2003 DRAFTING REQUEST

Bill

Received: **01/17/2003**

Received By: **mkunkel**

Wanted: **As time permits**

Identical to LRB:

For: **Scott Fitzgerald (608) 266-5660**

By/Representing: **Judi Rhodes-Engels**

This file may be shown to any legislator: **NO**

Drafter: **mkunkel**

May Contact:

Addl. Drafters:

Subject: **Health - miscellaneous**
Occupational Reg. - misc

Extra Copies: **DAK, PJH**

Submit via email: **YES**

Requester's email: **Sen.Fitzgerald@legis.state.wi.us**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Use of prescription drugs returned to inpatient health care facilities

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?							S&L
/1	mkunkel 01/21/2003	wjackson 01/21/2003	rschluet 01/23/2003		mbarman 01/23/2003		S&L
/2	mkunkel 01/23/2003	wjackson 01/23/2003	pgreensl 01/23/2003		lemery 01/23/2003		State

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/3	mkunkel 01/28/2003	wjackson 01/28/2003	chaskett 01/29/2003	_____ _____	lemery 01/29/2003	lemery 01/30/2003	State
/4	mkunkel 02/18/2003	wjackson 02/19/2003	jfrantze 02/19/2003	_____ _____	lemery 02/19/2003	lemery 02/19/2003	

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At intro.

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1/23/19 1/23/19

LRB-1573

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for Senate Pres office

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/2	mkunkel 01/23/2003	wjackson 01/23/2003	pgreensl 01/23/2003	_____ _____	lemery 01/23/2003		

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/?	mkunkel	/1 WLj 1/21					

1.20.3

FE Sent For:

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P/C to Judy Sen Fitzgerald 6-5660

DOC Pharmacists

If inmate leaves or dies, pharmacist must destroy prescription

Allow it to be returned to central DOC distribution facility.

Kunkel, Mark

From: Rhodes-Engels, Judi
Sent: Monday, January 13, 2003 4:09 PM
To: Kunkel, Mark
Subject: RE: Phar 7 - Reuse of drugs-DOC

Mark,
Let me know what you think of this.

Judi

-----Original Message-----
From: Dsida, Michael
Sent: Monday, January 13, 2003 4:06 PM
To: Rhodes-Engels, Judi
Cc: Kunkel, Mark
Subject: RE: Phar 7 - Reuse of drugs-DOC

I just talked to Mark Kunkel, an attorney in our office whose drafting areas include the board. Mark said that this is his draft, so I will forward your request to him.

Mike Dsida
Legislative Reference Bureau
608/266-9867
michael.dsida@state.legis.wi.us

-----Original Message-----
From: Rhodes-Engels, Judi
Sent: Monday, January 13, 2003 3:58 PM
To: Dsida, Michael
Subject: FW: Phar 7 - Reuse of drugs-DOC

I think this will explain it the best.
Thanks.
Judi

-----Original Message-----
From: Boushon, Michael C. DOC
Sent: Monday, January 13, 2003 3:44 PM
To: Rhodes-Engels, Judi
Subject: Phar 7 - Reuse of drugs-DOC

<< File: PHAR 7.tif >>
Here is a little more info to go along with the letter.

Phar 7.04 is attached. The problem is the language in 7.04(1)(b) "Inpatient health care facility means...but does not include...or prison facilities" and it's application under (2) allowing returns **and reuse** from inpatient health care facilities only. We must be exempt from (3) also or we will be able to accept the drugs as we now do under (2)(c), but must continue to destroy them.

Kennedy, Debora

From: Kunkel, Mark
Sent: Friday, January 17, 2003 10:39 AM
To: Kennedy, Debora
Subject: Inpatient health care facility

Debora:

I have to draft something in ch. 450 (pharmacists) that allows an "inpatient health care facility" to reuse prescription drugs that are returned to the pharmacy at the facility. (However, the drugs can only be reused if the pharmacist determines that the contents haven't be adulterated or misbranded.)

The pharmacy examining board already has a rule that allows this. The board defines "inpatient health care facility" as "any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities". S. Phar. 7.04 (1) (b), Wis. Admn. Code.

The reason I am drafting a bill is because the requester wants to also allow community-based residential facilities, jails, and prison facilities to also reuse prescription drugs.

Do you think I can use the definition of "inpatient health care facility" at s. 101.123 (1) (b), stats.? That definition is "a county home established under s. 49.70, a county infirmary established under s. 49.72 or a community-based residential facility or a nursing home licensed under s. 50.03." Of course, I would add a reference to jails and prisons.

My other question concerns tuberculosis sanitariums, which are referenced in the rule. I don't see a reference to that term in the statutes. What do you think I ought to do about them?

Mark D. Kunkel
Senior Legislative Attorney
Legislative Reference Bureau
(608) 266-0131

sanatorium 46.21 (4m)(a) Milwaukee

(252.14 (1)(d)

except:
45.365 Wis. vets home at King
48.62 licensed foster homes
51.05 Mental Health institutes
51.06 Centers for the developmentally disabled
233.40 UW Hosp & Clinics
233.41 " " "
233.42 " " "
252.10 Public health dispensaries

(p) Other technical functions that do not require the professional judgment of a pharmacist.

(3) A pharmacy technician may not do any of the following:

(a) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(b) Perform any of the following tasks:

1. Participate in final drug utilization reviews.

2. Make independent therapeutic alternate drug selections.

3. Participate in final drug regimen screening, including screening for therapeutic duplication, drug–to–drug interactions, incorrect dosage, incorrect duration of treatment, drug allergy reactions and clinical abuse or misuse.

4. Perform any act necessary to be a managing pharmacist.

5. Administer any prescribed drug products, devices or vaccines.

(c) Provide patient counseling, consultation, or patient specific judgment, such as interpreting or applying information, including advice relating to therapeutic values, potential hazards and uses.

(d) Transfer the prescription to the patient or agent of the patient.

(4) The pharmacist shall provide the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative.

History: Cr. Register, April, 2001, No. 544, eff. 5–1–01.

Phar 7.02 Prescription label; name of drug or drug product dispensed. No prescription drug may be dispensed unless the prescription label discloses the brand name and strength, or the generic name, strength, and manufacturer or distributor of the drug or drug product dispensed unless the prescribing practitioner requests omission of the above information. The prescription label shall not contain the brand or generic name of any drug or drug product other than that actually dispensed.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; Register, August, 1991, No. 428, eff. 9–1–91; am. Register, January, 1996, No. 481, eff. 2–1–96.

Phar 7.03 Prescription renewal limitations. A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription as needed (PRN) by the patient, shall not be renewed beyond one year from the date originally prescribed. No prescription order containing either specific or PRN renewal authorization is valid after the patient–physician relationship has ceased.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; Register, August, 1991, No. 428, eff. 9–1–91.

Phar 7.04 Return or exchange of health items. (1) In this section:

(a) "Health item" means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.

(b) "Inpatient health care facility" means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community–based residential facilities, jails or prison facilities.

(2) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned, except for any of the following:

(a) From an inpatient health care facility, provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their expiration date.

(c) When in the professional judgment of the pharmacist substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.

(3) Health items returned to a pharmacy pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.

(4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.

Note: The DEA does not permit the return of controlled substances to a pharmacy from a non–DEA registrant under any circumstances.

History: Cr. Register, January, 1983, No. 325, eff. 2–1–83; am. Register, August, 1991, No. 428, eff. 9–1–91; r. and recr., Register, December, 1998, No. 516, eff. 1–1–99.

But see DEA FAQ

Phar 7.05 Prescription records. (1) A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last renewal.

(2) All systems used for maintaining a record of any prescription dispensing shall include:

(a) Patient's identification.

(b) Name, strength and dosage form of the drug product dispensed.

(c) Quantity dispensed.

(d) Date of all instances of dispensing.

(e) Practitioner's identification.

(f) Pharmacist's identification.

(g) Retrieval designation.

(3) (a) Except as provided in sub. (5), the transfer of prescription order information for the purpose of dispensing is permissible between pharmacies on an unlimited basis pursuant to the following requirements:

1. The transfer is communicated directly between 2 pharmacists and the pharmacist making the transfer records the following information:

a. The word "VOID" is written on the face of the invalidated prescription order.

b. The name and address of the pharmacy to which it is transferred, the name of the pharmacist receiving the prescription order, the date and the name of the pharmacist transferring the information are recorded on the reverse side of the invalidated prescription order.

(b) The pharmacist receiving the transferred prescription order information shall record in writing the following:

1. The word "TRANSFER" on the face of the transferred prescription order.

2. The date of issuance of the original prescription order.

3. The original number of renewals authorized on the original prescription order.

5. The number of valid renewals remaining and the date of the last renewal.

6. The pharmacy's name, address, and the prescription order number from which the prescription order information was transferred.

7. The name of the pharmacist making the transfer.

8. The name, address and telephone number of the pharmacy from which the original prescription order was transferred if different from subd. 6.

(c) The original and transferred prescription orders shall be maintained for a period of 5 years from the date of the last renewal.

Frequently Asked Questions (FAQs)

General FAQ's

- Faxing of Schedule II Prescriptions for Hospice Patients
- Changes that Pharmacists are Allowed to Make on Controlled Substance Prescriptions
- Is it appropriate to provide a DEA registration number on prescriptions written for medications other than controlled substances?
- Is it appropriate to provide a DEA registration number when purchasing items other than controlled substances such as prescription drugs, over-the-counter drugs, or medical supplies from a distributor?
- Is it permissible to dispense a prescription for a quantity less than the face amount prescribed resulting in the actual number of dispensings being greater than the number of refills indicated on the prescription?
- Can a Long Term Care Facility store controlled substances in an emergency kit without being registered with DEA?
- Can an individual return their controlled substance prescription medication to a pharmacy?
- Can a long term care facility (LTCF) return a resident's unused controlled substance medication to a pharmacy?
- Can a patient in a Long Term Care Facility (LTCF) receive methadone for maintenance purposes?

Question: Can controlled substance prescriptions for hospice patients be faxed to a pharmacy?

Answer: Yes. Schedule II-V controlled substance prescriptions, written for a patient

enrolled in hospice, may be faxed to a pharmacy for dispensing. The hospice patient may reside in a personal residence or hospice facility.

DEA regulations allow for the transfer of a Schedule II prescription to a dispensing pharmacy by facsimile for patients enrolled in a Medicare certified or state licensed hospice. DEA's intent is to provide for the hospice patient's needs when a controlled substance is determined to be medically necessary. Therefore, controlled substance prescriptions for hospice patients residing at a personal residence may be faxed to a pharmacy.

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Question: What changes may a pharmacist make to a prescription written for a controlled substance?

Answer: The pharmacist may add the patient's address or change the patient's address upon verification. The pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted on the prescription as well as the patient's medical record. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions.

The majority of changes can be made only after the pharmacist contacts the prescribing practitioner.

After consultation with the prescribing practitioner, the pharmacist is permitted to add or change the dosage form, drug strength, drug quantity, directions for use, and issue date.

The pharmacist is permitted to make information additions that are provided by the patient or bearer, such as the patient's address, and such additions should be verified.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

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Question: Is it appropriate to provide a DEA registration number on prescriptions written for medications other than controlled substances?

Answer: DEA strongly opposes the use of a DEA registration number for any purpose other than the one for which it was intended, to provide certification of DEA registration in transactions involving controlled substances. The use of DEA registration numbers as an identification number is not an appropriate use and could lead to a weakening of the registration system. Although DEA has repeatedly made its position known to industries

such as insurance providers and pharmacy benefit managers, there is currently no legal basis for DEA to prevent or preclude companies from requiring or requesting a practitioner's DEA registration number.

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Question: Is it appropriate to provide a DEA registration number when purchasing items other than controlled substances such as prescription drugs, over-the-counter drugs, or medical supplies from a distributor?

Answer: DEA strongly opposes the use of a DEA registration number for any purpose other than the one for which it was intended, to provide certification of DEA registration in transactions involving controlled substances. The use of DEA registration numbers as an identification number is not an appropriate use and could lead to a weakening of the registration system. Although DEA has repeatedly made its position known to industries such as insurance providers and pharmacy benefit managers, there is currently no legal basis for DEA to prevent or preclude companies from requiring or requesting a practitioner's DEA registration number.

Back to Top

Question: Is it permissible to dispense a prescription for a quantity less than the face amount prescribed resulting in the actual number of dispensings being greater than the number of refills indicated on the prescription?

Answer: Yes. Partial refills of Schedule III, IV, and V controlled substance prescriptions are permissible under federal regulations provided that each partial filling is dispensed and recorded in the same manner as a refilling (i.e., date refilled, amount dispensed, initials of dispensing pharmacist, etc.), the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and no dispensing occurs after six months past the date of issue.

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Question: Can a Long Term Care Facility store controlled substances in an emergency kit without being registered with DEA?

Answer: DEA published the following Statement of Policy in the April 9, 1980 Federal Register regarding the placement of controlled substances in an emergency kit located in a Long Term Care Facility.

STATEMENT OF POLICY

The placement of emergency kits containing controlled substances in **non-federally**

registered Long Term Care Facilities (LTCF) shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, **if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate:**

A. The source from which a LTCF may obtain controlled substances for emergency kits. The source of supply must be a DEA registered hospital/clinic, pharmacy or practitioner.

B. Security safeguards for each emergency kit stored in the LTCF which include the designation of individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.

C. Responsibility for proper control and accountability of such emergency kits within the LTCF to include the requirement that the LTCF and the providing DEA registered hospital/clinic, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of these controlled substances plus the requirement to take periodic physical inventories.

D. The emergency medical conditions under which the controlled substances may be administered to patients in the LTCF to include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21.

E. Prohibited activities which can result in the state revocation, denial, or suspension of the privilege of having or placing emergency kits, containing controlled substances, in a LTCF.

Back to Top

Question: Can an individual return their controlled substance prescription medication to a pharmacy?

Answer: No. An individual patient may not return their unused controlled substance prescription medication to the pharmacy. Federal laws and regulations make no provisions for an individual to return their controlled substance prescription medication to a pharmacy for further dispensing or for disposal. There are no provisions in the Controlled Substances Act or Code of Federal Regulations (CFR) for a DEA registrant (i.e., retail pharmacy) to acquire controlled substances from a non-registrant (i.e. individual patient).

The CFR does have a provision for an individual to return their unused controlled substance medication to the pharmacy in the event of the controlled substance being recalled or a dispensing error has occurred.

An individual may dispose of their own controlled substance medication without approval from DEA. Medications should be disposed of in such a manner that does not allow for the controlled substances to be easily retrieved. In situations where an individual has expired, a caregiver or hospice staff member may assist the family with the proper disposal of any unused controlled substance medications.

Back to Top

Question: Can a long term care facility (LTCF) return a resident's unused controlled substance medication to a pharmacy?

Answer: No. There are no provisions in the Controlled Substances Act for a DEA registrant (i.e., retail pharmacy) to acquire controlled substances from a non-registrant (i.e., resident of a LTCF). Most long term care facilities are not licensed by their respective state to handle controlled substances and therefore are not registered with DEA. Long term care facilities act in a custodial capacity, holding controlled substances that, pursuant to a prescription, have been dispensed to and belong to the resident of the LTCF. Federal laws and regulations make no provisions for controlled substances that have already been dispensed to patients, regardless of the packaging method, to be returned to a pharmacy for further dispensing or disposal.

Back to Top

Question: Can a patient in a Long Term Care Facility (LTCF) receive methadone for maintenance purposes?

Answer: If a LTCF is registered with DEA as a hospital/clinic, it need not be separately registered as a Narcotic Treatment Program (NTP) to administer or dispense methadone as an adjunct to medical treatment of conditions other than addiction. [21 CFR 1306.07(c)]

If a LTCF that is not registered with DEA has a patient who is also currently enrolled in a licensed NTP, the NTP may transfer medication to the LTCF with the approval of the State Methadone Authority. (www.samhsa.gov/centers/csat/content/opat/statemeth.html)

If an individual is not currently enrolled in an NTP and is in a LTCF that is not registered with DEA, a practitioner may administer narcotic drugs to the individual for relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. No more than one day's medication may be administered to the individual or for the individual's use at one time. Such emergency treatment may be carried out for no more than three days and may not be renewed or extended. [21 CFR 1306.07(b)]

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Publications | Reports Required by 21 CFR | Title 21 Regulations & Codified CSA | Controlled Substance Schedules | Drugs and Chemicals of Concern | Federal Register Notices | Electronic Commerce Initiatives | Quotas | Import Export | Meetings and Events | Career Opportunities | Links | FAQ's | What's New | Site Map | Search | Home | On-Line Forms & Applications | NFLIS Contact Us

Sec. 460.300 Return of Unused Prescription Drugs to Pharmacy Stock (CPG 7132.09)

POLICY:

A pharmacist should not return drugs products to his stock once they have been out of his possession. It could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons, because he would no longer have any assurance of the strength, quality, purity or identity of the articles.

Many state boards of pharmacy have issued regulations specifically forbidding the practice. We endorse the actions of these State boards as being in the interest of public health.

The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he mix returned portions of drugs to his shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries.

Issued: 10/1/80

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THE NEWSPAPER FOR AMERICA'S PHYSICIANS

HEALTH & SCIENCE

Redirecting unused meds could save millions

The FDA cleared one hurdle, but others remain before a local medical society can advance its plan to recycle medications to needy patients.

By Stephanie Stapleton, *AMNews* staff. April 3, 2000. Additional information

Washington -- A Food and Drug Administration informal opinion issued last month adds momentum to an effort by some Oklahoma physicians to develop a program to provide poor patients with much-needed medicines.

The FDA's action was a response to an inquiry by the AMA; it clarifies rules on the recycling of unused medicines from long-term-care facilities. In a Feb. 25 letter, the agency said it wouldn't object to returning medications to the dispensing pharmacy for reuse, provided requirements of the AMA and FDA are met.

The Oklahoma program, however, still must overcome other hurdles -- including state laws -- before it could be a model for other jurisdictions across the country.

"It has been helpful to get the FDA to respond. ... We interpret this as a signal to go forward," said Paul Patton, executive director of the Tulsa County Medical Society. "We're trying to develop a system to distribute drugs to people who need them. There's a sense that this [waste] is wrong and there is no rational reason to continue to destroy medications when people could use them."

An emerging "obstacle"

For the past three years, this local medical society has been working to garner support for this initiative, which would direct nursing homes' unused and unopened medicines back to pharmacies for distribution to indigent patients. In a relatively small state like Oklahoma, it is estimated that between $3 million and $10 million a year in unused prescription drugs from such facilities are destroyed. As awareness of that dollar figure has grown, so has the momentum behind the initiative's

concept, Patton said.

However, a provision within the FDA Compliance Policy Guide emerged as an obstacle to progress. The provision -- issued in 1980 -- states that "a pharmacist should not return products to his stock once they have been out of his possession." It also asserts that it would be "a dangerous practice ... to accept and return to stock the unused portions of prescriptions returned by patrons, because he would not have any assurance of the strength, quality, purity or identity of the articles."

This language triggered frustration on the part of its supporters. "The policy statement was 20 years old," Patton said. "Things have changed. The need for indigent patients to have access to medications is greater. Also, the way medicines are packaged is now different."

In an effort to gain a more up-to-date clarification, the medical society turned to the AMA, which has policy on its books in support of indigent care programs and the return and reuse of medications to the dispensing pharmacy, provided certain conditions are satisfied.

For example, the Association has long backed efforts by the pharmaceutical industry to provide indigent patients access to medicines. Currently, more than 50 companies listed as members of the Pharmaceutical Research and Manufacturers of America are involved in such initiatives.

Additionally, a 1997 Council on Scientific Affairs report explored the concept of recycling unused medicines. "The decision was that evidence tended to support that there could be some savings," said Joseph Cranston, PhD, the AMA program director for drug policy. "But nowhere in that thinking did we consider using the drugs for indigent patients. We were thinking about crediting the patient or the third-party payer," he added.

The council also incorporated guidelines developed by the American Society of Consultant Pharmacists as part of its own recommendations for how unused drugs could be recouped.

Taking action

In a letter signed by E. Ratcliffe Anderson Jr., MD, AMA executive vice president, the AMA expressed concern that the FDA policy could have the effect of undermining the program.

The FDA responded by saying that its policy is directed toward returning unused portions of prescription drugs dispensed to patients and is not necessarily germane to the initiative in Oklahoma. Because the medications would be dispensed in unbroken, tamper-evident packaging and then returned with the packaging intact, "it would seem that this would protect against at least some of the concerns the policy was

originally designed to address."

The FDA also offered five specific criteria, in addition to the AMA guidelines, that should be followed in recovering these medications.

Still, gaining this clarification from the FDA was only one of the numerous steps necessary to get the program off the ground.

State law, as interpreted by the state pharmacy board, blocks the medical society's efforts. The rule within Oklahoma has "basically asserted" that drugs cannot be used for any other purpose than by the person to which they were prescribed. If they are no longer needed, "they literally have to be flushed down the toilet," Patton said.

There are two bills pending in the state Legislature that would address this policy. Each has passed the House and is pending in a Senate committee, with the support of both the Oklahoma Medical Society and the state nursing home board. And Patton acknowledged that what his organization is attempting to do will likely be subject to changes, amendments and compromises before it ever could be implemented.

The AMA's Dr. Cranston, for example, outlined some of the questions that will likely shake out as the program evolves.

For instance, is it duplicative to what industry programs accomplish? Would it be laborious for physicians to access or participate in? Also, "it's clearly altruistic," he said. But will other interests want the savings to go to the state, the patient or the patient's family instead of this charitable use? But Dr. Cranston also said the project is worth watching. "If Oklahoma is able to get it off the ground, it will be an interesting model to look at ... an interesting experiment."

And that's exactly what fuels the medical society's optimism. "We've been able to get further on this effort than anyone else," Patton said. The fact that it could provide others with an example "adds to the excitement of what we're trying to do."

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ADDITIONAL INFORMATION:

Rules for reuse

AMA conditions:

- Controlled substances can not be returned.
- Medications are dispensed in tamper-evident packaging and returned with packaging intact.
- Medications meet all federal and state standards for product

integrity in the professional judgement of the pharmacist.

- Policies and procedures are followed for the appropriate storage and handling of medications at the long-term-care facility and for the transfer, receipt and security of medications returned to the dispensing pharmacy.
- A system is in place to track restocking and reuse to allow medications to be recalled if required.
- A mechanism is in place for billing only the number of doses used or crediting the number of doses returned.

Additional FDA criteria:

- The dispensing pharmacy is affiliated by contract with the long-term-care facility.
- The pharmacy and responsible pharmacist are licensed and in good standing.
- The dispensed medications have not left the control of the nursing home after they are received from the pharmacy.
- The storage, handling and record-keeping systems of the long-term-care facility are adequate to document how the returned medications have been handled. Special attention must be given to documenting storage conditions.
- Only medication that has been dispensed in the original manufacturer's packaging may be returned.

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State of Wisconsin
2003 – 2004 LEGISLATURE

LRB–1573/1
MDK:/.....
WLJ

2003 BILL

GEN

AN ACT ...; **relating to:** dispensing of returned prescription drugs by certain pharmacies.

Analysis by the Legislative Reference Bureau

Under current law, the pharmacy examining board (board) has promulgated rules regarding returning health items, including prescription drugs, to pharmacies. The rules allow for the return of health items to an inpatient health care facility, but only if the health items are in their original containers and the pharmacist determines that the contents are not adulterated or misbranded. The rule does not apply to prescription drugs that are controlled substances because current federal law generally does not authorize the return of controlled substances to a pharmacy. The rule defines "inpatient health care facility" as a hospital, nursing home, county home, county mental hospital, tuberculosis sanitorium, or similar facility. Excluded from the definition are community–based residential facilities, jails, or prison facilities.

Under this bill, prescription drugs may be returned to pharmacies that primarily serve community–based residential facilities, jails, prisons, or houses of correction, in addition to the facilities that are specified in the board's rules. However, controlled substances may not be returned under the bill. Also, the bill specifies that a returned prescription drug may be dispensed to a patient other than the patient to whom the prescription drug was originally dispensed, but only if the prescription drug is returned in its original container and a pharmacist determines that the prescription drug has not be adulterated or misbranded.

For further information see the ***state and local*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.09 (7m) of the statutes is created to read:

450.09 **(7m)** INPATIENT HEALTH CARE FACILITIES. (a) In this subsection:

~~1. "Controlled substance" has the meaning given in s. 961.01 (4).~~

~~2.~~ "Inpatient health care facility" means a hospital, nursing home, community–based residential facility, county home, county mental hospital, tuberculosis sanitorium, or similar facility, or a prison, jail, or house of correction.

(b) A prescription drug, other than a controlled substance, that is returned to a pharmacy that primarily serves an inpatient health care facility may be dispensed to a patient other than the patient to whom the prescription drug was originally dispensed, but only if the prescription drug is returned in its original container and a pharmacist determines that the prescription drug has not be adulterated or misbranded.

(END)

LRB–1573/1
MDK:wlj

2003 BILL

AN ACT *to create* 450.09 (7m) of the statutes; **relating to:** dispensing of returned prescription drugs by certain pharmacies.

Analysis by the Legislative Reference Bureau

Under current law, the Pharmacy Examining Board (board) has promulgated a rule regarding returning health items, including prescription drugs, to pharmacies. The rule allows for the return of health items to an inpatient health care facility, but only if the health items are in their original containers and the pharmacist determines that the contents are not adulterated or misbranded. The rule does not apply to prescription drugs that are controlled substances because current federal law generally does not authorize the return of controlled substances to a pharmacy. The rule defines "inpatient health care facility" as a hospital, nursing home, county home, county mental hospital, tuberculosis sanitorium, or similar facility. Excluded from the definition are community–based residential facilities, jails, or prison facilities.

Under this bill, prescription drugs may be returned to pharmacies that primarily serve community–based residential facilities, jails, prisons, or houses of correction, in addition to the facilities that are specified in the board's rule. However, controlled substances may not be returned under the bill. Also, the bill specifies that a returned prescription drug may be dispensed to a patient ~~other than the patient to whom the prescription drug was originally dispensed, but~~ only if ~~the prescription drug~~ is returned in its original container and a pharmacist determines that ~~the prescription drug~~ has not be adulterated or misbranded.

For further information see the ***state and local*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.09 (7m) of the statutes is created to read:

450.09 **(7m)** INPATIENT HEALTH CARE FACILITIES. (a) In this subsection, "inpatient health care facility" means a hospital, nursing home, community–based residential facility, county home, county mental hospital, tuberculosis sanitorium, or similar facility, or a prison, jail, or house of correction.

(b) A prescription drug, other than a controlled substance, that is returned to a pharmacy that primarily serves an inpatient health care facility may be dispensed to a patient other than the patient to whom the prescription drug was originally dispensed, but only if the prescription drug is returned in its original container and a pharmacist determines that the prescription drug has not be adulterated or misbranded.

(END)

at the inpatient health care facility

at that facility

LRB–1573/2
MDK:wlj:

2003 BILL

AN ACT *to create* 450.09 (7m) of the statutes; **relating to:** dispensing of returned prescription drugs by ~~certain~~ pharmacies.

Analysis by the Legislative Reference Bureau

Under current law, the Pharmacy Examining Board (board) has promulgated a rule regarding returning health items, including prescription drugs, to pharmacies. The rule allows for the return of health items to an inpatient health care facility, but only if the health items are in their original containers and the pharmacist determines that the contents are not adulterated or misbranded. The rule does not apply to prescription drugs that are controlled substances because current federal law generally does not authorize the return of controlled substances to a pharmacy. The rule defines "inpatient health care facility" as a hospital, nursing home, county home, county mental hospital, tuberculosis sanitorium, or similar facility. Excluded from the definition are ~~community-based residential facilities, jails, or~~ prison facilities.

Under this bill, prescription drugs may be returned to pharmacies that primarily serve ~~community-based residential facilities, jails, prisons, or houses of correction,~~ in addition to the facilities that are specified in the board's rule. ~~However, controlled substances may not be returned under the bill.~~ The bill specifies that a returned prescription drug may be dispensed ~~again~~ to ~~another~~ patient ~~at the same facility~~. Also, the returned prescription drug may be dispensed only if it is returned in its original container and a pharmacist determines that it has not been adulterated or misbranded.

BILL

For further information see the ***state and local*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.09 (7m) of the statutes is created to read:

450.09 **(7m)** ~~INPATIENT HEALTH CARE FACILITIES.~~ (a) In this subsection, "inpatient health care facility" means a hospital, nursing home, community–based residential facility, county home, county mental hospital, tuberculosis sanitorium, or similar facility, or a prison, jail, or house of correction.

(b) A prescription drug, other than a controlled substance, that is returned to a pharmacy that primarily serves ~~an inpatient health care facility~~ may be dispensed to a patient ~~at the inpatient health care facility other than the patient at that facility to whom the prescription drug was originally dispensed~~ but only if the prescription drug is returned in its original container and a pharmacist determines that the prescription drug has not been adulterated or misbranded.

(END)

LRB–1573/3
MDK:wlj:

2003 BILL

AN ACT *to create* 450.09 (7m) of the statutes; **relating to:** dispensing of returned prescription drugs by state prison pharmacies.

Analysis by the Legislative Reference Bureau

Under current law, the Pharmacy Examining Board (board) has promulgated a rule regarding returning health items, including prescription drugs, to pharmacies. The rule allows for the return of health items to an inpatient health care facility, but only if the health items are in their original containers and the pharmacist determines that the contents are not adulterated or misbranded. The rule does not apply to prescription drugs that are controlled substances because current federal law generally does not authorize the return of controlled substances to a pharmacy. The rule defines "inpatient health care facility" as a hospital, nursing home, county home, county mental hospital, tuberculosis sanitorium, or similar facility. Certain facilities are excluded from the definition, including prison facilities.

Under this bill, prescription drugs, other than controlled substances, may be returned to pharmacies that primarily serve patients confined in state prisons. The bill specifies that a returned prescription drug may be dispensed to any patient confined in any state prison. The returned prescription drug may be dispensed only if it is returned in its original container and a pharmacist determines that it has not been adulterated or misbranded.

BILL

For further information see the ***state*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 450.09 (7m) of the statutes is created to read:

450.09 **(7m)** STATE PRISONS. A prescription drug, ~~other than a controlled substance,~~ that is returned to a pharmacy that primarily serves patients confined in a state prison may be dispensed to any patient in any state prison, but only if the prescription drug is returned in its original container ~~and~~ a pharmacist determines that the prescription drug has not been adulterated or misbranded.

(END)

all of the following are satisfied:
(a) The prescription drug was never in the possession of the patient to whom it was originally prescribed.

INSERT 1A:

it was never in the possession of the patient to whom it was originally prescribed. In addition, the prescription drug must be

INSERT 1B:

The bill does not affect the prohibition under federal law against returning controlled substances.