# OHIO STATE BOARD OF PHARMACY

**77 South High Street, Room 1702; Columbus, OH 43215-6126**

*TEL:* **614/466-4143** *E-MAIL:* **exec@bop.state.oh.us** *FAX:* **614/752-4836**


**O**hio **A**utomated **R**x **R**eporting **S**ystem

# Ohio's Dangerous Drug Database

# Past, Present, and Future

# *House Bill 93 Report*


By: William T. Winsley, M.S., R.Ph.
Executive Director

Danna E. Droz, R.Ph., J.D.
PMP Administrator


November 21, 2011

# INTRODUCTION

When House Bill 93 (HB 93) was passed by the Ohio legislature, it was a response to the epidemic of prescription drug abuse identified in Ohio. This law made sweeping changes to the practices of health care professionals and their licensing boards in order to address the problems of widespread drug abuse and the resulting overdose deaths. The overarching objective was to address those individuals who were masquerading as legitimate medical care providers but, in reality, were drug traffickers. As part of this legislation, several changes were made to the dangerous drug database statutes and a report was requested on several database issues. Therefore, pursuant to HB 93, Section 5, the Ohio State Board of Pharmacy submits this report.

# EXECUTIVE SUMMARY

In consultation with prescribers and pharmacists, their licensing boards, and their professional associations, the Board considered the following improvements to the dangerous drug database, also known as the Ohio Automated Rx Reporting System (OARRS).

## Real-time reporting of prescription data to OARRS

**(Page 4)**

At the present time, instantaneous reporting of prescription data and uploading of that data for immediate use by an OARRS user is not feasible. However, if daily reporting is deemed necessary, Ohio could implement this requirement within two years at a cost of nearly $900,000 in addition to $1.5 million required to maintain the system.

## Real-time access to patient reports from OARRS

**(Page 6)**

Most of the complaints about access to OARRS are a result of delays outside the control of OARRS. Processing time to provide an OARRS report is currently three seconds or less for 99.5% of the 7,000 reports processed daily. To improve access, OARRS staff is working with two large pharmacy systems and one health information exchange to incorporate requests for OARRS reports into their software systems and workflow. Most of the work on the OARRS system to facilitate such changes has already been done; therefore, the rate-limiting factors are under the control of the outside parties.

## Easier method for OARRS users to request reports

**(Page 7)**

HB 93 extended the individuals eligible to request OARRS reports to prescribers' delegates who register with OARRS. This allows the delegate to request a report and make it available to the prescriber in advance of the patient encounter. The Board is seeking a legislative change to allow delegates for pharmacists to provide the same benefit.

## Enhanced drug utilization review (Page 7)

While it seems reasonable that drug utilization review could be automated by OARRS and "red flag" patients, our experience has shown that this is not recommended. This function is best left to the prescriber or pharmacist and the exercise of professional judgment.

## Upgrading the existing database or obtaining a new database (Page 7)

The Board recommends that OARRS be enhanced with new software and additional hardware to provide more stability in the system and redundancy in the databases. These changes are necessary to keep the system available to OARRS users 24/7, and avoid outages for routine maintenance, emergency maintenance, and slowdowns for system overload. The estimated cost is $820,000 initially and $90,000 annually thereafter, in addition to the $1.5 million/year necessary to maintain OARRS in its current form.

## Systematic monitoring for misuse or diversion of controlled substances (Page 8)

The Board is currently in the process of hiring another pharmacist for the OARRS program. One of the duties will be to develop, implement, and maintain a systematic method of surveillance and referrals. The system will be automated and can be developed with the current database.

## Funding to implement recommendations (Page 9)

The Board is very concerned about future availability of federal grants and believes that other sources of revenue should be sought. If the enhancements discussed in this report are pursued, additional funds will be required. Possible sources of revenue include General Revenue Funds, third party health care payer fees, an additional court cost from criminal cases, an assessment to manufacturers of OARRS drugs on a market share basis, and a portion of health professional licensing fees.

## Other Accomplishments (Page 9)

OARRS leads the nation in number of reports produced, currently averaging 7,000 per day.

OARRS users are able to access data from two other states' prescription monitoring programs (PMPs) with at least one additional state PMP expected to be accessible this year, and several more in 2012.

OARRS provides quarterly (de-identified) data to Ohio Department of Alcohol and Drug Abuse Services for trending studies.

## BACKGROUND

In 2004, House Bill 377 was passed by both the Ohio House of Representatives and the Ohio Senate. It was signed by the Governor and became law in May, 2005. It allowed the Board of Pharmacy to develop and operate a dangerous drug database. [A dangerous drug database used in the manner described in the law is also called a prescription monitoring program (PMP), and Ohio's program is named Ohio Automated Rx Reporting System (OARRS).] The intent of the legislation was to provide:

1. a screening tool for physicians and pharmacists to assist them in making treatment decisions about their patients by providing a history of prescriptions; and
2. an investigative tool for law enforcement officers who are investigating drug offenses to minimize the time required for investigation and gathering evidence.

To date, the Board has primarily utilized federal and private grants to implement, develop, and enhance the program. Today, the Ohio program is recognized throughout the country as one of the premier programs because it provides stellar service to its clients and is a leader in the development of future programs and future enhancements.

## CURRENT PROGRAM OVERVIEW

The prescription drug database contains dispensing information on all schedules of controlled substances and any non-controlled substances that are required by rule of the Board of Pharmacy (OARRS drugs). Every pharmacy licensed by Ohio that services outpatients and dispenses any controlled substance or any selected non-controlled substance to an Ohio resident is required to submit this dispensing information to the Board of Pharmacy weekly in an electronic format. In addition, prescribers who dispense (personally furnish) from their offices to their own patients must report those dispensings to OARRS. The law also requires wholesalers who sell OARRS drugs to report information regarding those sales to the Board in an electronic format. The formats of all electronic reports are designed to utilize existing drug records so that separate record-keeping is not necessary.

Once reported, the prescription data is maintained in a high-security environment for two years.

The statute explicitly states that the data in the database is not a public record but permits limited disclosures to identified persons for specific purposes.

The Board of Pharmacy is a law enforcement agency with statewide jurisdiction with respect to drugs. The Board employs fifteen Compliance Agents, who have law enforcement backgrounds, and eight pharmacists to enforce the drug laws of Ohio through investigations and inspections. Therefore, the law requires the Board to review the data for indicators of criminal activity or possible violations of professional healthcare licensing

laws. If identified, the Board must investigate or refer the information to an appropriate law enforcement agency or licensing board.

In May 2011, HB 93 became effective. This law made sweeping changes to address the epidemic of prescription drug abuse and overdose deaths in Ohio. The objective was to address those individuals who were masquerading as legitimate medical care providers but, in reality, were drug traffickers. As part of this legislation, several changes were made to the OARRS statutes and a report was requested on several OARRS issues.

## HB 93 RECOMMENDATIONS

### Real-time reporting of prescription data to OARRS

Currently, Ohio-licensed pharmacies and other dispensers (e.g. prescribers and emergency rooms) are required to report all prescriptions dispensed for controlled substances, tramadol, and carisoprodol each week to the OARRS program. Most pharmacies submit an electronic report that is uploaded to the database within 24 hours after transmission. The 24 hour window is used to validate the data and reject any prescription that fails to meet submission requirements. Since each pharmacy or chain sets its own reporting schedule, new data is added daily. The prescription dispensing information is usually available in the database within 1-7 days of dispensing, if transmitted electronically. However, a few (5) Ohio pharmacies utilize software that is incapable of transmitting data electronically. These pharmacies create a floppy disk with the electronic report and send it to OARRS via U.S. Postal mail. Prescriptions delivered in this manner are usually available in the database within 10 days of dispensing. Non-pharmacy dispensers often use a manual data entry system on the OARRS web site. This data is available within 24 hours after data entry.

Many OARRS users are interested in obtaining “real-time” information about the patient they are treating or the person they are investigating. While this is understandable, OARRS was developed to provide a history of prescription drug use. A patient’s pattern of prescription drug use is more important to the evaluation of that patient than what the patient obtained within the past week. If the patient has a six month history of getting prescriptions from emergency rooms, then it is logical to assume that the patient followed the same pattern during the last week.

Nevertheless, it is reasonable to examine the costs of real-time reporting to the OARRS program. Because the term “real time” can have different interpretations, for purposes of this section, “real time” will mean instantaneous or reasonably close to instantaneous. First of all, no state program similar to OARRS has instituted real-time reporting of prescription data. The first reason is cost; the second reason is the value; and the third reason is technology.

Oklahoma has been working for the last two years to develop their law and their database to require their pharmacies to report in “real-time.” The

requirement becomes effective in January 2012. To their credit, they invited many stakeholders into the planning and implementation meetings and numerous pharmacy chains have participated. During the course of development, Oklahoma conceded that real-time reporting had insurmountable costs and technical difficulties at the present time. Therefore, the parties agreed that reporting within five minutes after dispensing would be acceptable. The Oklahoma PMP estimates that it has cost them $350,000 using in-house personnel. Their staff recognizes that the effect on emergency rooms and dispensing doctors has not yet been evaluated and that the preparation has been challenging both technologically and administratively.

**At the present time, instantaneous reporting of prescription data and uploading of that data for immediate use by an OARRS user is not feasible**.

If the Ohio Board of Pharmacy wants to replicate the Oklahoma model, and utilize a five minute reporting period, we estimate that the data would be available for retrieval in twenty minutes or less. The additional time is required for the OARRS system to process and load the data and is affected by the total volume of data coming in at that particular moment. Note: this is an estimate since it has not been tested in any state.

In order to initiate a five minute reporting period, the following hurdles must be overcome:

- Significant resistance is anticipated from independent pharmacies, from hospitals who must report emergency room dispensing, and from prescribers who dispense from their offices within the five-minute intervals. <u>If these entities are exempt, the value of five-minute reporting is lost.</u>
- The initial cost for additional OARRS servers and licenses is estimated at $160,000; new PMP database management software at $600,000, and additional staff at $130,000, total of $890,000.
- Annual costs estimate of on-going maintenance – $30,000 for hardware and $130,000 for staff.
- **Costs shown above are in addition to $1.5 million to continue operating OARRS in its current form**.
- Training for OARRS users will be required to interpret the new reports. Users must consider prescriptions “dispensed” but not yet picked up, prescriptions that have been rejected but not yet re-entered, and data entry errors that have not been corrected.
- Training for OARRS dispensers will be required to correctly name files. Any file with the same name as a previously transmitted file will overwrite the old file and the older data will be deleted.
- It is expected that two years will be required to make the changes and implement the processes.

Due to these factors, reporting of prescription data every five minutes and uploading of that data for use by an OARRS user within twenty minutes is not advisable at the present time.

Alternatively if more frequent reporting by dispensers to OARRS is deemed necessary, daily reporting of prescription data would minimize the impact on the dispensers compared to instantaneous or five-minute reporting.

## Real-time access to patient reports from OARRS

From the time OARRS began in Oct 2006, it has been available 24/7 via the Internet. Any OARRS user who has been authenticated and provided with credentials to access the secure web site can request and obtain a patient report at any time. The time required for the system to process the request and produce a report has decreased from three minutes in 2006, to 30 seconds in 2007, to ten seconds in 2009, to three seconds in 2011. At the same time the annual number of requests for OARRS reports has increased from 9,719 in 2006 (Oct-Dec only), to 177,966 in 2007, to 353,484 in 2008, to 512,486 in 2009, to 911,565 in 2010, and 915,942 thus far in 2011 (Jan-Sep). As of mid-November 2011, OARRS is processing nearly 7,000 requests every weekday.

When OARRS users talk about the difficulty of accessing OARRS, we find that the real problem is the time required to access the Internet, locate the OARRS web site, log-in, and perform the data entry to identify the individual whose records are being requested. The production times described in the previous paragraph are OARRS system times. They do not include the time necessary for internet access, log-in, data entry, etc. Thus, the overall time required by a user is affected by factors that are outside the control of OARRS, such as whether the user is already connected to the Internet, the internet connection speed, the speed of the computer he/she is using, and what other programs are running on the computer at the time of the request.

In order to address the issue, OARRS has begun working with an Ohio health information exchange and two large pharmacy systems to see if requesting an OARRS report can be incorporated into their software and workflow. If it works, a prescriber or pharmacist will have an icon on their computer screen at the time of the patient or prescription interaction. If the health care professional determines that reviewing the OARRS report is warranted, he/she can click on the icon and view the OARRS report. Thus, the time and effort required to access the Internet, reach the OARRS web site, log-in, and enter the data steps are automated and occur without involving personnel. Most of the effort to accomplish this must be done by the health information exchange or pharmacy system. Therefore, the time to implement it is beyond the control of OARRS, but most of the work on the OARRS system has already been done. The Board anticipates charging a reasonable annual fee for this service. It will save the prescribers and pharmacists an enormous amount of

time but also it will require additional maintenance of OARRS by Board staff. The current OARRS system will still be available free of charge.

## Easier methods for OARRS users to request reports

In order to assist OARRS users and facilitate access, the Board sought to allow prescribers to have delegates (with separate OARRS accounts) to be able to obtain a report so that it is available when the prescriber reviews the patient's medical record. This was accomplished with HB 93. Now the Board is seeking to further extend the availability of delegates for pharmacists.

## Enhanced drug utilization review

The question has been raised whether OARRS can evaluate the patient data and "red flag" certain patients so that health care providers can be alerted to a potential doctor shopper. This is not an appropriate use of OARRS for the following reasons:

- There is no unique identifier for patients. Thus, the system sometimes mixes patient records for more than one patient into a single report which could create a false positive. Such a label could be detrimental to patient care if the health care professional does not exercise due diligence in evaluating the OARRS reports.
- OARRS does not have sufficient information to make such an evaluation. The same OARRS report could reveal a doctor shopper or a cancer patient depending on other factors including the patient's diagnosis, the specialty of the prescribers, and the location of the pharmacies.
- Data entry errors at the pharmacy. The most frequent data entry error is wrong prescriber. While this rarely impacts patient care, it could have serious consequences when number or location of prescribers is a consideration.
- Evaluation of the data was never intended to be a function of OARRS. Evaluation should only be performed by a health care professional who is treating the patient and has access to additional medical information.

## Upgrading the existing database or obtaining a new database

The database and database management software currently being used by OARRS is licensed to the Board by Optimum Technology. It has worked reliably since it was installed in 2006. However, the software is a basic product that Optimum customized for Ohio. The original payment to Optimum for the license and the customization was over $420,000. Our

annual maintenance for the software is over $50,000. Any modifications require additional funds and the cooperation of the company and its staff. In 2009, we paid for an additional module for interstate data transmission. All funds have come from federal grants.

Due to budgetary constraints, the Board has been able to enhance the program in numerous ways by utilizing the skill of our in-house IT staff, without modifying the Optimum product. At the current time, the Board is concerned about the continuing ability of the Optimum product to handle the volume of requests that we expect to be receiving by this time next year. Informal inquiries lead us to believe that we could obtain completely new software for about $500,000. We would prefer to contract for these services in consultation with our IT staff to insure that future maintenance and enhancements could be achieved using these in-house staff.

Optimum Technology is currently offering the Board a new version of their software. However, we have reviewed their offering and feel that it does not offer anything that our IT staff has not already created for us. Moreover, if we convert to the new version, we will lose the ability to make in-house modifications.

The Board recommends that OARRS be enhanced with new software and additional hardware to provide more stability in the system and redundancy in the databases. These changes are necessary to keep the system available to OARRS users 24/7 and avoid outages for routine maintenance, emergency maintenance, and slowdowns for system overload.

The costs may be summarized as follows:

- Initial cost for additional servers and licenses at $160,000; new PMP database management software at $600,000, and additional staff at $60,000, total of $820,000.
- Annual cost of on-going maintenance – $30,000 for hardware (three-year replacement cycle) and $60,000 for staff
- **Costs shown above are in addition to $1.5 million/year to continue operating OARRS in its current form**

## Systematic monitoring for misuse or diversion of controlled substances

Current law requires the Board to conduct surveillance on the database to detect potential violations of law and refer suspicions to appropriate law enforcement agencies or health professional licensing boards for investigation. While the Board has met this requirement, the results have been less than satisfactory.

The Board is currently in the process of hiring a pharmacist to be assigned to the OARRS program. According to the Position Description, one of the duties

will be to develop, implement, and maintain a systematic method of surveillance and referrals. The system will be automated and can be developed with the current database. We anticipate that this procedure will result in an increased number of investigations and arrests.

## Additional funds to implement recommendations

To date, OARRS has survived primarily on federal and private grants. The Board has applied for and received grants from the Harold Rogers PMP Grant Program via the U.S. Department of Justice, Bureau of Justice Assistance in 2003, 2005, 2006, 2007, 2008, 2009, 2010, and 2011. The Board applied for and received National All Schedules Prescription Electronic Reporting (NASPER) grants from the U.S. Department of Health and Human Services in 2009 and 2010, the only years those grants were available. The Board also received a small grant from the National Association of State Controlled Substances Authorities in 2010.

The Board is very concerned about the future availability of federal grants. Given the state of the federal budget and the stability of all grant programs, we believe that other sources of revenue should be sought to implement the recommended enhancements. Several states provide general revenue funds while others utilize a small portion of professional licensing fees. Alternatively, or perhaps in addition to other sources, revenue could be generated by a small "per covered life" fee on health insurance companies and other third party payers. [New York's PMP is funded in this manner.] After all, these entities could see monetary benefits from the expanded use of OARRS by the prescribers, pharmacists, and law enforcement. Another potential source of funds could be a small court cost on all criminal cases. Other suggestions are a program whereby drug manufacturers (of all OARRS drugs) would contribute to a national fund for the support of all PMPs, administered by an appropriate agency/private corporation/non-profit foundation/etc. By utilizing various revenue streams, support for OARRS can be maintained without undue burden on any one entity and protect the program from unforeseen changes to revenues from one source.

# OTHER ACCOMPLISH-MENTS

No other state's PMP is as active in daily activities or enhancements as OARRS. For example, OARRS currently processes nearly 7,000 requests for reports daily and 99.5% of these are handled automatically within 3 seconds. While a number of states have their PMP on a web site, others still use paper, fax machines, and manual searches.

Ohio was the first state to participate in multi-state PMP queries. On August 4, 2011, a pilot group of OARRS users in Ohio was able to request data from Indiana's PMP using the same request as for Ohio. This pilot program used the PMP Interconnect℠ product from the National Association of Boards of Pharmacy (NABP) and went so well that within days, the option was provided

to all OARRS users. Later in August, Virginia established a pilot group to work with Ohio. Currently, Virginia is off-line temporarily for software upgrades but we expect it to be statewide in late November. The PMP Interconnect℠ product will allow Ohio OARRS users to obtain data from Michigan in December and probably 15 additional states in 2012. This product is provided free of charge for at least five years through funding provided by NABP. Using a different product, Ohio entered into a pilot project to share OARRS data with users of the Kentucky PMP. That pilot was in operation with a small group of OARRS users for about two months but the project is now completed and off-line. We are awaiting Kentucky's technological changes in order to re-establish the communication.

OARRS provides quarterly reports to Ohio Department of Alcohol and Drug Abuse Services with county-level data. Each county's Alcohol, Drug Abuse and Mental Health board (or equivalent) receives the same data for that county for the most recent eight quarters which allows counties to determine some of the trends for patients in their respective county. (Data is limited for counties with low rates in order to prevent possible identification of patients.)

## CONCLUSION

The Board of Pharmacy and the OARRS staff have created a premier PMP that is second to none and receives many accolades from health care providers for the service they receive. It has been said that the reward for good work is more work. If true, then OARRS does a good job because the most frequent requests are for additional features, faster access, and more reports. The ability to provide this free service that has a significant impact on patient care is a testament to the hard work and support of the Board, the Board staff and its leadership.