



---

---

## WISCONSIN LEGISLATIVE COUNCIL ACT MEMO

---

---

<b>2003 Wisconsin Act 175</b> [2003 Assembly Bill 845]	<b>Cancer Drug Repository</b>
2003 Acts: <a href="http://www.legis.state.wi.us/2003/data/acts/">www.legis.state.wi.us/2003/data/acts/</a>	Act Memos: <a href="http://www.legis.state.wi.us/lc/act_memo/act_memo.htm">www.legis.state.wi.us/lc/act_memo/act_memo.htm</a>

2003 Wisconsin Act 175 requires the Department of Health and Family Services (DHFS) to establish and maintain a cancer drug repository program under which persons may donate cancer drugs or supplies needed to administer cancer drugs for use by an individual who meets eligibility criteria specified by DHFS by rule. Donations may be made on the premises of a medical facility or pharmacy that elects to participate in the program. Such a facility or pharmacy may charge an individual who receives a cancer drug or supplies a handling fee.

Under the Act, a cancer drug or supplies needed to administer a cancer drug may be accepted and dispensed only if all of the following requirements are met:

- The cancer drug or supplies are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened.
- The cancer drug bears an expiration date that is later than six months after the date the drug was donated.
- The cancer drug or supplies are not adulterated or misbranded, as determined by a pharmacist, employed by or under contract with the medical facility or pharmacy, who inspects the drugs or supplies before they are dispensed.
- The cancer drug or supplies are prescribed by a practitioner for use by an eligible individual and are dispensed by pharmacists.

No cancer drug or supplies that are donated for use under the Act may be resold.

---

---

This memo provides a brief description of the Act. For more detailed information, consult the text of the law and related legislative documents.

Under the Act, a manufacturer of a cancer drug or supply is not subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the manufacturer's cancer drug or supply that is donated to the cancer drug repository. This includes immunity from liability for failure to transfer or communicate product or consumer information or the expiration date of the donated cancer drug or supply. The immunity does not apply if the manufacturer of a drug or supply exercises bad faith.

In addition, the Act provides that persons other than the manufacturer of a drug or supply are immune from civil liability for injury to or the death of the individual to whom the drug or supply is dispensed and may not be found guilty of unprofessional conduct for their acts or omissions relating to donating, accepting, distributing, or dispensing a cancer drug or supply under the Act. This immunity does not apply to donation, acceptance, distribution, or dispensation of a cancer drug by a person whose act or omission involves reckless, wanton, or intentional misconduct.

The Act requires that DHFS promulgate all the following as rules:

- Requirements for medical facilities and pharmacies to accept and dispense donated cancer drugs or supplies, including all of the following: (1) eligibility criteria; (2) standards and procedures for accepting, safely storing, and dispensing donated cancer drugs or supplies; (3) standards and procedures for inspecting donated cancer drugs or supplies to determine if they are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packed in single-unit doses, the single-unit dose packaging is unopened; and (4) standards and procedures for inspecting donated cancer drugs or supplies to determine that they are not adulterated or misbranded.
- Eligibility criteria for individuals to receive donated cancer drugs or supplies. The standards must prioritize dispensation to individuals who are uninsured or indigent, but permit dispensation to others if an uninsured or indigent individual is unavailable.
- A means, such as an identification card, by which an individual who is eligible to receive donated cancer drugs or supplies may indicate that eligibility.
- Necessary forms for administration of the cancer drug repository program, including forms for use by persons who donate, accept, distribute, or dispense the drugs or supplies.
- The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated cancer drugs or supplies.
- A list of cancer drugs and supplies, arranged by category or by individual cancer drug or supply, that the cancer drug repository program will accept for dispensing.
- A list of all cancer drugs and supplies, arranged by category or individual cancer drug or supply, that the cancer drug repository will not accept for dispensing. This list must include a statement that specifies the reason that the drugs or supplies are ineligible for donation.

**Effective Date:** The Act takes effect on July 1, 2005. Rules that are required under the Act must be submitted to the Legislative Council Rules Clearinghouse by January 1, 2005.

**Prepared by:** Richard Sweet, Senior Staff Attorney

April 15, 2004