

Why Florida Needs A Prescription Validation Program

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Florida has a serious problem with illegal prescription drug diversion and abuse. Scheduled drugs that are prescribed by physicians are diverted from their intended use and then abused or illegally sold. Drugs diverted include Schedule II, III, and IV controlled substances. Prescription drug abuse accounts for 30% of the drug problem nationwide. In 2004, Florida experienced 12,610 drug overdose deaths. Of these, 6,035 deaths (48%) involved prescription drugs. Prescription drugs directly caused 2,181 overdose deaths in 2004. This translates to 6 Floridians dying per day. For the year 2004, Schedule IV benzodiazepines (such as Xanax and Valium) were found to be present in more overdose deaths than cocaine.

Prescription drug diversion is the channeling of licit pharmaceuticals for illegal purposes or abuse. Both patients and doctors are to blame for the problem. The majority of illegal prescription drug diversion in Florida begins with a stolen, forged, counterfeit, or altered prescription form. Patients often seek out multiple doctors (doctor shopping) to prescribe drugs, fill the same prescription at multiple pharmacies (pharmacy shopping) and present fraudulent prescriptions to pharmacies. Patients also deceive or manipulate physicians into prescribing controlled substances. In some cases, doctors may overprescribe powerful drugs not realizing their potential for abuse. Finally, there are some unscrupulous physicians who simply sell prescriptions to patients (known as operating a pill mill) knowing the patients are substance abusers. These criminal physicians are nothing more than drug dealers with a medical license.

What the Program Will Do:

The Florida Prescription Validation Program, administered by the Department of Health, consists of two major components – an electronic database in the Department of Health containing prescription history of certain scheduled controlled substance for patients 16 years of age and older and the voluntary use of counterfeit-proof prescription forms. Once a prescription is presented at the pharmacy for a Schedule II, III, or IV controlled substance, the pharmacy enters the data electronically in the pharmacy computer. At least every 35 days (or sooner as technology permits), the pharmacy will submit all their data on prescribed Schedule II – IV drugs to a centralized data collection center. This data collection center will collect all the data from around the state and then provide it to the Department of Health. The Department of Health will, upon

request, provide this data to requesting physicians, pharmacists, as well as health and law enforcement officials pursuant to an ongoing investigation.

The primary purpose of this system is to assist physicians in proper treatment of their patients. The secondary purpose is to assist law enforcement during investigations. The use of counterfeit-proof prescription forms for Schedule II-IV controlled substances will serve as a deterrent to those who would forge or copy ordinary doctor scrip pads.

Further, this bill sets requirement to reduce prescription fraud by:

1. Requiring the quantity on the prescription to be written out
2. Requiring positive identification to pick up prescriptions
3. Sets penalties for unlawful possession or sale of counterfeit-resistant prescription forms

This program will use the Internet and have very comprehensive security requirements. Physicians will be able, with patients' consent, to request their patient's prescription history on their office computer. A similar system in place in Kentucky has been a great aid to physicians in that state. Of all the requests for information from their database, 92% come from physicians on their patients. Approximately 5% come from law enforcement and about 3% from pharmacists.

In developing this program, we will attempt to get information in real time to deter and prevent illegal diversion and abuse. This means that doctors and pharmacists will know immediately when prescriptions have been filled to prevent multiple fillings by pharmacy and doctor shoppers.

Protection of Information:

The Department of Health will maintain strict confidentiality ensuring that both patient and doctor privacy rights are protected. Queries will only be accepted from:

1. Physicians (concerning their own patients and only after consent of the patient)
2. Florida-licensed pharmacists – upon presentation of a prescription in order to determine its legitimacy
3. Florida Department of Law Enforcement engaged in a specific investigation
4. Agency for Health Care Administration for Medicaid fraud investigations
5. Department of Health for specific investigations

The system will assist doctors by providing them with a record of prescriptions previously received by the patient so that the physician can appropriately treat the patient. The physician can then see exactly what the patient has been prescribed in the past by other physicians. This will quickly identify a patient who visits many physicians for the same medications. Pharmacies who suspect that a patient is presenting an invalid prescription can check to insure the prescription they are filling is legitimate.

According to DEA, in the U.S., since the first prescription monitoring system in California was established in 1940 until today, there has not been one single unauthorized disclosure of patient information in any system in the nation.

The entire program will be HIPAA compliant.

The entire prescription history of all patients in Florida, even beyond the Schedule II – IV drugs specified by our program, is currently available in many different locations in the private sector. Complete prescription information resides in the local pharmacy computer database, the pharmacy's regional headquarters database, and the pharmacy's national headquarters database. Moreover, the health insurance companies and their agents who pay for medications maintain the same information in a database. **The Prescription Validation Program mandates much more stringent controls on prescription history and, in fact, imposes much greater penalties for unauthorized disclosures than anywhere in any of the many private sector databases.**

How the Program Will Work:

When the patient fills a prescription at the pharmacy for a controlled substance, Schedule II – IV, the pharmacist enters this information in his desktop computer. This is the normal practice for every prescription filled at the 17,000 pharmacies across the state. Once every 35 days (or sooner as technology permits), the pharmacy sends the information from its desktop computer for only the prescriptions for Schedule II – IV controlled substances on all patients age 16 and older to a central data collection center. The collection center accumulates all the data and sends it on to the Department of Health to be incorporated into a comprehensive database. Upon receiving queries, the Department of Health will make this information available to only the entities specifically authorized by law to receive the information.

Physicians can request the prescription history of only their own patients and only with the prior consent of the patient. The physician can request the patient's prescription history and see what medications of Schedule II, III, or IV controlled substances the patient has received from other practitioners. Physicians are not required to view the prescription history of every patient before meeting with a patient or writing subsequent prescriptions. However, the information is available to the physician to better treat patients, avoid prescribing drugs that might be contraindicating, and to protect the physician from being "shopped" by unscrupulous patients.

Pharmacists can request the prescription history of the patient when presented with a prescription they believe to be forged or somehow fraudulent. Pharmacists are bound by law to only fill legitimate prescriptions. This allows the pharmacist to ensure the prescription is valid. If it is not, the pharmacist will not fill the prescription until the physician verifies that the prescription is indeed valid. This protects the pharmacies from being "shopped" by unscrupulous patients.

The Department of Health will only be able to request information when they have an investigation on a practitioner. This will enable the Department of Health to quickly assemble information on a practitioner who is being investigated for inappropriate prescribing practices.

Agency for Health Care Administration will only be able to request information when they have an investigation involving Medicaid fraud related to inappropriate prescribing by Medicaid providers or "doctor shopping" by Medicaid recipients.

Law enforcement will only be able to request information when they have an active criminal investigation relating to drug diversion. The Florida Department of Law Enforcement will control access.

Benefits of the Program:

The benefits of this program are numerous. First, the electronic system will assist physicians in treating their patients. The physician can query the system concerning his patient and quickly receive information as to what medications the patient has been prescribed. The use of this program will greatly reduce doctor and pharmacy shopping as well as the overprescribing of prescription drugs. Secondly, it will reduce Medicaid prescription drug fraud. Additionally, the use of counterfeit -proof pads will help eliminate the forgery and counterfeiting of prescription forms, thereby greatly reducing the illegal diversion of prescription drugs. Finally, this will improve law enforcement's ability to investigate, prosecute, and stop criminal activity. The benefit to both physicians and pharmacies will be the reduction of doctor and pharmacy shopping by unscrupulous patients. **In short, the establishment of this system in Florida**

will prevent a great number of deaths from the illegal diversion and subsequent abuse and overdose of prescription drugs in our state.

In developing this program, we began with the clear understanding that most of the illegal diversion of pharmaceuticals is perpetrated by patients. The number of health care practitioners who engage in this criminal activity is relatively small, although those few can certainly cause great harm. Therefore, we expect this program to deter much of the diversion activity on the part of the patients and small number of health care practitioners. The fact that the system will be in place will deter much of the activity, but state health and law enforcement officials will now be able to more quickly and efficiently investigate diversion cases.

Existing Law:

During the 2001 legislative session, the Florida Legislature passed Florida Law 2002-81. This law makes it a crime (3rd degree felony) for doctors to write prescriptions for fictitious persons, write prescriptions solely to make money, and knowingly assist patients in fraudulently obtaining controlled substances. It also makes it a crime (3rd degree felony) for a patient to withhold information regarding previous receipt of a prescription for a controlled substance (doctor shopping). This law is good, but only gets at part of the problem. The proposed electronic prescription validation program reduces the chances for patients to repeatedly and illegally divert prescription drugs. The program will dramatically reduce doctor and pharmacy shopping. Moreover, the proposed validation program allows for law enforcement officials to rapidly investigate cases where abuse of controlled substances is suspected and better enforce Florida Law 2002-81.

Scope of the Problem

Nationally -- The diversion and abuse of pharmaceutical controlled substances is a multi-billion dollar illicit market operating in the United States. DEA consistently estimates that the diversion of pharmaceutical drugs constitutes almost 30% of the overall drug problem in the United States. The National Survey of Drug Use and Health released in 2004 revealed that the misuse of psychotropic drugs (pain relievers, tranquilizers, stimulants and sedative) was the 2nd leading category of illicit drug use, following marijuana. Perhaps the most recent and impressive data on the scope of this problem nationally comes from a three-year study conducted by the National Center on Addiction and Substance Abuse (CASA) at Columbia University and released in July 2005. It showed that the number of Americans who abuse controlled drugs has nearly doubled from 7.8 million to 15.1 million from 1992 to 2003 and abuse among teens has more than tripled in that time. The 15.1 million abusing prescription drugs exceeds the combined

number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million), and heroin (.3 million). In the CASA study, most physicians (59.1 percent) and pharmacists (51.8 percent) blamed patients, who obtain controlled prescription drugs by faking symptoms treated with opioids, depressants and stimulants, visiting a number of doctors to obtain prescriptions from each (doctor shopping), and altering prescriptions.

Florida – In the past few years, Florida has experienced a significant growth in the abuse of prescription drugs. The overdose death rate due to prescription drugs has increased every year and now stands at 6 per day. The Florida Youth Substance Abuse Survey conducted every year since 2000 shows that our youth, ages 12-18, are turning away from almost all illicit drugs. However, one of the few areas of increased drug use among youth is depressant, a category of prescription drugs.

Over the past few years, we have seen in Florida a very high demand for prescription drugs “on the street”. Those who use and abuse drugs often view prescription drugs as “safer” precisely because they are prescribed by physicians, approved by the government, are precise in their dosages, and have very predictable effects on the user. Users feel like they know what they are getting when they illegally buy prescription drugs in a bottle with a label. Demand for these drugs is up, thereby creating a new category of drug trafficking. Dealers who normally peddle “designer” or “club” drugs such as Ecstasy and GHB also include prescription drugs like Xanax, Valium, Ritalin and OxyContin in their inventory. The increased demand for prescription drugs and the high profit margin that can be made by selling them on the street has subsequently created a significant market for forged or stolen prescription pads. Reproducing a practitioner’s prescription form is almost effortless. Not only are such pads left unsecured in medical offices, but once a prescription pad is obtained, it is a relatively easy task to “white out” the previous writing and then duplicate the blank form on a copying machine. The forging and counterfeiting of prescription forms is one of the major contributors to the illegal diversion of prescription drugs in Florida.

Some recent cases where doctors have prescribed drugs in excess of normal practice have brought significant public attention to this problem. In all cases, the doctor’s prescriptions have resulted in the numerous patient deaths due to overdose. Dr James Graves of Pensacola was convicted of 4 counts of manslaughter for prescribing excessive amounts of oxycodone to his patients. In 2003, Dr Sarfraz Mirza of Melbourne was arrested for the fraudulent prescription of over \$500,000 in prescription drugs and 11 counts of trafficking in Oxycontin. Dr. Mitchell Wick of Plantation was barred in April 2003 from prescribing narcotics because the Medical Examiner’s Office discovered 16 overdose deaths among his patients. In 2004, Dr. Asuncion Luyao of Port St Lucie was charged with six counts of manslaughter for overdose deaths due to medications she

prescribed. **Florida has prosecuted almost 30 physicians and practitioners over the past few years for excessive prescribing of drugs.**

Prescription Monitoring Programs in Other States

Several other states have already taken the initiative by instituting prescription programs. As of August 2005, 20 states have prescription monitoring programs. These states are California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Mississippi, Nevada, New York, Oklahoma, Rhode Island, Texas, Utah, Virginia, West Virginia, Tennessee, Maine, and Wyoming.

The GAO Report issued in March 2004 credits ongoing monitoring systems with reducing the unwarranted prescribing and subsequent diversion of abused drugs in their states. GAO also noted that drug prescription history checks serve as a deterrent to prevent individuals from visiting multiple physicians to obtain prescriptions. Moreover, states with systems in-place have greatly reduced the time spent on investigations of drug diversion.

The Issue of Patient Confidentiality

The confidentiality of the information held in the database is paramount. Accompanying legislation will make it a felony to reveal any patient information to anyone other than a requesting physician (concerning his own patient), the pharmacy, Florida Department of Law Enforcement (pursuant to an active criminal investigation), Agency for Health Care Administration (for Medicaid fraud) and the Department of Health (for Medical Quality Assurance). No fishing expeditions for information will be allowed. In more than 20 years, there has not been a single breach of patient confidentiality after 65 million prescriptions have been processed by the other state prescription monitoring programs.

The “Chilling” Effect

DEA reports that from 1990 – 1998, the overall aggregate production quotas for Schedule II and Schedule III narcotic drugs have continually risen. The quantity of fentanyl produced in 1998 is eight times what it was in 1990. Oxycodone, hydromorphone and hydrocodone production have tripled since 1990, while morphine production has more than doubled during that same period. The Automated Records and Consolidated Orders System (ARCOS) reports for 1997-1998 reflect a rise in the overall consumption of oxycodone, hydrocodone, hydromorphone, methadone, morphine and fentanyl. National data reflects a

steady rise in the number of prescriptions for Schedule II –IV controlled substances nationwide despite over 15 states having some kind of prescription monitoring program in place.

ARCOS data indicates that despite the fact that more and more states are beginning to collect controlled substance prescription data, it appears not to have any impact on the overall consumption and prescribing of analgesic drugs. Under the Florida Prescription Validation Program, all Schedule II, III, and IV benzodiazepines are included, thereby negating the tendency to prescribe a lower schedule just to avoid the monitoring program. Additionally, most doctors in this state have shown they are professional enough to prescribe the correct drug to best treat their patients.

Costs:

The Department of Health estimates that the proposed program will cost \$4.4 million per year for the first year and then \$3 million annually after that.

MOST FREQUENTLY ASKED QUESTIONS

1. What is the intent of this program?

The intent of this program is to reduce illegal diversion of prescription drugs. The program will reduce doctor shopping by allowing physicians to view the prescription history of their patients. Pharmacists will be able to check prescription history on a patient who presents a questionable prescription to be filled, thereby further reducing prescription fraud. This program will also allow health officials to follow up more quickly and completely on investigations of physicians who abet the illegal diversion of drugs as well as physicians who may be involved in Medicaid fraud. Finally, the program will allow law enforcement diversion investigations to be completed more quickly.

2. Will this program place a financial burden on the physicians or the pharmacies? What about additional costs to the consumer?

No. This program will not create an additional administrative burden on physicians nor will it cost the physicians any money. Pharmacies will be required to submit data every 35 days (or sooner as technology permits). This involves sending an electronic disc through the mail to the data collection center or executing a file transfer electronically. The only cost to the pharmacies would be the incidental cost of mailing a disc. This program will not provide any additional costs to the consumers.

3. Is the program proposed for Florida in compliance with the federal Health Insurance Portability and Accountability Act (HIPAA)?

Yes. In fact, Florida's concept meets all the security requirements from the Florida Department of Health that are more stringent than HIPAA requirements.

4a. Isn't the accessibility to controlled substance prescription data a violation of patient confidentiality?

The Florida prescription-validation program provides safeguards to protect patient confidentiality and access to controlled substance prescription information through statute. The law prohibits unauthorized access to and use of confidential patient information. Moreover, the statute provides for a third degree felony for anyone who makes an unauthorized disclosure of this confidential information. After decades of operation, no program in any other state has reported a breach of confidentiality.

4b. Who will have access to the information in the statewide database?

In Florida, access to information will be restricted to physicians inquiring about their own patients, pharmacies suspecting illegal activity by doctors or patients, Florida Department of Law Enforcement pursuant to an active criminal investigation, Agency for Health Care Administration and the Department of Health, also pursuant to investigations. Those with access must request the information from the Department of Health's database. The information will be stored for a maximum period of 2 years. Unauthorized disclosure of patient information will be a third degree felony offense.

5. What are the annual costs to operate a prescription-monitoring program?

The cost of implementing and operating a prescription-monitoring program for Florida would total approximately \$4.4 million for the first year and then \$3 million per year after that..

6. What are some of the beneficial uses of prescription validation programs?

Prescription validation programs can be used to identify those patients engaged in the crime of "doctor shopping" (which is a felony in Florida). Doctors will be able to query the system and identify patients who obtain multiple prescriptions for the same drugs from many different doctors. Pharmacies will also be able to check on patients who fill multiple prescriptions for the same drugs. When an illegal diversion pattern for drugs is identified, the information is then disseminated to the doctors and pharmacies involved alerting them to the problem. This assists health care professionals in their practice and allows them to intervene on the patient's behalf and assist them in obtaining treatment. This also then allows law enforcement to conduct investigations into criminal activity. It has been an extremely successful program to thwart diversion in a number of other states. Additionally, the counterfeit-proof prescription pads will reduce the use of fraudulent prescriptions often used to illegally obtain prescription drugs

7. What about children who are prescribed Schedule II drugs such as Ritalin? Will they be registered in the database?

Only patients 16 years and older will be included in the electronic database. This program will not highlight or stigmatize anyone who legitimately receives and uses medications prescribed by a doctor, but it will highlight illegal diversion and abuse of controlled substances. Ritalin is the brand name of the Schedule II controlled substance methylphenidate. Methylphenidate is a central nervous system stimulant similar to amphetamine in the nature and duration of its effects. In medicine, Ritalin is used to treat Attention Deficit Disorder (ADD) and narcolepsy. Prescriptions of Ritalin have increased more than 600% over the past five years according to DEA. In recent years, Ritalin has been increasingly diverted and abused by both youth and adults. Under Federal law, dealing in Ritalin is a felony.

8. Is this system providing an unconstitutional invasion of privacy?

No. The US Supreme Court has ruled that prescription monitoring systems do not violate an individual's right to privacy under the US Constitution. The court rejected the following privacy-related arguments:

- Patient identification might become publicly known thereby adversely affecting a patient's reputation.
- Patients will be reluctant to use medically-necessary drugs due to public disclosure fears
- Doctors will be reluctant to prescribe such drugs, thereby interfering with their right to practice medicine

9. How long will the prescription history be kept?

Information will be kept for 2 years and then destroyed.

10. Does this program apply only to Medicaid patients?

This program applies to all Floridians over the age of 16 who are prescribed Schedule II – IV controlled substances. Medicaid accounts for approximately 20% of all prescriptions written for these schedules.

11. Does the Prescription Validation Program overlap with the handheld PDA now being used by 1,000 Medicaid physicians?

The Prescription Validation Program will include all patients over age 16 receiving Schedule II-IV controlled substances – not just Medicaid recipients. Medicaid only accounts for 20% of all Schedule II – IV prescriptions in Florida. This system will include 100% of those prescriptions for both Medicaid and non-Medicaid patients.

12. What other grants or Federal funding will be used to pay for the Prescription Validation program?

For 2003 and 2004 combined, Florida received \$650,000 from the Harold Rogers Prescription Monitoring Program Grant managed by the US Department of Justice. Florida will apply in January 2006 for an additional \$350,000 of Federal funding. Use of the funds is contingent upon passing legislation to establish the program in Florida.

13. Why does the collection of information exclude children under the age of 16?

The intent of the program is to reduce diversion of controlled substances. Diversion is primarily a crime perpetrated by the adult population. This program will both deter doctor shopping by patients, but also allow law enforcement to more efficiently investigate diversion cases. In Florida, you must be over 16 to pick up a controlled substance at a pharmacy.

14. What is the savings realized by the state of Florida and is it worth the cost of \$3 million per year?

Prescription drug abuse is the fastest growing drug problem in our state and in our nation today. Every day, we lose 6 Floridians dead to prescription drugs. To do nothing is not an option. Without establishing this system, we will see even more abuse and death. This system will save Florida in both human lives and taxpayers dollars. In the illegal diversion of pharmaceuticals, we allow more drugs to be available in our schools and communities. This system will prevent some diversion and deter much more. We lose millions of dollars in prescription drug Medicaid fraud every year. Medicaid spends over \$150 million every year on Schedule II – IV controlled substances. **If we reduce Medicaid fraud by even 10%, then we save Florida \$15 million every year. This amount would pay for the system seven times over.**

15. How many people will Department of Health need to operate this system and maintain the database?

The Department of Health will require 3 additional FTE's to operate and maintain the system. This will include system administrators and a 24-hour help desk.

16. Why does the program cost \$3 million per year?

The largest single cost is the security system that protects the confidentiality of the information. In order to preserve privacy, the system must have the highest degree of security available to prevent unauthorized persons from hacking into the database and retrieving information. That security protection alone reaches almost \$1 million in the third year. System administration services and data collection account for the remainder of the big-ticket items associated with this program.

17. Does this Prescription Validation Program violate the Florida Constitution (which has more stringent provisions protecting privacy than the US Constitution) in regard to the invasion of privacy?

In the opinion of the Governor's legal office, this bill does not raise significant constitutional concerns and does not unlawfully infringe on the constitutional right to privacy in the Florida Constitution.

18. Why is it not mandatory for physicians and pharmacists to check this database every time on every patient?

The database provides a tool for physicians to protect themselves from dishonest patients who seek to obtain prescription narcotics to abuse. In essence, this serves to reduce the supply of prescription drugs available for nonmedical use or abuse. Moreover, physicians can use the prescription history information to better treat their patients.

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