

February 28, 2006

TO: OHCA Members

FROM: Stephen L. Mould, APR  
Director of Public Affairs

SUBJECT: Ohio's Drug Repository Program (Karon's Law)

The Ohio General Assembly passed HB 221 in 2003, establishing the Ohio Drug Repository Program after a legislator was contacted by a constituent who wanted to donate his wife's medications following her death, but was unable to do so due to the law at the time. The legislation has been deemed "Karon's Law" in recognition of this individual. Effective in April 2004, the Ohio Board of Pharmacy (OBP) rolled out rules for the new program, with the goal of the donated drugs benefiting Ohioans who are not able to meet the cost of their prescription medications.

OHCA supports this program as good public policy, and as a positive program that can generate goodwill in the community, in the media, and with legislators, regulators and others. The Association has been working with the Ohio Association of Free Clinics (O AFC) to assist facilities and clinics in their efforts to implement and promote the program.

The program, overseen by OBP, allows drugs that have been previously dispensed to a patient, but that have been in the possession of a health care professional, to be donated to an Ohio pharmacy, hospital or non-profit clinic to be re-dispensed to patients meeting certain criteria. Controlled substances and drug samples may not be donated. The drugs must be in their original sealed and tamper-evident unit dose packaging. The donation can be made by a pharmacy, a wholesaler, or directed by an individual or guardian through an inpatient facility, including nursing homes. The law also extends immunity from prosecution to facilities and others participating in the program in good faith.

Enclosed in this packet is a copy of the OBP rules implementing the program; a question and answer sheet; copies of sample forms that may be used by donors and drug recipients; a listing of O AFC members and federally qualified health centers that might be interested in partnering with nursing facilities in this effort; and a sample set of procedures to be followed in implementing the program. We also recommend that facilities work with their institutional pharmacy to implement the program.

As this program is a positive public policy initiative, we have also enclosed a sample press release you may use for the opportunity to promote your facility's participation in the program.

OHCA members who are interested in donating unused drugs that would otherwise be destroyed may wish to contact one of the clinics listed or their institutional pharmacy about participating in this program and assisting with the drug donation process. A list of clinics in Ohio is also available at [www.ohiofreeclinics.org/CurrentMembers.htm](http://www.ohiofreeclinics.org/CurrentMembers.htm). To learn more about this program, please visit the Ohio Board of Pharmacy's website at [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov), select "What's New," and scroll down to the section titled "Drug Repository Program Rules." If you have any questions about the rules, please contact Mark Keeley, R.Ph., at the Board of Pharmacy, 614/466-4143, [mkeeley@bop.state.oh.us](mailto:mkeeley@bop.state.oh.us). For additional information please contact Stephen L. Mould, APR ([smould@ohca.org](mailto:smould@ohca.org)), 614/540-1325.

# Ohio's Drug Repository Program (Karon's Law) Questions & Answers

February 14, 2006

**Q: Is the Drug redistribution program mandatory?**

A: No. The program allows drugs that have been dispensed to a patient, but that have been in the possession of a health care professional, to be donated; a facility is not required to participate in the program. Likewise, a patient within a participating facility must authorize the donation, but is not required to do so.

**Q. What drugs may be donated?**

A. The law allows the donation of all dangerous drugs, except controlled substances and drug samples, provided they meet specific requirements regarding packaging and storage, and that have not been in the possession of the ultimate user.

**Q. Who owns the drugs, and does this affect donation?**

A. In general, the drugs are "owned" by the patient; this is why a donation consent form is required from patients to participate in the program. The patient or a person designated by durable power of attorney, a guardian or other individual responsible for the care and well-being of a patient may make the decision to donate an eligible dangerous drug.

**Q. Does the method of payment affect donations?**

A. Drugs from any payer may be donated as long as there is patient consent; facilities may want to consult with their institutional pharmacy, however, as credit may be given to the facility for drugs from certain payers (Medicare Part A, managed care). The resident may also receive a credit from the pharmacy if they are private pay.

**Q. Is the facility liable for prosecution if drugs are bad, labeled incorrectly, or for any misuse of the drugs?**

A. The law specifically extends to all parties immunity from criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action for matters related to donating, accepting, or dispensing drugs under the program.

**Q. How much paperwork is involved in the drug redistribution program?**

A. The facility must obtain a signed donor form from residents wishing to donate drugs (a blanket consent form for all eligible drugs may be included in the admissions packet), and record all information for each donated drug (a copy of label or medication card information is usually adequate). Records must be maintained for three (3) years. The paperwork is comparable to that done for drugs returned to a pharmacy following the discharge/death of a resident.

**Q. What about privacy requirements?**

A. Identifying resident information should be removed or blacked out from all medication records to ensure compliance with HIPAA requirements.

**Q. Who is responsible for delivering or picking up donated drugs?**

A. This is an arrangement between the donating facility and pharmacy or clinic accepting donated drugs. In general, the facility notifies the recipient that drugs are available for pickup. The facility stores the drugs to be donated in a secure/locked area until they are picked up.

**Q. Where do I get additional information?**

A. Copies of the rules, forms, sample procedures, a listing of free clinics and other information is included in this packet, or is available from OHCA. Other information is available at the Ohio Board of Pharmacy website at [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov); select "What's New" and scroll down to "Drug Repository Program." Questions about the rules should be directed to Mark Keeley, R.Ph., at the Board of Pharmacy ([mkeeley@bop.state.oh.us](mailto:mkeeley@bop.state.oh.us)), 614/466-4143. You may also contact your local free clinic or visit the Ohio Association of Free Clinics website ([www.ohiofreeclinics.org](http://www.ohiofreeclinics.org)), or the Ohio Primary Care Association web site ([www.ohiopca.org](http://www.ohiopca.org)).

## **Sample Procedures to Implement Karon's Law**

*Following are the procedures used by one Ohio facility to implement the drug repository program (Karon's Law). OHCA recommends that facilities review procedures to implement the program with their institutional pharmacy, participating clinic and legal counsel prior to implementation.*

- Upon admission, explain the program to the resident/legal guardian, and ask the resident if they would be interested in participating in the Karon's law program.
- If they agree, have the resident or legal guardian sign the consent form, and include the form in the resident's records.
- During review of discharged residents, the individual's medication is pulled and stored in a secure/locked area by the assistant director of nursing services (ADNS), or other assigned individual.
- All discharged resident's narcotics are destroyed per policy.
- The ADNS (or assigned individual) then assures that the medication is not that of a private pay or insurance-paid resident.
- All Medicare Part A and managed care residents' medication is returned for credit.
- A copy is made of all the discharged resident's medication cards with the name blackened out to meet HIPPA requirements.
- The ADNS (or assigned individual) files the copied medication cards and consent form.
- The medication is boxed and stored in a secure/locked area until the free clinic picks them up. The clinic is contacted for pickup; pickup usually occurs the same day.
- The process may take an hour a week.

**DRAFT PRESS RELEASE FOR FACILITIES PARTICIPATING IN  
OHIO DRUG REPOSITORY PROGRAM**

*Type on facility letterhead and fill in the appropriate information where indicated*

FOR IMMEDIATE RELEASE

CONTACT: *(administrator, facility)*  
*(phone number, email address)*

*(date)*

***(City)* Nursing Facility Participates in Medication Donation Program**

A *(city)* nursing home has teamed with area *(free clinic/pharmacy/hospital)* to donate unused medications to Ohioans who are not able to meet the cost of their prescription drugs.

*(Nursing home)* is making its donations of unused medications through the Ohio Board of Pharmacy's (OBP) Drug Repository Program. Deemed "Karon's Law," the program was named in recognition of the woman whose death prompted the legislature to enact the measure, when her husband was unable to donate her unused medications.

The program, overseen by OBP, allows unused medications that have been dispensed to a patient, but that have been in the possession of a health care professional, to be donated to an Ohio pharmacy, hospital or non-profit clinic to be re-dispensed to patients meeting certain criteria. *(Nursing home)* donates the unused drugs, with the prior approval of the patient, to *(pharmacy/clinic/hospital)*.

"We believe this program will significantly benefit the needy in our community," said *(administrator)*, administrator at *(nursing home)*. "With the advent of Karon's Law, we are able to donate *(hundreds/thousands)* of dollars in medications each *(month/year)* that would previously have been destroyed."

The voluntary program allows the donation of all dangerous medications, except controlled substances and drug samples, provided they meet specific requirements regarding packaging and storage, and that have not been in the possession of the ultimate user. These restrictions help ensure the quality of the medications to be re-dispensed. The law also extends immunity from prosecution to facilities and others participating in the program in good faith.

Details regarding the program are available by contacting *(administrator, nursing facility)*, or through the Ohio Board of Pharmacy web site at [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov); select "What's News" and click on the section titled "Drug Repository Program Rules."