation, MagenDavidMeds was receiving around 400 orders per day.

"I'd love to claim I was the person who came up with the idea of online pharmacies but that was started in Canada," Jacobson told ISRAEL21c. "But I'm close to some of the people who were involved with online meds in Canada. We took the Canadian model and replicated it."

In reality, it wasn't as easy as it sounds. To set up MagenDavidMeds, Jacobson retained an Israeli lawyer and a doctor and spent six months researching not only whether it was economically feasible, but whether it could also be done out of Israel legally. After the research was completed, the plan was presented to health minister Danny Naveh. "We got his support and then created an alliance with the Association of Independent Pharmacists of Israel and got them on board."

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And MagenDavidMeds.com was born.

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Customers can either order their prescriptions online or by fax by simply typing in the name and dosage of their drug, attaching the prescription from their physician, filling in a customer agreement form and customs declaration and paying either by electronic check or credit card. Orders are processed within 72 hours, and the medications arrive on the customers' doorstep within 2-3 weeks. It's that simple.

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This leads to the question why other companies haven't jumped on the Israeli medication bandwagon.

"Money," responds Jacobson. "So far we don't have any other competition from Israel, because most people don't have the money to do this. It's a heavy investment. And it's all self-funded." But it's an investment, he says, that is well worth both his money and his effort.



"I love Israel and I can't say that in strong enough words," says Jacobson, who had a Jewish day school education in Canada. "I grew up living, eating, breathing, Israel."

So great was his love, that as soon as he turned 18, he moved to Israel just so that he could join the Israeli Army. His stay was cut short when he had to return to Canada after he completed his army service because his father was very ill, and he remained. Yet to this day, he still retains strong ties to the country, including owning a home in Tel Aviv.

"I sit on the board of the Tel Aviv Foundation and was recently approached to join the board of the Meir Medical Center in Kfar Saba," he says.

It's this personal connection to Israel that makes MagenDavidMeds' mission two-fold; not only to provide affordable prescription drugs, but also to support the country.

Two percent of all gross sales at MagenDavidMeds are donated to the Israel non-profit charity Aleh Negev, which provides medical and rehabilitative care for severely disabled children. And MagenDavidMeds also helps independent pharmacists in Israel by helping them do business.

"They're being beaten up by large chains, and the local neighborhood pharmacies are being wiped out," says Jacobson.

While MagenDavidMeds is marketed heavily towards the Jewish community, particularly those who want kosher medications, or simply wish to support Israel, the network also has non-Jewish purchasers.

Look through the Internet and you'll discover what appear to be "other" online companies providing medications from Israel, including CanadaMeds, CrossBorderMeds and TotalCarePharmacy. They are, in fact, MagenDavidMeds.

"These are also our sites," says Jacobson "which focus heavily on promoting the safety and security of Israeli medications as well as the prices of the Israeli medications.

"Israel has the safest drugs in the world," he states proudly. "It needs to, in the same way unfortunately that El Al has to be the safest airline in the world. So Israel's packaging is the safest packaging against counterfeiting and tampering." Safety, naturally, is a key concern of customers when it comes to buying medication online.

Jacobson says the network is growing every month. "We're very successful and I'm thrilled." He credits his success to what he terms "doing the job properly. We take care of our clients, we have professional customer support, and a very good Website."

Another huge feather in MagenDavidMeds' cap is that the network has worked closely with the Israeli Postal Authority. "We're their largest client," says Jacobson. "We've been able to convert their system to English for our patients to track their medications online during the shipping process."

Jacobson sees no reason why the purchase of online medications from Israel will slow down as long as the pharmaceutical companies still retain a powerful lobby in the US and can block regulation of pharmaceutical prices. In fact, he's already looking for ways to expand.

"I recently had a senior representative of the African-American community in the US come to me to talk about creating a specific African-American site for Israeli medications," he says.

In the meantime, MagenDavidMeds is continuing to thrive, and while Jacobson runs several other successful businesses, this one is very close to his heart. "I wanted to have a reason to spend more time in Israel," he says. "And this was an opportunity that allowed me to do so."

Kelly Hartog is a free-lance writer based in Los Angeles.

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Prescription Drugs | Prescription Drug Names in U.S., Abroad Lead to U.S. Consumers' Confusion When Buying Medications in Other Countries
 [Aug 16, 2005]

The *Wall Street Journal* on Tuesday examined a safety alert issued by the not-for-profit [Institute for Safe Medication Practices](#) identifying several drugs in the U.S. that have the same name as drugs with different ingredients sold by other manufacturers on the global market. Problems can arise when travelers refilling prescriptions abroad or U.S. residents importing less-expensive medications get the wrong drug, possibly causing unexpected drug interactions or delayed treatment. No regulatory body exists to track brand names globally, but the [World Health Organization](#) works to match generic drug names with standardized [International Nonproprietary Names](#). [FDA](#) has the authority to approve drug names only in the U.S. but acknowledges that the conflicts can exist abroad. The international drug name problem came to light recently after a Michigan man was hospitalized following a trip to the former country of Yugoslavia during which his prescription for hypertension drug Dilacor XR was mistakenly refilled with the Serbian version of Dilacor, which is a heart-failure drug. Because of the large number of drugs worldwide, the problem of identical or similar brand names is likely to grow, according to the *Journal*. The U.S. market includes 10,800 brand-name and generic drugs, according to the [Pharmaceutical Research and Manufacturers of America](#). Some experts believe hundreds of thousands of drugs exist worldwide. In order to address the drug name issue, companies, hospitals and doctors can use consulting references books such as "Martindale: The Complete Drug Reference" or electronic databases such as Micromedex, but those references might not be exhaustive or up to date, according to the *Journal* (Chase, *Wall Street Journal*, 8/16).



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Prescription Drugs | Generic Medications More Expensive in Canada Than in U.S., Research Suggests [Aug 09, 2005]

The *Los Angeles Times* on Tuesday examined the prices of generic prescription drugs in Canada and the U.S. Various research shows that, while brand-name prescription drugs are usually cheaper in Canada than in the U.S., generics are usually more expensive in Canada than in the U.S., the *Times* reports. An [HHS](#) study of five popular generic medicines found that U.S. prices for generic drugs were about 32% lower than Canadian prices. In addition, a study released earlier this year by the [Fraser Institute](#) -- a Toronto-based public policy organization that opposes price controls on brand-name drugs -- found that Canadian prices were an average of 78% higher than U.S. prices for the 100 top-selling generic drugs and that Canadians could save \$2 billion to \$5 billion annually if the Canadian generic market was as competitive as the one in the U.S. Brett Skinner, director of pharmaceutical and health policy research for the Fraser Institute, said U.S. generics are generally cheaper than Canadian generics because there is more competition in the generics market in the U.S. According to Skinner, it is difficult for foreign generic competitors to enter the Canadian market because of government drug-approval regulations. He said, "We have very few companies competing for sales -- two companies take up nearly 70% of the market for the top 100 drugs." The reimbursement policies in Canada's provinces also inflate prices, Skinner said. Many U.S. consumers are unaware that generics are more expensive in Canada, and they might be spending more than \$100 million annually on Canadian generic drugs, Skinner estimates. Tom McGinnis, director of pharmacy services for [FDA](#), said, "We have a feeling that there is a lot of misconception that everything outside the United States is cheaper" (Alonso-Zaldivar, *Los Angeles Times*, 8/9).



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Prescription Drugs | Frist To Allow Senate Floor Vote on Vitter Prescription Drug Reimportation Bill
[Jul 28, 2005]

Senate Majority Leader Bill Frist (R-Tenn.) has agreed to hold at least one floor vote on a bill ([S 109](#)) sponsored by Sen. David Vitter (R-La.) that would allow the purchase of lower-cost prescription drugs from other nations, *The Hill* reports (Young, *The Hill*, 7/27). The legislation is identical to a companion bill ([HR 328](#)) introduced in the House by Rep. Gil Gutknecht (R-Minn.) in January and a revised version of legislation that Gutknecht sponsored in 2003. The original bill would have allowed U.S. pharmacists to import prescription drugs manufactured in 25 industrialized nations, provided that the medications are manufactured by companies that use counterfeit-resistant technologies and that the companies have registered their production operations with FDA (*Kaiser Daily Health Policy Report*, 3/30). According to *The Hill*, Vitter earlier this month agreed to lift a hold on the confirmation vote for FDA Commissioner Lester Crawford "only after he was satisfied that Frist would not block his efforts to move legislation on drug imports." Vitter said that the vote on the bill likely will occur this fall as a proposed amendment to the fiscal year 2006 agriculture appropriations bill, which funds FDA. According to Vitter, Frist said that he would "work in good faith" to hold a separate debate and vote on Vitter's bill in the event the amendment receives more than 60 votes in the Senate; lawmakers likely would remove the amendment from the larger bill in conference. Vitter said that the amendment likely would receive 60 votes, adding, "Reimportation, in general, has clear majority support." He added that Frist did not specify when the debate would occur. Amy Call, a spokesperson for Frist, said that he did not make an "absolute commitment" to hold debate on the Vitter bill but would "work in good faith to find floor time" (*The Hill*, 7/27).

AGENDA ITEM B

Memorandum

To: ENFORCEMENT COMMITTEE

Date: September 7, 2005

From: SUSAN CAPPELLO
Enforcement Analyst
Board of Pharmacy

Subject: Proposed Revisions to the Disciplinary Guidelines

Enclosed with your enforcement committee packet are portions of the Disciplinary Guidelines with suggested revisions for your review. Sections of the guidelines provided are the Introduction, Factors to be Considered in Determining Penalties, Mitigating Evidence and Standard and Optional Terms and Conditions of Probation. Suggested revisions to the remaining sections of the Disciplinary Guidelines – Categories of Violations and Recommended Penalties and Model Disciplinary Orders – will be provided at a subsequent meeting.

The Disciplinary Guidelines are being revised to clarify language, ensure that the terms and conditions are consistent for all license types (where appropriate), to revise language to ensure consistency with statutory changes and to add new terms of probation. Strike-outs indicate deleted language and underlines indicate new language.

Suggested changes, in part, to the Standard Terms and Conditions (pages 27-28) include: *(Please note that all standard terms will be the same for all license types where appropriate. All terms will be renumbered where needed.)*

- Reporting to Board: Added language clarifying that failure to comply with term constitutes a violation of probation and results in an extension of probation.
- Notice to Employers: Requires that direct supervisor, owner **and** pharmacist-in-charge are required to be provided with notice of respondent's probation; requires that each new PIC be notified of respondent's probation; and clarifies that failure to comply constitutes a violation of probation.
- No Preceptorships, Supervision of Interns....: Deletes preceptorship to reflect new law changes re: preceptors, adds cannot serve as a consultant and that assumption of any unauthorized supervision responsibilities constitutes a violation of probation.
- Reimbursement of Board Costs: Adds option of revocation of license without further notice or opportunity to be heard for failure to pay costs as directed, and clarifies that failure to pay costs will be considered a violation of probation.
- Tolling of Probation: Language added to further define the circumstances and when probation is considered tolled, clarified definition of "cessation of practice" and that

failure to comply with notification requirements in this provision constitute a violation of probation.

- Violation of Probation: Language added to clarify that automatic termination of any stay ordered by the board will take place as directed in specific conditions.
- Reexamination Prior to Resuming Work, page 58: Deleted this provision as examination of a designated representative (exemptee) is no longer required.

Significant changes were made to the optional conditions of probation for pharmacists and interns, pages 28 – 39 as follows:

- Actual Suspension: Language moved to Model Orders
- Restricted Practice: Added option of not working in a compounding pharmacy during probation.
- Pharmacist Examination: Updated condition to reflect new statutory examination requirements (Multi-State Jurisprudence Examination), and adds the requirement for additional semester units for failing to pass the exam after four attempts.
- Mental Health Examination: Adds clarifying requirements for submission of name and qualifications of a licensed mental health practitioner for board prior approval, submission of commencement of psychotherapy, changes in treatment and practitioner, frequency of therapy and requirement of evaluation.
- Psychotherapy and Medical Evaluation: Added provision of ongoing treatment until therapist recommends and board approves that no further treatment is needed, and that respondent must cease practicing at any time the treating therapist finds that the respondent cannot practice safely.
- Pharmacists Recovery Program: Clarified automatic suspension for participants not in compliance with program, added requirement of respondent to pay administrative fees as invoiced by the PRP and added the option of requiring the respondent to work in a pharmacy setting with access to controlled substances for a period of six months prior to successful completion of probation
- Random Drug Screening: Clarified automatic suspension for confirmed positive tests.
- Abstain from Drugs and Alcohol Use: Added provision that respondent shall not be in the same physical location as individuals who are using illicit drugs even if respondent is not personally ingesting the drugs.
- Pharmacy Intern Experience: Deleted for Intern Pharmacist. This provision was intended for requiring pharmacists to obtain additional on-site experience.
- Supervised Practice: Added requirement that respondent cannot practice pharmacy and that his or her license is automatically suspended until a supervisor is approved by the board.

New terms and conditions of probation are:

- Prescription Monitoring (for pharmacists and interns), page 36: This term requires the coordination and monitoring of respondent's prescriptions for controlled substances and/or dangerous drugs by a physician, nurse practitioner or psychiatrist.
- Pharmacy Self-Assessment Mechanism (PSAM) (for pharmacists and interns), page 38: Requires respondent to complete the Pharmacy Self-Assessment Mechanism as provided by the National Association of Boards of Pharmacy.

- No Being Designated Representative in Charge (DRIC), page 59: As a standard condition of probation that designated representatives cannot be designated representatives in charge.
- Posted Notice of Probation (premises), page 86: Requires that all licensed premises on probation post a notice of probation during the entire period of probation.

Terms and conditions for pharmacists and interns begin on page 24, pharmacy technicians on page 47, designated representatives on page 58, premises on page 84.

**DEPARTMENT OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY**

**DISCIPLINARY GUIDELINES
(Rev. ~~4/2004~~10/2005)**

INTRODUCTION

The Board of Pharmacy is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- ❑ protecting the health, safety, and welfare of the people of California with integrity and honesty;
- ❑ advocating the highest quality of affordable pharmaceutical care;
- ❑ providing the best available information on pharmaceutical care; and
- ❑ promoting education, wellness and quality of life.

Pharmacists are patient advocates who provide pharmaceutical care and exercise clinical judgment for the citizens of California enlightening them about their drug therapy through effective communicating and listening, assessing, collaborating, understanding and intervening. ~~In addition, enforcement officials are provided the resources to act quickly, consistently and efficiently in the public's interest~~ to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with section 1760 of the California Code of Regulations, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, board licensees, the courts, board staff and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. ~~The~~ Subject to judicial review, the board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III violations are involved.

~~The board has found that accusations are rarely filed except in serious cases.~~ In general, the position of the board is that revocation should always be an option whenever grounds for

discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not upon the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which he or she works, but the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of their employees who operate the pharmacy. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board.

For purposes of these guidelines "board" includes the board and/or its designees.

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s) ~~of record(s)~~, including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
- ~~7-8.~~ mitigating evidence
- ~~8-9.~~ rehabilitation evidence
- ~~9-10.~~ compliance with terms of any criminal sentence
- ~~10-11.~~ overall criminal record
- ~~11-12.~~ if applicable, evidence of proceedings for case being set aside and dismissed pursuant to section 1203.4 of the Penal Code
- ~~12-13.~~ time passed since the act(s) or offense(s)
- ~~13-14.~~ whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
- ~~14-15.~~ financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures he or she has taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate his or her rehabilitative efforts and competency:

- a. Recent, dated written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice of pharmacy including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
- b. Recent, dated letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery and the psychologist's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
- c. Recent, dated letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
- d. Recent, dated laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such letters and reports will be subject to verification by board staff.
- e. Recent, dated physical examination or assessment report by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely.
- f. Recent, dated letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

RPH/INTERNS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state and or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

2. Reporting to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable notice, respondent shall appear in person for interviews with the board or its designee upon request at various intervals at a location to be determined by the board or its designee. Failure to appear for a scheduled interview without prior notification to board staff shall be considered a violation of probation.

4. Cooperation with Board Staff

Respondent shall cooperate with the board's inspectional program and in with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate or comply shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, rRespondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows: ---Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and/or owner to report to the board in writing acknowledging that the employer has read the decision in case number _____ and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify the direct supervisor, pharmacist-in-charge, and/or owner at every pharmacy of the ~~and~~ terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each pharmacy.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or in any position for which a pharmacist licenses is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor.

7. No Preceptorships, Supervision of Interns, Being Pharmacist-in-Charge (PIC), or Serving as a Consultant

During the period of probation, rRespondent shall not supervise any intern pharmacist ~~or perform any of the duties of a preceptor, nor shall respondent be the pharmacist-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.~~

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, rRespondent shall pay to the board its costs of investigation and prosecution in the amount of \$_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

Option: If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

9. Probation Monitoring Costs

Respondent shall pay the any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board ~~at the end of each year of probation~~ on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender while on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Notification of Employment, Name, Mailing Address Change

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving ~~and/or~~ the address of the new employer, supervisor or owner and work schedule, if known. Respondent shall notify the board in writing within ten (10) days of a change in name, mailing address or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

At all times while on probation, respondent shall be employed as a pharmacist in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease

practicing pharmacy as a pharmacist for a minimum of _____ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of the practice of pharmacy or, and must further notify the board in writing within ten (10) days of the resumption of the practice of pharmacy. ~~Such periods of time shall not apply to the reduction of the probation period. Any failure to provide such notification(s) shall be considered a violation of probation.~~

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding three consecutive year

"Cessation of practice" means any period of time exceeding 30 days calendar month in during which respondent is not employed for at least _____ hours as a pharmacist, as defined by Business and Professions Code section 4000 et seq. engaged in the practice of pharmacy as defined in Section 4052 of the Business and Professions Code.
"Resumption of practice" means any calendar month during which respondent is employed for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

~~**Option:** Respondent shall work at least 40 hours in each calendar month as a pharmacist and at least an average of 80 hours per month in any six consecutive months. Failure to do so will be considered a violation of probation. If respondent has not complied with this condition during the probationary term, and respondent has presented sufficient documentation of his or her good faith efforts to comply with this condition, and if no other conditions have been violated, the board or its designee, in its discretion, may grant an extension of respondent's probation period up to one 1 year without further hearing in order to permit respondent additional time within which to comply with this condition.~~

13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

~~If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.~~

14. Completion of Probation

Upon successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

(This condition will be included in the Model Order language.)

1. ~~Actual Suspension~~

~~As part of probation, respondent is suspended from the practice of pharmacy for _____ beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or an exemptee for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

2. ~~Restricted Practice~~ (Where this condition is imposed, optional condition #7 should also be imposed)

~~Respondent's practice of pharmacy shall be restricted to [specify setting or type of practice] for the first _____ years of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.~~

~~Option: Respondent shall not work in a compounding pharmacy during the first _____ years of probation. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.~~

3. Pharmacist Examination

~~Respondent shall take and pass the _____ section(s) Multi-State Jurisprudence Examination (MPJE) for California within six (6) months of the pharmacist licensure examination as scheduled by the Board after the effective date of this decision at respondent's own expense. If respondent fails to take and pass the examination within six (6) months after of the effective of this decision, respondent shall be automatically suspended from practice upon written notice. Respondent shall not resume the practice of pharmacy until he or she takes and passes the same section(s) at a subsequent examination MPJE and is notified, in writing,~~

that he or she has passed the examination. Respondent shall bear all costs of the examination.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to take and pass the examination within one (1) year of the effective date of this decision shall be considered a violation of probation. ~~Suspension and probation shall be extended until respondent passes the examination and is notified in writing. If respondent fails to take and pass the MPJE after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of education pharmacy as approved by the board.~~

4. Mental Health Examination (Appropriate for those cases where evidence demonstrates that mental illness or disability was a contributing cause of the violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a board-appointed or board-approved psychiatrist or psychologist. The approved evaluator shall be provided with a copy of the board's accusation and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.

If the psychiatrist or psychotherapist recommends, and the board or its designee directs, respondent shall undergo psychotherapy. ~~Respondent shall, within 30 days of written notice of the need for psychotherapy, submit to the board for its prior approval, the recommended program for ongoing psychotherapeutic care. Respondent shall undergo and continue psychotherapy, at respondent's own expense, until further notice from the board. Respondent shall have the treating psychotherapist or psychiatrist submit written quarterly reports to the board as directed.~~ Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of

ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Therapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and such other information as may be required by the board or its designee.

If at any time the approved evaluator or respondent's treating psychotherapist determines that respondent is ~~determined to be~~ unable to practice safely or independently as a pharmacist, the evaluator or therapist shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, ~~upon notification,~~ respondent shall immediately cease practice and shall not resume practice until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Option: Commencing on the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board that respondent is has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Option: If recommended by the evaluating psychiatrist or psychotherapist and approved by the board, respondent shall be suspended from practicing pharmacy until the respondent's treating psychotherapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, ~~or~~ be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

5. Psychotherapy (Appropriate for those cases where the evidence demonstrates mental illness or alcohol or drug abuse was involved in the violations.)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for its prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of

psychotherapy with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Therapy shall be at least once a week unless otherwise determined approved by the board. Respondent shall provide the therapist with a copy of the board's accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and to provide such other information as may be required by the board or its designee.

If at any time the treating therapist finds determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and followed up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall immediately cease practice and shall not resume practice until notified by the board.

~~Upon approval of the licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist and at respondent's own expense, until the board deems that no further psychotherapy is necessary. The board may require respondent to undergo a mental health evaluation(s) by a board-appointed or board-approved licensed mental health practitioner.~~

6. Medical Evaluation (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's accusation and decision. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.

~~If respondent is required by the board the physician recommends, and the board or its designee directs, that respondent to undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board for its prior approval, the name and qualifications of a physician of respondent's choice. Upon board approval of the treating physician, respondent shall undergo and continue medical treatment, with that physician and at~~

respondent's own expense, until further notice from the board. Respondent shall have the treating physician submit written quarterly reports to the board. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within 30 days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board for its prior approval. submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and such other information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a pharmacist, the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall immediately cease practice and shall not resume practice until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Option: Upon the effective date of this decision, respondent shall not engage in the practice of pharmacy until notified in writing by the board of its determination that respondent is medically fit to practice safely and independently, and the board or its designee approves said recommendation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, **or** be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Option: If recommended by the evaluating physician and approved by the board, respondent shall be suspended from practicing pharmacy until the treating physician recommends, in writing, stating the basis therefor, that respondent can safely and independently resume the practice of a pharmacist, and the board or its designee approves said recommendation. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, **or** be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or ~~an exemptee~~ a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

7. Rehabilitation Program - Pharmacists Recovery Program (PRP) (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling))

Within thirty (30) days of the effective date of this decision, respondent shall contact the Pharmacists Recovery Program (PRP) for evaluation and shall immediately thereafter enroll,

successfully participate in and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4363, ~~as of the effective date of this decision~~. Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Probation shall be automatically extended until respondent successfully completes ~~his or her treatment contract~~ the PRP. Any person terminated from the PRP program shall be automatically suspended ~~upon notice~~ by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not paid to the PRP shall constitute a violation of probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP. The board shall retain jurisdiction to institute action to terminate probation for any violation of this term.

Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing probation. If respondent fails to do so, probation shall be automatically extended until this condition has been met.

8. Random Drug Screening (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully complete the PRP before completion of the probation period; terms also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required.)

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or a other drug screening program approved as directed by the board or its designee. ~~The length of time shall~~

be for the Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to submit to testing as directed shall constitute be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment drug test shall result in the immediate automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

9. Abstain from Drugs and Alcohol Use (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs.

Prescription Monitoring (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling))

Respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history with the use of alcohol, controlled substances, and/or dangerous drugs and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a

quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Any determination by the coordinating physician, nurse practitioner, physician assistant, or psychiatrist that respondent is no safe to practice will result in the automatic suspension of respondent's license.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

10. Community Services Program

Within ~~sixty~~ (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for its-prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within ~~thirty~~ (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, comply or complete the program hours shall be considered a violation of probation.

11. Restitution (For Pharmacist and Premises) – (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of \$ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

12. Remedial Education

Within [~~thirty~~ (30), ~~sixty~~ (60), ~~ninety~~ (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for its-prior approval, an appropriate program of remedial education related to [~~the grounds for discipline~~]. The program of remedial education shall consist of at least _____ hours, which shall be completed within _____ months/year at respondent's own expense. ~~The period of probation shall be extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is~~

provided to the board. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to complete the approved remedial education as set forth hereinabove is grounds for the filing of a petition to revoke probation shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board.

Following the completion of each course, the board may administer or its designee may require the respondent, at his or her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

13. Pharmacy Self-Assessment Mechanism

Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NAPB). Respondent shall submit a record of completion to the board demonstrating they have completed this program. Respondent shall bear all costs for the examination.

13. Pharmacy Intern Experience (For Intern Pharmacist)

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for its prior approval, a pharmacy intern training program consisting of _____ hours to be served as a pharmacy intern in community and/or institutional pharmacy as directed. Respondent shall successfully complete the intern hours within the first year of probation and shall by no later than (1) year from the effective date of this decision submit a "Pharmacy Intern Experience Affidavit" and "Pharmacy Intern Hours Affidavit" signed by a currently licensed pharmacist not on probation with the board. Failure to timely complete or document the required intern experience shall be considered a violation of probation.

14. Supervised Practice

During the period of probation, Respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

Continuous - 75% to 100% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number _____ and is familiar with the required level of supervision as determined by the board or its designee. It shall be respondent's responsibility to ensure that

his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent changes employment, respondent shall have his or her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number _____ and is familiar with the level of supervision as determined by the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

15. No Supervision

During the period of probation, rRespondent shall not supervise any ancillary personnel, including, but not limited to, registered pharmacy technicians or exemptees designated representative, of any entity licensed by the board.

16. No Ownership of Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective of this decision.

17. Separate File of Records (For pharmacist owners and pharmacist in charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

18. Report of Controlled Substances (For pharmacist owners and pharmacist in charge)

Respondent shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten(10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

19. No Access to Controlled Substances

During the period of probation and as determined by the board or its designee, rRespondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedule II, III, IV or V (Health and Safety Code sections 11055-11058 inclusive). Respondent shall not order, receive or retain any ~~triplicate~~ security prescription forms.

20. Criminal Probation/Parole Reports

Respondent shall provide a copy of the conditions of any criminal probation/parole to the board, in writing, within ten (10) days of the issuance or modification of those conditions. Respondent shall provide the name of his or her probation/parole officer to the board, in writing, within ten (10) days after that officer is designated or a replacement for that officer is designated. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after respondent receives a copy of such a report. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

21. Consultant for Owner or Pharmacist-in-Charge

(Option #1 for pharmacist owners - primarily intended for appropriate cases where the respondent is the owner and pharmacist of his or her own pharmacy, the standard language should be used in most cases.)

During the period of probation, rRespondent shall not supervise any intern pharmacist, perform any of the duties of a preceptor or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for its-prior approval, within thirty (30) days of the effective date of this decision.

Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner.

(Option #2 - appropriate for pharmacists who are not pharmacy owners, but who wish, because of their current employment, to remain as the pharmacist-in-charge, and have provided documentation mitigating evidence to warrant this option.)

During the period of probation, Respondent shall not supervise any intern pharmacist, perform the duties of a preceptor or serve as a consultant to any entity licensed by the board. In the event that the respondent is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for its prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the current PIC. The board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude the respondent from acting as a pharmacist-in-charge.

22. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

If respondent leaves California during the period of suspension for any period exceeding ten (10) days, including vacation, respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume practice as a(n) [pharmacist, etc.] until notified by the board that the period of suspension has been satisfactorily completed. ~~to reside or practice outside this state, for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.~~

~~Respondent shall not practice pharmacy upon returning to this state until notified by the board that the period of suspension has been completed.~~

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

PHARMACY TECHNICIAN

1. Certification Prior to Resuming Work

Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified by the Pharmacy Technician Certification Board (PTCB) and provides satisfactory proof of certification to the board. Failure to take and pass the PTCB within one year shall be considered a violation of probation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Subject to the above restrictions, respondent may continue to own or hold an interest in any entity licensed by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy.~~

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state and or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

3. Reporting to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if

the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable notice, respondent shall appear in person for interviews with the board or its designee upon request at various intervals at a location to be determined by the board or its designee. Failure to appear for a scheduled interview without prior notification to board staff shall be considered a violation of probation.

5. Cooperation with Board Staff

Respondent shall cooperate with the board's inspectional program and ~~in with~~ the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate or comply shall be considered a violation of probation.

6. Notice to Employers

During the period of probation, rRespondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows: - Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner employer to report to the board in writing acknowledging that the employer has read the decision in case number _____ and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify the direct supervisor, pharmacist-in-charge and/or owner at every pharmacy of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each pharmacy.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor.

7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, rRespondent shall pay to the board its costs of investigation and prosecution in the amount of \$_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to

reimburse the board its costs of investigation and prosecution.

Option: If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

8. Probation Monitoring Costs

Respondent shall pay the costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board ~~at the end of each year of probation on a schedule as directed by the board or its designee.~~ Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active current technician registration/certification with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's technician registration/certification ~~expires or is cancelled by operation of law or otherwise~~ at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. Notification of Employment/Name, Mailing Address Change

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and ~~the~~ the address of the new employer, supervisor or owner and work schedule, if known. Respondent shall notify the board in writing within ten (10) days of a change in name, mailing address or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

11. Tolling of Probation

At all times while on probation, respondent shall be employed as a pharmacy technician in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

It is a violation of probation for respondent to work less than _____ hours per month as a pharmacy technician/exemptee. Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacy technician or an exemptee in California, respondent must notify the board in writing within ten (10) days of the cessation of practice or and must further notify the board in writing within ten (10) days of the resumption of the practice. Such periods of time shall not apply to the reduction of the probation period. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding three consecutive yearsthirty-six (36) months.

"Cessation of practice" means any period of time exceeding 30 days in which respondent is not engaged in the practice of a pharmacy technician as defined in sSection _____4115of the Business and Professions Code.

12. Violation of Probation

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

13. Completion of Probation

Upon successful completion of probation, respondent's technician registration will be fully restored.

~~14. License Surrender While on Probation/Suspension~~

~~Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer~~

~~be subject to the terms and conditions of probation.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

OPTIONAL CONDITIONS OF PROBATION

(This condition will be included in the Model Order language.)

1. ~~Actual Suspension~~

~~As part of probation, respondent is suspended from the duties of a pharmacy technician for _____ beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any entity licensed by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~During suspension, respondent shall not perform any of the duties of a pharmacy technician as provided by Section 1793.2 of the California Code of Regulations.~~

2. ~~No Ownership of Licensed Premises~~

~~Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.~~

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity.

3. ~~Attend Substance Abuse Recovery Relapse Prevention and Support Groups~~

(Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a board-approved recognized and established substance abuse recovery support group in California, (e.g., Alcoholic Anonymous, Cocaine Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

4. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or a other drug screening program approved as directed by the board or its designee. The length of time shall be for the Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to submit to testing as directed shall constitute be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment drug test shall result in the immediate suspension of practice by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

5. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. The Respondent shall be responsible for ensuring that the work site monitor shall report reports in writing to the board quarterly. Should the designated work site

monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

6. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

~~If respondent leaves~~ Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return, prior to leaving. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

7. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Additionally, respondent shall cause the prescribing practitioner to notify the board in writing, indicating their awareness of the chemical dependency. ~~Additionally, respondent shall cause the prescribing physician to notify the board in writing, indicating their awareness of the chemical dependency.~~

8. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

If respondent leaves California during the period of suspension for any period exceeding ten (10) days, including vacation, respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume practice as a(n) [pharmacist, etc.] until notified by the board that the period of suspension has been satisfactorily completed. to reside or practice outside this state, or for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.

~~Respondent shall not act as a pharmacy technician upon returning to this state until notified by the board that the period of suspension has been completed.~~

STANDARD CONDITIONS - TO BE INCLUDED IN ALL PROBATIONS

DESIGNATED REPRESENTATIVE

1. ~~Reexamination Prior to Resuming Work~~

~~Respondent shall be suspended from working as an exemptee until he or she takes and passes the exemption examination as scheduled by the board after the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving wholesaling, or repackaging or manufacturing, nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not direct or control any aspect of the practice of pharmacy.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy or wholesaler in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state and or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

3. Reporting to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable notice, respondent shall appear in person for interviews with the board or its designee upon request at various intervals at a location to be determined by the board or its designee. Failure to appear for a scheduled interview without prior notification to board staff shall be considered a violation of probation.

5. Cooperation with Board Staff

Respondent shall cooperate with the board's inspectional program and ~~in-with~~ the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate or comply shall be considered a violation of probation.

6. Notice to Employers

During the period of probation, rRespondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows: - Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner employer to report to the board in writing acknowledging that the employer has read the decision in case number _____ and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify the direct supervisor, pharmacist-in-charge and/or owner at every pharmacy of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each pharmacy.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician designated representative or in any position for which a pharmacy technician license designated representative certificate is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor.

6. No Being Designated Representative-in-Charge (DRIC)

During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, rRespondent shall pay to the board its costs of investigation and prosecution in the amount of \$ _____. Respondent shall make said payments as follows: _____. There shall be no deviation from this

schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

Option: If respondent fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

8. Probation Monitoring Costs

Respondent shall pay the costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board at the end of each year of probation on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active current technician registration/certification with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's technician registration/certification expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. Notification of Employment/, Name, Mailing Address Change

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and/or the address of the new employer, supervisor or owner and work schedule, if known. Respondent shall notify the board in writing within ten (10) days of a change in name, mailing address or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

11. License Surrender while on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the

date the application for that license is submitted to the board.

11. Tolling of Probation

At all times while on probation, respondent shall be employed as a designated representative in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

It is a violation of probation for respondent to work less than _____ hours per month as an exemptee. Should respondent, regardless of residency, for any reason (including vacation) cease practicing as an exemptee/designated representative in California, respondent must notify the board in writing within ten (10) days of the cessation of practice ~~or~~ and must further notify the board in writing within ten (10) days of the resumption of the practice. Such periods of time shall not apply to the reduction of the probation period. Any failure to provide such notification(s) shall be considered a violation of probation

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any period of time exceeding thirty (30) days in which respondent is not engaged in the practice of a ~~pharmacy technician~~ designated representative as defined in section _____ 4053 of the Business and Professions Code ~~or as an exemptee as defined in section _____ of the Business and Professions Code.~~

12. Violation of Probation

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

13. Completion of Probation

Upon successful completion of probation, respondent's certificate will be fully restored.

14. License Surrender while on Probation/Suspension

~~Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.~~

~~Upon acceptance of the surrender, respondent shall relinquish his or her pocket license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.~~

OPTIONAL CONDITIONS OF PROBATION

(This condition will be included in the Model Order language.)

1. Actual Suspension

~~As part of probation, respondent is suspended from the duties of a pharmacy technician for _____ beginning the effective date of this decision.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any entity licensed by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~During suspension, respondent shall not perform any of the duties of a pharmacy technician as provided by Section 1793.2 of the California Code of Regulations.~~

2.14. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer,

director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity.

3.15. Attend Substance Abuse Recovery Relapse Prevention and Support Groups

(Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a board-approved recognized and established substance abuse recovery support group in California, (e.g., Alcoholic Anonymous, Cocaine Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

4.16. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or a other drug screening program approved as directed by the board or its designee. The length of time shall be for the Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to submit to testing as directed shall constitute be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment drug test shall result in the immediate suspension of practice by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a representative-in-charge for any entity licensed by the board. Subject to the above restrictions, respondent may continue to own or hold an interest in any pharmacy in which he or she holds an interest at the time this

decision becomes effective unless otherwise specified in this order.

5.17. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. The Respondent shall be responsible for ensuring that the work site monitor shall report reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

6.18. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

If respondent leaves Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return, prior to leaving. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

7.19. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Additionally, respondent shall cause the prescribing practitioner to notify the board in writing, indicating their awareness of the chemical dependency. Additionally, respondent shall cause the prescribing physician to notify the board in writing, indicating their awareness of the chemical dependency.

8.20. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

If respondent leaves California during the period of suspension for any period exceeding ten (10) days, including vacation, respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and

~~return, respondent shall not resume practice as a(n) [pharmacist, etc.] until notified by the board that the period of suspension has been satisfactorily completed. to reside or practice outside this state, or for any period exceeding 10 days (including vacation), respondent must notify the board in writing of the dates of departure and return. Periods of residency or practice outside the state or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.~~

~~Respondent shall not act as a pharmacy technician upon returning to this state until notified by the board that the period of suspension has been completed.~~

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS PREMISES

1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations ~~substantially related to or governing the practice of pharmacy.~~

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state ~~and~~ or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

2. Reporting to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable notice, respondent shall appear in person for interviews with the board or its designee upon request at various intervals at a location to be determined by the board or its designee. Failure to appear for a scheduled interview without prior notification to board staff shall be considered a violation of probation.

4. Cooperation with Board Staff

Respondent shall cooperate with the board's inspectional program and ~~in~~ with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate or comply shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, rRespondent owner shall pay to the board its costs of investigation and prosecution in the amount of \$_____. Respondent owner shall make said payments as follows: _____. There shall be no deviation from

this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner shall not relieve respondent owner of his or her responsibility to reimburse the board its costs of investigation and prosecution.

Option: If respondent owner fails to make any payment by the directed deadline(s), the stay shall terminate and the license shall be revoked without further notice or opportunity to be heard.

6. Probation Monitoring Costs

Respondent owner shall pay the costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board at the end of each year of probation on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondent shall, at all times while on probation, maintain a current license with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender while on Probation/Suspension

Following the effective date of this decision, should respondent cease practice ~~due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation to operate,~~ respondent owner may tender his or her premises license to the board for surrender. The board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish his or her ~~pocket wall and renewal~~ license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner may not reapply for any new ownership license from the board for three years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all

employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days, that this term has been satisfied. Failure to submit notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

~~11.~~ 12. Violation of Probation

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

42.13. Completion of Probation

Upon successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

(This condition will be included in the Model Order language.)

1. Actual Suspension

~~As part of probation, respondent pharmacy is suspended from the operation of pharmacy for _____ days beginning the effective date of this decision.~~

~~During suspension, respondent pharmacy may not order, maintain or dispose of any dangerous drugs and devices or controlled substances. The pharmacy may not make demand or bill for any drugs or services during the period of suspension and may not process any claims for pharmacy services during the period of suspension, except as to services rendered prior to the effective date of the suspension period. The pharmacy shall not receive or transmit any prescription, new or refill, during the period of suspension. Where the pharmacy does not maintain dangerous drugs and devices or controlled substances in an area which can be closed off from the rest of the pharmacy and locked, the entire pharmacy must be closed during the period of suspension.~~

2.14. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent owner shall submit to the board or its designee, for its prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

3.15. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent owner shall pay restitution to _____ in the amount of \$ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

4.16. Separate File of Records

Respondent owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

5.17. Report of Controlled Substances

Respondent owner shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent owner shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent owner shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

6.18. Surrender of DEA Permit

Respondent pharmacy shall surrender its his or her federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation, within 30 days of the effective date of this decision. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from practicing as a pharmacist until notified by the board that satisfactory proof of cancellation has been received. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent pharmacy may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent pharmacy shall not order, receive, or retain any federal order forms, including 222 forms, for controlled substances.

7.19. Posted Notice of Suspension

Respondent owner shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public. The suspension notice shall remain posted during the entire period of actual suspension ordered by this decision.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

10/2005

AGENDA ITEM C

Memorandum

To: Enforcement Committee

Date: September 6, 2005

From: Patricia F. Harris 
Executive Officer

Subject: **Self-Assessment Form for
Wholesalers**

Attached is a draft self-assessment form for your review. Supervising Inspector Judi Nurse modeled this form after the self-assessment form for pharmacies.

Staff is requesting that the Enforcement Committee review the form and recommend to the board that it be adopted as a regulatory requirement. During the interim, it will be made available to wholesalers as a compliance guide for California law.



WHOLESALE DANGEROUS DRUGS & DANGEROUS DEVICES SELF- ASSESSMENT

All legal references used throughout this self-assessment form are explained on the last page.

All references to “drugs” throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B & P) section 4022 (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

Wholesaler Name _____

Address _____ Phone _____

Wholesaler E-mail address (optional) _____

Ownership: Please mark one

_____ sole owner _____ partnership _____ corporation _____ LLC
 _____ non- licensed owner _____ Other (please specify) _____

CA Wholesaler Permit # _____ Exp. Date _____

Other Permit # _____ Exp. Date _____

DEA Registration # _____ Exp. Date _____

Date of most recent DEA Inventory _____

Hours: Daily _____ Sat _____ Sun _____ 24 Hours _____

Designated representative-in-charge (DRIC) / pharmacist (RPH) _____

DRIC#/RPH# _____ Exp. Date _____

Licensed Wholesaler Staff (designated representative (DR), pharmacist) :

1. _____ DR#/RPH# _____ Exp. Date _____

2. _____ DR#/RPH# _____ Exp. Date _____

3. _____ DR#/RPH# _____ Exp. Date _____

4. _____ DR#/RPH# _____ Exp. Date _____

5. _____ DR#/RPH# _____ Exp. Date _____

6. _____ DR#/RPH# _____ Exp. Date _____

7. _____ DR#/RPH# _____ Exp. Date _____

8. _____ DR#/RPH# _____ Exp. Date _____

9. _____ DR#/RPH# _____ Exp. Date _____

10. _____ DR#/RPH# _____ Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B & P 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B & P 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

2. Facility

Yes No N/A

Premises, fixtures and equipment:

Are clean and orderly

Are well ventilated

Are free from rodents and insects

Are adequately lit

Have plumbing in good repair

Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

Is access to areas where dangerous drugs are stored limited to authorized personnel?

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

Yes No N/A

Does this business operate only when a designated representative-in-charge or pharmacist is on the premises? (CCR 1781)

The wholesale premises is equipped with the following specific security features:

- There is an alarm to detect after-hours entry.
- The outside perimeter of building is well lit (CCR 1780[c]).
- The security system provides protection against theft and diversion including tampering with computers and or electronic records.

Explain how your security system complies with these requirements.

Yes No N/A

Is this business a “reverse distributor”, that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs?

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

- Is the owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory? (B & P 4081[b])

- Is the designated representative-in-charge is responsible for the wholesaler's compliance with all state and federal laws for wholesale distribution of drugs. The designated representative-in-charge may be a pharmacist. (B & P 4160[d])

- The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B & P 4305.5[a])

- The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B & P 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge" and is available on the Board's website.

- The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B & P 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

4. Designated Representative/Pharmacist

Yes No N/A

- If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B & P 4100, 1704)

CORRECTIVE ACTION OR ACTION PLAN _____

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

- Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B & P 4163[b], 4169)

Yes No N/A

- If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B & P 4081, 4332)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

- When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])
- When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Drug Stock

Yes No N/A

- Is all drug stock open for inspection during regular business hours? (B & P 4081[a])
- Are all drugs you order maintained in a secure manner at your licensed wholesale premises?. You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B & P 4167)
- Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B & P 4342[a])

Yes No N/A

Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR1307.21)

When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Sale or Transfer of Dugs by this Business

Yes No N/A

Are drugs sold only to businesses or persons that are licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

Describe how you verify a business or person is appropriately licensed. (B & P 4059.5[a] [b][d], B & P 4169)

List any businesses or individuals that order drugs from you that are not licensed according to the list above:

Yes No N/A

Are drugs only furnished by your business to an authorized person? (B & P 4163[a]) Note: An authorized person can be a business or natural person.

Does your business only receive drugs from a pharmacy if:

- the pharmacy originally purchased the drugs from you?
- your business is a "reverse distributor"?
- the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B & P 4126.5[a])

All drugs that are purchased from another business or are sold, traded or transferred by your business are:

- done with a business licensed with this board as a wholesaler or pharmacy?
- free of adulteration as defined by the CA Health & Safety Code section 111250?
- free of misbranding as defined by CA Health & Safety Code section 111335?
- beyond their use date (expired drugs)? (B & P 4169)

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

Yes No N/A

Do all drugs sold or transferred by your business outside of this state or country, comply with all state and federal regulations? Is the business or person receiving these drugs authorized to receive prescription drugs by their state or country?

Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B & P 4059.5[e])

Yes No N/A

When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). Effective January 1, 2007, an electronic pedigree must accompany all drugs (B & P 4163), even those for which your business is an authorized distributor.

If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B & P 4380)

Yes No N/A

Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B & P 4341, B & P 651, CCR 1766)

Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B & P 650)

Yes No N/A

Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B & P 4066, CFR 1301.25)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

9. Outgoing Shipments of Drugs

Yes No N/A

Before you ship drugs to a purchaser, you inspect the shipment to assure the drugs were not damaged while stored by your business. (CCR 1780[d][2])

Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B & P 4166[a])

List the common carriers (shipping or delivery companies) you use.

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

- Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B & P 4059.5[a])
- Are all drugs ordered by a manufacturer or prescriber are delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B & P 4059[d])
- All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B & P 4059.5[c])
- If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B & P 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

11. Controlled Substances

Yes No N/A

- Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)
- Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])
- Are DEA requirements for storage of Schedule III controlled substances being met? (specific requirements are listed in CFR 1301.72[b])
- Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

Yes No N/A

Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, and retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

The person within your business who signed the original DEA registration, or the last DEA registration renewal, has created a power of attorney for each person allowed to order Schedule II controlled substances for this business (CFR 1305.07)

List the individuals at this location authorized by power of attorney to order controlled substances.

Yes No N/A

Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

Do all controlled substances purchased, sold or transferred by your business , done so for legitimate medical purposes? (H & S 11153.5[a][b][c])

If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances.

Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances (CFR 1301.74 [a])

Yes No N/A

If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances.(CFR 1301.74[f])

Yes No N/A

- If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[f])
- Are all Schedule II controlled substances ordered from your business use a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)
- When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 form? Is copy 1 retained and copy 2 sent to DEA at the close of the month filled? (CFR 1305.09 [b])
- If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.11)
- When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1309.05[b])
- For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.09[e])
- Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.12)
- Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B & P 4081, CCR 1718, CFR 1305.09[d], 1305.13[a] [b], and H & S 11252, 11253, 1304.03)
- Are records of Schedule II controlled substances stored separate from all others?
- Are records for Schedule III controlled substances stored so that they are easily retrievable?

Does your business always comply with the following requirements:

Yes No N/A

- Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
- Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.16)

Yes No N/A

Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1304.74[c])

CORRECTIVE ACTION OR ACTION PLAN _____

12. Policies and Procedures

Does this business maintain and adhere to policies and procedures for:

Yes No N/A

Receipt of drugs?

Security of drugs?

Storage of drugs? (including maintaining records to document proper storage)

Inventory of drugs? (including correcting inaccuracies in inventories)

Distributing drugs?

Identifying, recording and reporting theft or losses?

Correcting errors?

Physically quarantining and separating:

returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?

drugs that have been partially used?

drugs where the outer or secondary seals on the container have been broken?

drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity? (CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN _____

13. Training

Yes No N/A

Is training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

CORRECTIVE ACTION OR ACTION PLAN _____

14. Dialysis Drugs

Yes No N/A

- Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B & P 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.
- Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B & P 4059[d])
- Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])
- Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)
- Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

15. Record Keeping Requirements

Yes No N/A

- Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B & P 4059[b])

Yes No N/A

- Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B & P 4081[a], 4105[c], 4081, 4332, 4059.5[a])
- Are all purchase and sales records retained in a readily retrievable form? (B & P 4105[a])
- Is a current accurate inventory maintained for all dangerous drugs? (B & P 4081, 4332, 1718)
- If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B & P 4105[b])
- Are required records stored off-site only if a board issued written waiver has been granted?

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address _____

Yes No N/A

- Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])
- If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])
- Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])
- Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])
- Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B & P 4162[a][4]):

Yes No N/A

- Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B & P 4083)
- Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B & P 4315[e])
- If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

- A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B & P 4101[b], 4305.5[c]).
- The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B & P 4305.5[a])
- The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
- The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1304.74[c])
- Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
- The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B & P 4201[i], CCR 1709[b])
- When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B & P 4164[a])

Yes No N/A

Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
2. identify purchases of any dangerous drugs at preferential or contract prices
3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B & P 4164[b])

I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the change of ownership application is being processed by the board and until the new permanent permit issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B & P 4201[g])

The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN _____

17. Additional Licenses/Permits Required

List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B & P 4107, CFR 1305.11[a], B & P 4059.5[e])

DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:

I, (please print) _____, DRIC# / RPH # _____
hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

Legal References

All references to California Business & Professions Code (B & P) are Chapter 9, Division 2 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Code of Regulations (CCR) are to Title 16 unless otherwise specified (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

All references to California Health & Safety Code (H & S) are to Division 10, Uniform Controlled Substances Act (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) or Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws (<http://www.dhs.ca.gov/ps/fdb/PDF/Sherman1-1-2004.pdf>).

All references to United States Code of Federal Regulations (CFR) are Title 21, Chapter II Part 1300, Drug Enforcement Administration, Food and Drugs and codified Controlled Substances Act (CSA) (<http://www.deadiversion.usdoj.gov/21cfr/index.html>).

California Board of Pharmacy

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Atlantic Associates, Inc. (CURES)

Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
(888) 492-7341

California Pharmacy Law may be obtained
by contacting:

Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

Medical Board of California

1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
www.medbd.ca.gov

Pharmacist Recovery Program

(800) 522-9198 (24 hours a day)

The **Drug Enforcement Administration**
may be contacted at:

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles CA 90012
(213) 894-2216, 2217, 4697, or 6711
(213) 894-4016 (Diversion or Investigation)

DEA – San Francisco

450 Golden Gate Avenue
San Francisco CA 94102
(415) 436-7900
(415) 436-7854 (Theft Reports or Diversion)

DEA - Sacramento

1860 Howe Avenue
Sacramento CA 95825
(916) 566-7160

DEA - Riverside

4470 Olivewood Avenue
Riverside, CA 92501-6210
(909) 328-6200

DEA - Fresno

2444 Main Street, Suite 240
Fresno, CA 93721
(559) 487-5402

DEA – San Diego

4560 Viewridge Avenue
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DEA – Oakland

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AGENDA ITEM D