State of West Virginia
Board of Medicine

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ROBERT C. KNITTLE
EXECUTIVE DIRECTOR

SUMMARY OF COMMENTS REGARDING 11 CSR 5

On July 12, 2016, the West Virginia Board of Medicine filed a Notice of Comment Period on a Proposed Rule, 11 CSR 5. The Notice established a thirty day comment period on the proposed rule, which concluded at 4:30 pm on August 11, 2016. During the comment period, the Board received fifteen written comments from the following individuals and/or entities:

	Commenter	**Date Received**
1	Gerry Stover, WVAFP	July 20, 2016
2	West Virginia Academy of Family Physicians	July 27, 2016
3	Wassim Saikali, M.D.	August 5, 2016
4	U.S. Myint, M.D.	August 5, 2016
5	Mark A. Spitzer, M.D. and Kamila Spitzer, M.D.	August 5, 2016
6	Stephen M. Cohen, MD, MBA, FACS, FASCRS	August 5, 2016
7	Matthew Page Jones, MD	August 6, 2016
8	Eric Bonnem, MD	August 9, 2016
9	Belington Community Medical Services Association, Inc.	August 10, 2016
10	West Virginia State Medical Association	August 10, 2016
11	Karen J. Rudolph, M.D.	August 10, 2016
12	HID Global	August 11, 2016
13	Michael Rezaian, M.D.	August 11, 2016
14	MedExpress Urgent Care, Inc.	August 11, 2016
15	Terrence Reidy, MD, MPH	August 11, 2016

A meeting of the West Virginia Board of Medicine convened at 4:30pm on Monday, August 22, 2016, to consider and review the comments received regarding 11 CSR 5. The Board has carefully considered each of the comments submitted. Based upon deliberations spurred by the many thoughtful comments received, the Board has determined that certain modifications proposed by the commenters, or emanating from such comments, are reasonable and appropriate, and are consistent with the purpose of this rule. The Board has also determined that while well intentioned, other proposed modifications do not adequately protect the public, and are therefore not incorporated as proposed.

Copies of all comments received are attached hereto, and a summary of the comments and the Board's response thereto is provided herein below.

Three commenters submitted comments which support and/or approve of the proposed amendments to 11 CSR 5, and do not identify any proposed modifications.[1] One additional commenter, after seeking clarification regarding the application of the rule to emergency department and ambulatory surgical centers (11 CSR 5 is intended to apply only to office-based practice) expressed approval of the proposed amendments.[2]

Eleven commenters offered either general or specific proposed modifications to the Board's proposed rule. These comments are addressed in detail herein below, and are organized by subject matter rather than commenter.

A. Comment Regarding Use of the Term "Legend Drug"

The proposed rule as promulgated modified the existing definition of the term "legend drug" as follows:

> 2.10. "Legend drug" means a drug that may be prescribed, administered or dispensed under federal or state law only pursuant to the prescription of an authorized prescriber. Legend drugs are commonly referred to as prescription drugs.

One commenter remarked that the term "legend drug" is antiquated and unnecessary.[3] The commenter suggested that the Board replace the term legend drug with "prescription drug," which is a more familiar term for most practitioners.

The Board agrees that the term "legend drug" is an older term and is less recognized by practitioners than "prescription drug." However, the term legend drug continues to be widely used in federal law, particularly in DEA regulations and guidance, and still appears in some Board of Medicine and Board of Pharmacy legislative rules.

In an effort to maximize clarity of this rule while ensuring that the term legend drug remains defined during this transition period, the Board has modified the proposed rule to strike the term "legend drug" from the definition section and replace it with the term "prescription drug." Due to the prevalent use of the term legend drug in federal law, the new definition clarifies that legend drug is interchangeable with the term prescription drug:

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[1] See attached comments from: U.S. Mynt, M.D. (Comment 4); Stephen M. Cohen, MD, MBA, FACS, FASCRS (Comment 6); and HID Global (Comment 12).
[2] See attached comment from Mark A. Spitzer, M.D. and Kamila Spitzer, M.D. (Comment 5).
[3] See attached comment from Gerry Stover, WVAFP (Comment 1).

2.1.12. "Prescription drug" means a drug that may be prescribed, administered or dispensed under federal or state law only pursuant to the prescription of an authorized prescriber. Prescription drugs are also referred to as legend drugs.

Consistent with this definition change, the term "legend drug" is replaced with "prescription drug" *passim*.

B. Comment Regarding Applicability of 11 CSR 5 to Emergency Departments and Ambulatory Surgical Centers

One commenter requested clarification regarding the practice settings to which 11 CSR 5 is applicable.[4] While proposed subsection 3.2 explicitly excludes dispensing or administering medications in an inpatient setting, it was not clear to the commenter whether the rule applied to the practice of administering in emergency departments and/or ambulatory surgical centers. Based upon this comment, the Board reviewed subsection 3.2 as originally promulgated and concluded that additional clarity would be helpful. 11 CSR 5 has always dealt with the regulation of office-based dispensing. The Board has modified subsection 3.2 as follows to clarify that the rule does not apply to emergency departments and ambulatory surgical centers:

3.2. Every practitioner who administers any controlled substance to a patient under his or her care **in an office based setting** within West Virginia shall first register with the Board as a registered controlled substance dispensing practitioner. A separate registration is required for each and every practice location where the practitioner administers controlled substances. This registration requirement does not apply to practitioners who administer controlled substances exclusively to patients who are receiving inpatient health care services **at a hospital or other inpatient health care facility, a hospital-based emergency department, or an ambulatory surgical center.**

C. Registration As A Controlled Substance Dispensing Practitioner

The currently enacted version of 11 CSR 5 requires all dispensing practitioners to register with the Board, regardless of whether or not the practitioner dispenses a controlled substance or a non-controlled substance unless he or she: (1) only administers, and does not dispense, non-controlled substances; (2) only dispenses free professional samples; or (3) only dispenses legend drugs as part of services provided by a free clinic or a state authorized Medicaid, family planning, maternal and child health or early and periodic screening, diagnosis and treatment program. All other office based dispensing and administering activity currently requires a

[4] See attached comment from Mark A. Spitzer, M.D. and Kamila Spitzer, M.D. (Comment 5).

dispensing registration. The Board has found that these carve-outs have caused some confusion over the years. In modernizing this rule, the Board sought to simplify the determination of who must be register with the Board as a dispensing practitioner.

Accordingly, the proposed rule simplifies the criteria by requiring registration by any practitioner who administers or dispenses controlled substances in an office-based practice setting, including free samples of controlled substances. Practitioners who exclusively administer or dispense non-controlled substances would not be required to register, however they do have to comport their practice to the guidelines established in the rule. This change was made to decrease the regulatory burden on practitioners whose dispensing practice is limited to non-controlled substances, while maintaining regulatory safeguards associated with the administering and dispensing of controlled substances.

Specifically, the proposed rule as promulgated establishes:

> 3.1. Every practitioner who dispenses any controlled substance to a patient under his or her care within West Virginia, including free or professional samples of controlled substances, shall first register with the Board as a registered controlled substance dispensing practitioner. A separate registration is required for each and every practice location where the practitioner dispenses controlled substances.

Four commenters have offered comments on the criteria regarding who must register as a registered controlled substance dispensing practitioner.

One commenter, the West Virginia State Medical Association (WVSMA), notes that practitioners are not required to "access the WV Controlled Substance Monitoring Program (CSMP) database for Schedule V medications."[5] Chapter 60A requires all practitioners to be registered to use the CSMP if they prescribe or dispense Schedule II, III or IV drugs. W. Va. Code §60A-9-5a. The WVSMA proposes that the Board modify the language of section 3 "to stipulate that practitioners are only required to register with the Board to access the CSMP if they dispense or administer Schedule II, III, or IV medications."

Similarly, the West Virginia Academy of Family Physicians (WVAFP) proposes that "physicians that are providing and appropriately maintaining Schedule V samples to their patients" be exempt from the proposed changes. In support of its position, the WVAFP opines:

> The practice of providing Schedule V samples is an old practice that has benefited the patients. Schedule V samples provide the physician with starting medication for patients that are newly diagnosed with a chronic disease or as a supplement to those patients that are newly diagnosed with a chronic disease or as a supplement

[5] See attached Comment 10.

to those patients that cannot tolerate generics where the physician is trying to find what will work.

The WVAFP also notes that the dispensing of Schedule V controlled substances is not currently required to be reported to the CSMP. The WVAFP concludes that "exempting schedule V from 11 CSR 5" would result in the CSMP and BOM polices being "more aligned."

A third commenter also proposes that Schedule V controlled substances be "dropped" from the rule "as this will impose undue burden on physicians." This commenter specifically references the controlled substances Ultram and Lyrica in his comment.[6]

Finally, a fourth commenter contends that the proposed rule "unintentionally penalizes those facilities that only administer medication," and proposes that a practitioner who administers Schedule IV and V controlled substances not be required to register.[7] Of note, the currently enacted version of 11 CSR 5 requires physicians who administer controlled substances to be registered with the Board. This requirement has been in place since 1989.

With the exception of the dispensing free professional samples of controlled substances, each of the scenarios raised by these four commenters already requires practitioner registration with this Board under the currently enacted rule. Nothing in the proposed rule prohibits or otherwise restricts a practitioner from dispensing free samples of controlled substances, so long as the practitioner is registered with the Board.

The Board has carefully considered the commenters' suggestion that registration not be required for the dispensing or administration of Schedule V controlled substances (as well as one commenter's suggestion that registration not be required for Schedule IVs), and has concluded that the currently proposed rule is not a significant change from current law, and is reasonably tailored to protect the public interest. Drugs are listed in the schedule of controlled substances because they have a potential for abuse and physical or psychological dependence. While Schedule V controlled substances are classified as having a lower potential for abuse and physical or psychological dependency than Schedules II through IV, the potential for abuse and dependence still exists. In the landscape of the prescription drug abuse epidemic in West Virginia, the Board believes that it is in the public interest for practitioners who dispense or administer controlled substances in an office-based setting to register with the Board as controlled substance dispensing physicians. The Board contends that it is reasonable and appropriate to require practitioners to register with the Board when they administer or dispense any controlled substances, including Schedule IV and V controlled substances (to include samples).

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[6] See attached comment from Wassim Saikali, M.D. (Comment 3).
[7] See attached comment from Belington Community Medical Services Association, Inc. (Comment 9).

However, as a result of these comments, the Board recognizes that some practitioners who will need to register with the Board as controlled substance dispensing physicians may not currently be required to register for access to the West Virginia Controlled Substance Monitoring Program pursuant to W. Va. Code §60A-9-5a. Accordingly, the Board has modified the application requirements for registration as a controlled substance dispensing practitioner as follows:

> 3.3.c. Verification by the applicant that he or she is currently registered to access the West Virginia Controlled Substance Monitoring Program ("WVCSMP"), **if required to be so registered by law,** and that he or she understands his or her obligation to report the dispensing of controlled substances to the WVCSMP; and

D. Prohibition on Dispensing Another Practitioner's Prescription/ Multiple Practitioners in One Office-Based Setting

The currently enacted version of 11 CSR 5 establishes that "dispensing physicians may dispense drugs to their own patients but not fill prescriptions written by other physicians or podiatrists[.]" This dispensing limitation is also incorporated into the proposed rule:

> 5.1. Drug dispensing practitioners may not fill prescriptions written by other practitioners.
>
> 5.2. Drug dispensing practitioners may only administer or dispense legend drugs to a patient under the practitioner's care in the course of his or her professional practice.

One commenter has suggested that "it is unclear whether this provision would prevent a physician from filling prescriptions written by physician assistants."[8] The commenter suggests a revision to section 5.1 "that would permit drug dispensing physicians to fill prescriptions written by a PA under a physician supervision that practices in the same location as the dispensing physician."

Both the current and proposed versions of 11 CSR 5 prohibit a physician from dispensing a prescription written by another practitioner. However, there is nothing in either version which prohibits a supervising physician from prescribing, and ultimately dispensing, a medication to a patient evaluated by a physician assistant who is practicing under the supervision of the prescribing/dispensing physician.

This commenter raises a similar concern regarding the language of subsection 5.5, which states:

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[8] See attached comment from MedExpress Urgent Care, Inc. (Comment 14).

5.5. A drug dispensing practitioner may administer those drugs to a patient under his or her care, which are, in the practitioner's medical judgment, therapeutically beneficial or necessary for the patient's treatment and in keeping with approved use of the medication.

The commenter is concerned that this language would prohibit a physician working in the same location as a physician assistant from administering medication to a patient. The concern raised by the commenter is inconsistent with the intent of this subsection. A prescription is not required for the office-based administration of medication, and there is no prohibition on one or more practitioners having a patient under his or her care during an office visit. A physician assistant may administer medication within the appropriate scope of his or her authorized practice. A supervising physician may also administer medication to a patient initially evaluated and treated by physician assistant so long as the administered medication is, in the practitioner's medical judgment, therapeutically beneficial or necessary for the patient's treatment and in keeping with approved use of the medication.

Based upon its review of these comments, the Board has determined that the limitations on dispensing which are incorporated within the rule are reasonable and appropriate. A dispensing practitioner is not a pharmacist; and may only be authorized to dispense his or her own prescriptions. The Board has made no changes to the proposed amendments based upon these comments.

E. Security of and Access to Controlled Substance Inventory

The proposed rule includes language regarding the security of a practitioner's dispensing inventory, including new requirements for the safekeeping of controlled substances:

6.4. Legend drugs must be stored in a locked or otherwise secure area to prevent access when the drug dispensing practitioner is not present in the office. All registered controlled substance dispensing practitioners shall provide effective, enhanced controls and procedures to guard against theft and diversion of controlled substances. Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. At a minimum, such security controls shall include the storage of all controlled substances in an environmentally controlled, separately locked safe with the access code or key limited to registered controlled substance dispensing practitioners.

One commenter noted that while "well intentioned, this change would add unnecessary complexity to the practice of dispensing practitioners, while doing little to enhance the security of controlled substances."[9] Specifically, the commenter highlighted concerns that this rule

[9] See attached comment from MedExpress Urgent Care, Inc. (Comment 14).

change would prohibit nurses who are working with dispensing physicians from accessing controlled substances, and that the use of actual safes versus locked cabinets for securing controlled substances is impractical. The commenter proposes that the language be modified to require storage of controlled substances in a "separately locked, climate controlled area with only the controlled substance dispensing practitioner(s) and/or their professionally licensed designee having the access code or key."

The Board considered this comment and acknowledges that it is reasonable and appropriate to allow practitioners to maintain controlled substances in environmentally controlled cabinets as well as safes. The goal of security for controlled substances can be achieved, in some cases, without the necessity of a safe. However, the Board further concluded that access to the locked safe or cabinet should be restricted to the dispensing practitioner(s).

> 6.4. Legend drugs must be stored in a locked or otherwise secure area to prevent access when the drug dispensing practitioner is not present in the office. All registered controlled substance dispensing practitioners shall provide effective, enhanced controls and procedures to guard against theft and diversion of controlled substances. Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. At a minimum, such security controls shall include the storage of all controlled substances in an environmentally controlled, **separately locked safe or cabinet** with the access code or key limited to registered controlled substance dispensing practitioners.

F. Typographical Error Identified

One commenter identified a typographical error in subsection 6.11.[10] The internal reference in that section should, as the commenter mentioned, refer to subsection 6.9 rather than subsection 6.8. This typographical error has been corrected in the agency approved filing.

G. Prohibition on Reuse of Surrendered Drugs by Practitioners

Consistent with federal law, section eight of the Board's proposed rule prohibits practitioners from accepting unused or unwanted controlled substances from or on behalf of patients. It also prohibits licensees of this Board from the reuse/re-dispensing of returned non-controlled substances. Specifically, this section provides:

> 8.1. In accord with current federal Drug Enforcement Agency (DEA) regulations, licensees of the Board are prohibited from accepting unused and/or unwanted controlled substances from or on behalf of patients.

[10] See attached comment from MedExpress Urgent Care, Inc. (Comment 14).

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8.9. A practitioner may not dispense, administer or reuse any returned or surrendered drug.

The purpose of this rule is to ensure that practitioners who are licensees of this Board are familiar with the federal prohibition on the return and reuse of controlled substances, and to ensure patient safety by prohibiting practitioners from dispensing potentially misbranded or adulterated medications that have been surrendered to the practitioner as unwanted and unused by another patient as part of the practitioner's office-based dispensing practice.

The Board received five comments regarding this section.[11] Specifically, the commenters objected to the prohibition on reuse of returned or surrendered non-controlled substances as set forth in subsection 8.9. These comments universally reflect a desire to assist patients who cannot afford or otherwise obtain authorization for expensive non-controlled substance medications, and to work within an imperfect system beleaguered by insurance coverage and preauthorization issues and, in certain situations, medication shortages.

One commenter, practicing in the areas of hematology and oncology, suggests that prohibiting the reuse of returned and surrendered medications is not in the best interest of patients and results in unnecessary waste. This commenter suggests that subsection 8.9 be eliminated, and that quality of care issues surrounding the reuse of medications be left to the treating physician to make in the context of specific patient presentations, situations and needs.

A second commenter, a physician practicing internal medicine and geriatrics in West Virginia, opined that "being barred by law from giving an unopened and appropriately labelled package of a medication which has been returned to me by a patient, or family of a deceased patient, for whom the medication is no longer needed with a request to pass it along to another patient who could use it seems unnecessary and ill-advised. Examples would be inhalers, some of which are quite expensive and often not covered by prescription plans." This commenter indicated that such a prohibition may impact oncological, infectious disease and pulmonology practitioners as well.

Another commenter, a practicing rheumatologist, proposes that there be an exemption from the prohibition on reuse for biologics. The commenter notes that "biologic drugs are extremely expensive and out of reach of a small but significant population of rheumatology patients in the state of West Virginia. These drugs are refrigerated, mostly individually wrapped and cost thousands of dollars."

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[11] See attached comments from Matthew Page Jones, MD (Comment 7), Eric Bonnem, M.D. (Comment 8), Karen J. Rudolph, M.D. (Comment 11), Michael Rezaian, M.D. (Comment 13) and Terrance Reidy, M.D., M.P.H (Comment 15).

Two additional commenters, both of whom practice oncology, raised additional concerns, particularly in the context of the reuse of donated cancer drugs. The first of these two commenters provides the landscape of oncology care today, including obstacles to treatment and authorization for treatment by insurance companies and the use of specialty pharmacies for certain cancer drugs. This commenter notes that as the price of oral cancer drugs has skyrocketed, "more and more families donate unused drugs to Oncology practices, Rheumatology practices and infectious disease practices. It has, therefore, become a common practice around the country for physicians to accept donated drugs and provide these to patients in order to fill the two month gap which can occur in care of the patients while working through" the laborious process of authorization and access. This commenter asserts that proposed subsection 8.9 is contrary to how practitioners help patients, and suggests that if safety concerns are at issue, patients receiving donated medications can be asked to sign an informed consent acknowledging that the drug has been returned.

The second of these two commenters indicated that subsection 8.9 would constitute "a serious setback for West Virginia oncology patients whose treatment is often delayed due to government and/or private insurers' delay in approval." This commenter indicates that prior West Virginia law has been interpreted to permit the return and reuse of any medication. The commenter also asserts that all of the states surrounding West Virginia permit some type of surrender and reuse.

The Board spent considerable time reviewing and considering these comments. Currently, there is no state law in West Virginia which expressly authorizes physicians to dispense, administer or otherwise reuse returned or surrendered drugs. Under very limited circumstances, Board of Pharmacy rules permit a pharmacist to accept a returned non-controlled substance for purposes other than destruction. Specifically, the returned drugs must be in a manufacturer's original, sealed and visibly tamperproof container, or in extemporaneously prepared unit does packaging which is returned to the pharmacy by an institution. All such drugs must be identified as to lot and control number and expiration date. W. Va. Code R. §15-1-12.1. Presumably, before redispensing such medications, they are checked by a licensed pharmacist for misbranding and adulteration.

There is a growing trend towards establishing state-based (non-controlled substance) prescription drug donation programs, some of which are specific to cancer drugs. Most of these programs are administered and regulated through either the specific state's Board of Pharmacy and/or the state's Department of Health. Most of state drug donation programs: (1) establish strict criteria for what drugs may be donated; (2) identify whether donations will be accepted from institutions and/or from individuals; (3) identify and require registration of who may accept such donations; (4) require donated drugs to be inspected by a pharmacist for adulteration and misbranding prior to redispensing; (5) enumerate medications which may not be donated (such controlled substances and medications which require refrigeration or a controlled temperature

environment); (6) establish criteria for eligibility to receive donated medications; and (7) provide immunity for participating practitioners.

For example, Maryland's Prescription Drug Repository Program is administered by the Maryland Board of Pharmacy. Code of Maryland §15-609(b)(3). It does not accept donations of compounded drugs, medications that will expire within ninety days of donation, or medications requiring refrigeration because the potency and quality may not be guaranteed. Donor sites, where donations are accepted are prohibited from dispensing donations; the medications are forwarded to the repository where they are inspected by a pharmacist. Recipients of donated drugs must be certified as financial eligible. Participating entities have immunity from liability. In contrast, the Ohio Drug Repository Program permits pharmacies, hospitals and nonprofit clinics to participate. The program, which is administered by the Ohio Board of Pharmacy, is a closed system which does not permit the donation of drugs which have been in the possession of a patient. Ohio Revised Code §3715.87; Ohio Administrative Code §1729-35.

Currently, West Virginia does not have any legislation in effect which authorizes a prescription drug repository or donation program. The Board believes that properly established and regulated prescription drug donation programs can assist in the effective treatment of patients, and would support statutory efforts to create a prescription drug donation program that facilitates the donation of useful, sometimes expensive or scarce, unadulterated medications for use by eligible patients and protects participating practitioners from liability. The creation of such a program, however, is the province of the Legislature, and would require participation and regulation by entities other than the Board of Medicine.

In the absence of a legislatively created prescription drug donation program, the casual reuse of patient donated medications (including medications which require refrigeration) as suggested and described by the commenters is not supported by any existing West Virginia law, and constitutes an unacceptable safety risk to West Virginia patients.

Accordingly, the Board elected to make the following modification to subsection 8.9:

8.9. A practitioner may not dispense, administer or reuse any returned or surrendered drug **unless such dispensing, administering or reuse occurs pursuant to a prescription drug donation program established by this state.**

H. General Comment Unrelated to Specific Provisions

One commenter[12] indicated that he "could not find clarification/exemption for the use of analgesics when doing a procedure or therapeutic joint injection." As written, the proposed rule does not make use-based distinctions. If a drug is administered by a practitioner to a patient, the

[12] See attached comment from Gerry Stover, WVAFP (Comment 1).

practitioner must comply with the rules appropriate to the drug, and must be registered with the Board if the drug is a controlled substance. No changes were made to the proposed rule as a result of this comment.

Knittle, Robert C

From: Gerry Stover <gerry.stover@wvafp.org>
Sent: Wednesday, July 20, 2016 8:04 AM
To: Knittle, Robert C
Cc: Frame, Jamie C; Brian Foy
Subject: Re: Proposed Rule Revision - 11CSR5 - question and feedback

Bob,

Our concern is with those private physicians that have 'samples closets'. Was it discussed how this would impact them? If yes, what are the pros/cons for them that was brought forth?

Is this regulation common language in other states?

Here are some preliminary feedback --

1) I read the proposed legislation looking for relevance to a traditional practice. I could not find clarification/exemption for the use of analgesics when doing a procedure or a therapeutic joint injection. While I sense these are exempt, I think they fit the use of the term "dispensing" or "administering" by the proposed bill's definition.

2) The use of the term "legend" is antiquated and unnecessary. This would be a good chance to stop its use. No physician is going to do a legal search to review the evolution of the word and stopping its use would keep the law current. The law looses nothing by its omission.

Thanks
gerry

From: "Knittle, Robert C" <[redacted]>
To: "Gerry Stover (gerry.stover@wvafp.org)" <gerry.stover@wvafp.org>
Cc: "Frame, Jamie C" <[redacted]>
Sent: Wednesday, July 13, 2016 4:21 PM
Subject: Proposed Rule Revision - 11CSR5

Gerry,
On Monday the Board approved the attached revised rule for drug dispensing, 11CSR5, which was filed with the Secretary of State's office for the 30 day comment period. The Rule is also available on our website to invite public comment. As you may know the previous rule was enacted in 1989 and was thought to be difficult to interpret. We believe the revised rule modernizes and clarifies the requirements for those who are dispensing and administering legend drugs. I'd like to bring this rule to your attention and invite you to make any comments and share any thoughts regarding the revised rule prior to the deadline of August 11, 2016 at 4:30 p.m. As always if you have any questions please feel free to call.
Bob

Comment 1

Robert C. Knittle
Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311
Telephone: 304/558-2921 x 70005

WEST VIRGINIA ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR WEST VIRGINIA

July 27, 2016

Ahmed D. Faheem, MD
President
WV Board of Medicine
101 Dee Drive, Suite 103
Charleston, WV 25311

Dear Dr. Faheem,

On behalf of the over 1,000 members of the West Virginia Academy of Family Physicians, the largest medical specialty society in our state, we are asking for consideration of exempting Schedule V samples from the proposed change to 11 CSR 5. We support the WV Board of Medicine proposed language in 11 CSR 5 as it pertains to Controlled Substances and view these changes as in keeping with the mission of the Board of Medicine to 'protect the public'.

The practice of providing Schedule V samples is an old practice that has benefited the patients. Schedule V samples provide the physician with starting medication for patients that are newly diagnosed with a chronic disease or as a supplement to those patients that can not tolerate generics where the physician is trying to find what will work.

We believe that the regulation should add that Schedule V drugs are exempt.

Thank you,

Adam Breinig, DO
WVAFP President

Comment 2

Knittle, Robert C

From: Wassim Saikali, MD <pulma2@suddenlinkmail.com>
Sent: Friday, August 05, 2016 2:00 PM
To: Knittle, Robert C
Subject: PROPOSED CHANGES

Please consider dropping class v controlled medications as this will impose undue burden on physicians.As you recall ultram was not on this list for over 15 years,and we use it as first choice for pain in arthritis to avoid adding codeine and hydrocodone products.How about Lyrica for Fibromylgia?I appreciate your help and input in this matter.

Regards,

Wassim Saikali MD

Comment 3

Knittle, Robert C

From: BOM Newsletter
Sent: Friday, August 05, 2016 3:37 PM
To: Frame, Jamie C; Knittle, Robert C
Subject: FW: Comment period for proposed changes to 11 CSR 5

From: U Soe Myint [ ]
Sent: Friday, August 05, 2016 12:16 PM
To: BOM Newsletter
Subject: Re: Comment period for proposed changes to 11 CSR 5

The Changes to 11 CS R5 have been reviewed and amended
Best Regard
U S Myint

-----Original Message-----
From: WV Board of Medicine < >
To: MYINTFACRO < >
Sent: Fri, Aug 5, 2016 7:59 am
Subject: Comment period for proposed changes to 11 CSR 5

This is a reminder that the comment period for proposed changes to 11 CSR 5 ends next week. 11 CSR 5 establishes the rules of the Board of Medicine related to the office based dispensing of prescription drugs by licensees of the Board. The rule has not been reviewed or amended since 1989. Proposed changes have been available for review on the Board's website since July 12, 2016. Written comments on the proposed amendments are being accepted through **August 11, 2016 at 4:30 p.m.** and should be submitted to:

Robert Knittle, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311

To view the proposed amendments, please click on the following link:

Comment 4

Knittle, Robert C

From: mark spitzer <markspitzer@mac.com>
Sent: Friday, August 05, 2016 4:33 PM
To: Knittle, Robert C
Subject: Re: Proposed Changes to Controlled Substances

Yes, thank you!
My wife just informed me that the office-based (GYN) surgery she provides anesthesia services for is in VA, not WV, so she should not see any change in practice.

Thank you for the very prompt response.
The new language otherwise appears good; I have no comments to add other than "good work"!

Cordially,

Drs Mark A. and Kamila Spitzer

Sent from my iPhone

On Aug 5, 2016, at 15:57, Knittle, Robert C <Robert.C.Knittle@wv.gov> wrote:

Dr. Spitzer,

Thank you for submitting your questions regarding 11CSR5 - Drug Dispensing Certification. Let me first bring your attention to 11-5-3.2 which states, "This registration requirement does not apply to practitioners who administer controlled substances exclusively to patients who are receiving inpatient health care services at a hospital or other inpatient health care facility at the time when the administration of controlled substances occurs." As such this rule does not apply to hospitals or day surgery centers where general sedation is used. As you practice in a hospital based Emergency Department you may administer and dispense in accordance with hospital policy and do not have to concern yourself with this Rule nor does your wife in her practice of general anesthesia in Surgi-Centers. The rule is specific to outpatient office based practices where it provides oversight and some controls over the administration and dispensing of drugs in general practice.

I hope this helps clarify the purpose of this rule for you.

Robert C. Knittle

-----Original Message-----
From: mark spitzer [mailto:markspitzer@mac.com]
Sent: Friday, August 05, 2016 2:20 PM
To: Knittle, Robert C
Subject: Proposed Changes to Controlled Substances

Greetings.

I am a WV licensed MD (Emergency Medicine) and my wife is a WV licensed MD (Anesthesiology); we have questions to which I cannot find answers in the document.

Comment 5

The document describes rules for Inpatient facilities: how do these changes affect medication (controlled substances) direct administration in free-standing Surgi-Centers as well as Office Based (Anesthesia services for) minor Surgery?

Also, I understand that as a hospital based Emergency Medicine practitioner I do not need to change my practice/registration for the administering of appropriate controlled medications for the patients I treat while in the facility, but I do not understand how this new language allows for the dispensing of single dose of pain control medication. (example: dislocated shoulder reduction using Moderate Sedation at 22:00 with discharge home at 24:00, no local pharmacy available until after 07:00 following morning. How does an Emergency Medicine practitioner provide for the patient's (residual) pain control until a pharmacy can fill a short-course prescription?)

I may have missed these points in the document; if so, I apologize and would appreciate direction to the specific clauses.

Cordially,

Mark A. Spitzer, M.D.

Sent from my iPhone

Knittle, Robert C

From: stephen cohen <stephencohen615@gmail.com>
Sent: Friday, August 05, 2016 4:48 PM
To: Knittle, Robert C
Subject: 11 CSR 5

I approve.
No comments
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Comment 6

Knittle, Robert C

From: Diane Sheehey <1260diane@gmail.com>
Sent: Saturday, August 06, 2016 10:20 AM
To: Knittle, Robert C
Cc: Jones, Matthew P; ebonnem@wvumedicine.org
Subject: Comments on proposed Drug Return, Reuse and Recycling Program

Hello,
The proposed changes prohibit the reuse of returned or surrendered drugs.

This is a serious setback for West Virginia oncology patients whose treatment is often delayed due to government and/or private insurers' delay in approval.

Prior West Virginia law has been interpreted to have allowed "the return and use of any medication." See the National Conference of State Legislatures, "State Prescription Drug Return, Reuse and Recycling Laws" July 1, 2016.

All of West Virginia's neighboring states allow some type of surrender and reuse: Virginia, Maryland, Pennsylvania, Ohio, and Kentucky.

Four of the five most densely populated counties in West Virginia border a neighboring state that allows reuse. One can see how the restrictive proposed policy of the Board of Medicine may influence the choices made by patients in these counties. It may also influence oncology referral patterns.

One can also see how the restrictive policy may affect oncology physicians' choices of where to practice medicine.

Respectfully,

Matthew Page Jones, M.D.
Hematology Oncology, West Virginia University
2000 Foundation Way, Suite 2600
Martinsburg, WV 25401
304.267.1944

On Fri, Aug 5, 2016 at 10:51 AM, WV Board of Medicine <bomnewsletter@wv.gov> wrote:

This is a reminder that the comment period for proposed changes to 11 CSR 5 ends next week. 11 CSR 5 establishes the rules of the Board of Medicine related to the office based dispensing of prescription drugs by licensees of the Board. The rule has not been reviewed or amended since 1989. Proposed changes have been available for review on the Board's website since July 12, 2016. Written comments on the proposed amendments are being accepted through **August 11, 2016** at **4:30 p.m.** and should be submitted to:

Robert Knittle, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311
Robert.C.Knittle@wv.gov

Comment 7

To view the proposed amendments, please click on the following link:

NATIONAL CONFERENCE of STATE LEGISLATURES

STATE PRESCRIPTION DRUG RETURN, REUSE AND RECYCLING LAWS

July 1, 2016

NCSL has identified and tracked state legislation to create prescription drug "recycling," "repository" or "redistribution" programs for unused medication. While details of the laws most allow the return of prescription drugs in single use or sealed packaging from state programs, nursing homes and other medical facilities. The medicines are then redistribute use by needy residents who cannot afford to purchase their prescribed drugs. Some states include provisions for the financial terms of the donations or regulating resale. Virtuall laws include some restrictions designed to assure purity, safety and freshness of the products. Unless otherwise noted, all programs require:

All donated drugs must not be expired and must have a verified future expiration date. [see consumer guidelines]

Controlled substances, defined by the federal Drug Enforcement Administration (DEA) usually be excluded and prohibited.

A state-licensed pharmacist or pharmacy to be part of the verification and distribution process.

Each patient who is to receive a drug must have a valid prescription form in his/her own name.

At least 41 states and Guam have enacted such laws and programs to date. Of these one dozen are currently operational, accepting and dispensing donated medication.. See st tables below for further details and definitions.

2016 SNAPSHOT: Operational State Pharmaceutical Reuse Programs

Arizona Statute 32-1908 - HB 2382 (2006)

California SB 1329

Colorado Colorado Revised Statute 12-42.5-135

Georgia HB430 http://www.[illegible]/20052006/44735.pdf

Iowa House File 724 https://coolice.legis.iowa.gov/legislation/enrolled/hf724.html

Kansas (KSA 65-1668 through 1675) http://www.pharmacy.ks.gov/docs/default-source/default-document-library/ks-pharmacy-laws-and-regs-updated-2014-(pdf).pdf?sfvrsn=0

New Hampshire 318:58 http://nhrsa.org/law/318-58-donating-accepting-and-redispensing-unused-drugs/

Ohio 3281.87 http://codes.ohio.gov/orc/3715.87

Oklahoma §59-367.1. http://tcmsok.org/mc/wp-content/uploads/2012/08/ok_statute_591.pdf

Oregon 689.770 http://www.oregonlaws.org/ors/689.772

Texas SB 1243 https://legiscan.com/TX/bill/SB1243/2015

Wyoming 35-7-1601 http://www.health.wyo.gov/Media.aspx?mediaId=10966

Drugs for Cancer: The enacted program designs in five states, **Colorado, Florida, Kentucky, Minnesota,** and **Nebraska**, focus on accepting and distributing cancer-related prescription drugs. A program is referenced in Michigan but may not be operational. In 2009, the Wisconsin legislature passed SB 455 which deleted specific references to canc drugs from the statutory language of the prescription drug donation program.

Legislative History: 1997-2013 (Enacted laws in bold)

ARCHIVE DISCLAIMER - This table *does not include* all measures enacted into law 2014-present. A planned future update will add more recent material. Also see NCSL's 2015-2016 Prescription Drug Legislation Database for bills considered during 2015-2016.

YEAR	STATES WITH ACTIVITY OR LAWS
1997-98	**Georgia** passed the first known state law permitting reuse within a long-term care facility. In 1998 **Louisiana** began a pilot program without statutory authority.
2000	**Connecticut** enacted the second of the earliest laws
2001	**Oklahoma** and **Montana** authorized long-term-care based programs
2002	**New Jersey** and **Virginia** enacted authorizing language
2003	**Ohio** and **Florida** authorized a program; **Alabama** Department of Health adopted Administrative Code CHAPTER 420-11-1: Procedures for Donation of Ce Prescription Drugs to Charitable Clinics.
2004	**Massachusetts** and **Louisiana** enacted similar laws; **Michigan** permitted the Department of Corrections to redistribute drug products
2005	The following 21 states considered legislation on this topic: **Arkansas, California, Colorado**, Connecticut, Georgia, **Indiana, Iowa, Kentucky, Maine,** Massachusetts, Michigan, Minnesota, **Nebraska, Oklahoma**, Pennsylvania, **Rhode Island, Virginia**, Washington, West Virginia, **Wisconsin** and **Wyoming.**
2006	The following 25 states considered legislation on this topic: Alabama, **Arizona, Florida, Georgia**, Illinois, **Louisiana, Maryland**, Massachusetts, Michigan, Minnesota, **Missouri**, Mississippi, **Nebraska**, Ohio, **Oklahoma**, Pennsylvania, Rhode Island, South Carolina, **Tennessee**, Vermont, Washington, West Virginia and Wisconsin.
2007	

	The following 15 states considered legislation on this topic: Alabama, **Colorado**, Illinois, **Maine**, Massachusetts, Minnesota, Mississippi, New Mexico, New York, **North Dakota**, Oklahoma, Pennsylvania, **Rhode Island**, South Carolina, **Texas** and **Wisconsin.**
2008	**Kansas** added a reuse program, signed into law 3/20/08; **Minnesota** expanded an earlier program; **Pennsylvania** created a cancer reuse repository. Ten other states, including Alaska, Illinois, Massachusetts, Nebraska, New Mexico, New York, Oklahoma, South Carolina and West Virginia considered legislation that was not passed.
2009	**New Mexico** created a reuse program within the Corrections Department; **Virginia** expanded its program to allow both hospitals and clinics to dispense donated drugs Additional laws passed in IA, ID, MT, NE, NV (2), OR, VA (4) and WY
2010	Pennsylvania Senate OKs bill allowing jails to recycle unused medicine (Pittsburgh Tribune-Review). The state Senate this week approved legislation allowing jails to redistribute their unopened prescription medicines. It's a cost-cutting measure that's already being done at the Armstrong County J Rayburn. Read More
2011	Both **Alabama** and **Indiana** passed bills related to unused drugs and each state's Department of Corrections. **New Hampshire** passed legislation to allow manufacture samples to be donated as an 'unused prescription drug' to the preexisting NH program. **New Mexico** passed legislation allowing for a prescription drug donation progra enacting a new section of the New Mexico Drug, Device and Cosmetic Act. This new section provided standards and procedures for accepting, storing, labeling and redistributing donated prescription drugs by clinics
2012	**California** passed and signed SB 1329, which significantly expanded the prescription drug donation and distribution law enacted in 2005.
2013	Colorado updated their program.

Source: NCSL legislative research

Evidence of Effectiveness: It is still too early to know the overall impact these programs have on offsetting the costs of caring for the uninsured in emergency rooms and clinics hopes are high in some states. For example, between 2007 and 2012, **Iowa**'s drug recycling program reports $5,896,000 worth of drugs donated to 26,800 eligible residents. The obstacles: lack of awareness about the programs and added work for repository sites accepting the donations.

EPA 2010 Guidelines for Safe Permanent Disposal

The U.S. Environmental Protection Agency released draft guidelines on September 8, 2010 for the proper disposal of unused pharmaceuticals by hospitals and other health care facilities. The 43-page document describes techniques for reducing or avoiding pharmaceutical waste, practices for identifying and managing types of unused pharmaceuticals, a applicable disposal regulations. EPA is seeking public comment on the draft until Nov. 8 and expects to publish a final draft later this year. *Note that this NCSL report is cited a source for pages A1-A5 of the EPA document.*

Practical Guidelines for Consumers Hoping to Donate Drugs

Most state programs described in this report have substantial restrictions on who can donate, and what types of prescription products may be donated. Very strict safety rules a apply, intended to protect the patient that ultimately obtains and takes the drug. See the state law table below for specific examples or language.
In many states, all donations must meet standards such as:

Only certain, professionally-designated persons can make a donation. For example the Kansas law states, "Health facilities and pharmacies;" Connecticut, Pennsylvania Rhode Island have similar limitations. Other states do allow patients to donate directly, for example, Arizona, Florida and Iowa.

Pills in opened or partly used bottles are never accepted. Generally the packaging must be intact, meeting an exact standard such as the Kentucky law, "Upon inspection the drug must be in its original, unopened, sealed, and tamper-evident unit dose packaging."

Old drugs are never accepted. Expiration dates must be visible, and usually at least six months later than the date of donation. (Many prescription products carry an expi date approximately one year after the original date of the purchase)

Commonly, donated drugs must be delivered to a specific type of medical or pharmacy facility. Some may require the donor to sign a form or waiver.

Usually financial compensation is prohibited. Donations may be tax-deductible if paid for by the individual patient and taxpayer. Beyond donation programs, patients and individuals may not sell any prescription drugs - such transactions are strictly regulated by State Boards of Pharmacy and other state and federal laws.

If your goal as a consumer is simply to protect your local water supply or clean out your medicine cabinet, these programs will not meet your needs.

If you wish to participate, check with a local pharmacy or prescriber for practical advice on what may work in your situation, in your state.

Disclaimer: NCSL provides material about state laws as general information, primarily for policymakers. No information in this report is intended as personal legal or medical ad NCSL is not responsible for any such uses or application of material in this report.

NOTE: This report is being updated and redesigned for summer 2016.

Some descriptions and features may appear out of order or in more than one section. Please revisit this report by August for full information.

ENACTED LEGISLATION COMPARISONS (2016)

As of mid-2016, **forty-two states** have passed laws establishing drug redistribution programs. Many of these programs are not operational or small, but successful prograi growing.

Most state programs have a number of provisions in common:

No controlled medication is allowed to be accepted or transferred

No adultered or misbranded medication is allowed to be accepted or transferred

All pharmaceuticals must be checked by a pharmacist prior to being dispensed

All pharmaceuticals must not be expired at the time of receipt. Often they must have six-months or more before expiration.

All pharmaceuticals must be unopened and in original, sealed, tamper-evident packaging

Liability protection for both donors and recipients usually is assured

Some differences in legislation of different states currently include:

Drugs accepted for re-distribution: Prescription only vs. Over the Counter vs. Drug specific (i.e. only cancer drugs)

Eligible Donors, Recipients and Patients

Protocol for Transfers and Repackaging

Maximum dispensing fees

Centralized / Decentralized

Programs Funded or Unfunded

State Programs - Alphabetical Order

The state table below includes two categories: 39 states with some enacted and/or operational program and 4 additional states with restricted purpose programs or policies. For details of each law, please click the hyperlinked state name or see the state's website. This chart reflects the language enacted into law on the dates indicated; recent enacted la updated as of May 2009. States may have additional regulations or executive agency guidelines that clarify or modify the terms described below.

STATE Bill #; Year	DESCRIPTION; HISTORY
Alabama SB 113 (2011)	**What Rx**: A Prescription drug that has been dispensed and has left the control of the pharmacy if the prescription drug is being returned by a correctic facility **Who can donate**: A corrections facility that has met certain requirements and has a registered professional or licensed practical nurse who is respons for the security, handling and administration of the drugs. **Who Accepts**: Department of Corrections or operated by a company under contract with the department **Program Status**:
Arizona HB 2382 Rep. Groe (2006)	**What Rx**: Accept only in original sealed & tamper-evident unit dose packaging. Rx Board will issue list of un-acceptable products. **Who can donate**: Person, manufacturer or health care institution. **Who accepts**: Pharmacy, hospital, nonprofit clinic that volunteers to participate. **Donated to**: Only state residents who meet eligibility standards set by Board. **Restrictions**: Expiration must be more than 6 months from donation date. Recipient must sign waiver form about the source and non-liability. **Program Status**: Final Regulations promulgated, effective 6/6/08. As of February 2011, the Arizona Pharmacy Board had not published information o Prescription Medication Repository Program on their website.
Arkansas HB 1031 Rep. Mahony (2005)	**What Rx**: Accepts drugs only in their original sealed and tamper-evident packaging. **Who can donate**: Nursing facility by the clinic pharmacy. **Who accepts**: Charitable clinic pharmacies. **Donated to**: Appropriately screened and qualified indigent patients who are not eligible for Medicaid but cannot afford private health insurance. **Restrictions**: The charitable clinic pharmacy cannot accept controlled substances. No product of which the integrity cannot be assured is accepted fc dispensing. **Program Status**: Signed into law by governor as Act 132, 2/15/05. Scheduled effective date: August 2005; Program currently operational.
California SB 1329 (2012) SB 798 (2005) Sen. Simitian	**What Rx**: Drugs that are received and maintained in their unopened, tamper-evident packaging. **Who can donate**: Licensed health facilities, licensed pharmacies, and drug manufacturers that are legally authorized under federal law to manufactur sell pharmaceutical drugs. **Who accepts**: Local ordinances established by counties that elect to create such a repository and distribution program. **Donated to**: Persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. **Restrictions**: Must be ensured that drugs received have not been in the possession of any individual member of the public. **Program Status**: Signed into law by governor as Chapter 444, 9/30/05; Program currently operational; In September 2012 California passed and sign SB 1329, which significantly expanded the prescription drug donation and distribution law enacted by SB 798 in 2005. It authorizes counties to ac adds primary care clinics and pharmacies to those who can participate in the program
Colorado SB 07-231 Sen. Tochtrop (2007)	**What Rx**: Unused cancer drugs or medical devices. **Who can donate**: Cancer patients or the patients' family. **Who accepts**: Health care facilities, medical clinics or pharmacies that elect to participate in the program. **Donated to**: Eligible health care facilities, medical clinics or pharmacies for use under the program as well as eligible patients. **Restrictions**: Cancer drugs or medical devices needs to be prescribed by a practitioner, as defined in section 12-22-102 (27), C.R.S., for use by an el patient and is dispensed by a pharmacist. **Program Status**: The Act took effect 8/8/07; Program currently operational.
Connecticut HB 6002 Rep. Lyons (2000)	**What Rx**: Drug products. **Who can donate**: Long-term care facilities. **Who accepts**: Vendor pharmacy or the Department of Social services for drug repackaging and reimbursement. **Donated to**: Eligible patients. **Restrictions**: Prescription drug products that are not controlled substances, sealed in individually packaged units, returned to the vendor pharmacy w the recommended period of shelf life for the purpose of redispensing such drug products, determined to be of acceptable integrity by a licensed pharm **Program Status**: Signed by governor 6/21/00; Program currently operational.
Delaware	**Who can donate**: State **does not** allow a drug repository/Donation program **Who accepts**: State permits the return and use of medication, in specific cases (Source: NABP, 2014)
Florida SB22A (2003) HB 371 Rep. Harrell (2006)	**What Rx**: Unused cancer drugs or supplies in its original, unopened, sealed and tamper-evident unit dose packaging. **Who can donate**: A person, health care facility, hospital, pharmacy, drug manufacturer, medical device manufacturer or supplier, wholesaler of drugs supplies, or any other entity may donate. **Who accepts**: A physician's office, pharmacy, hospital, hospice, or health care clinic that participates in the program. **Donated to**: Residents, except those Medicaid-eligible or under any other prescription drug program funded in whole or in part by the state are ineligil participate. **Restrictions**: All drugs submitted to the program will be administered by a pharmacist to determine the drugs and supplies are not adulterated or misbranded. Additionally a cancer drug may not be accepted or dispensed under the program if such drug bears an expiration date that is less than si

	months after the date the drug was donated. **Program Status:** Fla. Stat. §409.908. The act took effect July 1, 2006; Program currently Operational.
Georgia HB 430 Rep. Cooper (2006)	**What Rx:** Unused prescription drugs, but not those defined as controlled substances. **Who can donate:** Any person, including a drug manufacturer or any health care facility, may donate prescription drugs to the drug repository program **Who accepts:** Any pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program and meets criteria for participation in program. **Donated to:** Medically indigent persons who are residents of Georgia. **Restrictions:** Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit d packaging is undisturbed. Drugs donated by individuals must have an expiration date that is more than six months from the date the drug is donated. **Program Status:** The state-wide program required by this Code section was to be implemented no later than January 1, 2007.
Guam Chapter 5 (2004)	**What Rx:** Prescription drugs, non-prescription drugs, over the counter drugs, medical supplies, and other items that are identified, dated, and transpo the Medicine Bank in accordance with accepted and required standards established by Guam law, Federal law and/or Federal guidelines to include th United States, Food and Drug Administration. **Who can donate:** Any pharmacy, wholesale prescription drug distributor, pharmaceutical company, institutional facility, or practitioner, as well as, cha religious, or nonprofit organizations. **Who accepts:** Medicine Bank, created at Community Health Centers and various institutional facilities that are government owned and operated. **Donated to:** Eligible individuals in need as defined by the Guam MIP law or the Medicaid Poverty Guidelines. **Restrictions:** No medication which has been previously dispensed by a practitioner to a private citizen will be accepted. Materials received which are prescription medicines such as over-the-counter medicines, home health equipment, medical supplies, and any other items, will also be carefully insp upon receipt. They must be judged fit for use before being distributed or will be properly disposed of in accordance with Guam law. **Program Status:** Signed into law, 2004 as §5103 & 5104.
Hawaii HB 2005 final Rep. Say (2004)	**What Rx:** Prescription drugs previously dispensed or distributed by a pharmacy for administration to patients in an institutional facility by personnel of institutional facility may be returned to the pharmacist. **Who can donate:** Patients or personnel of an institutional facility with unused drugs. **Who accepts:** Institutional facilities or repositories of the state of Hawaii. **Donated to:** Pharmacists. **Restrictions:** The prescription drugs should be returned only to the original dispensing pharmacy. Also, prescription drugs from individual members o public are not accepted for reuse **Program Status:** This act was effective July 1, 2004, and will sunset on July 1, 2010; Law has been **REPEALED**
Idaho ID APPA 27.01.01.262	**Who can donate:** Only pharmacy wholesalers, manufacturers, hospitals, nursing homes. (Source: NABP, 2014) **Who accepts:** Indigent care clinics
Indiana HB 1251 Rep. Becker (2004)	**What Rx:** Unused medications. **Who can donate:** Health facilities with unused drugs. **Who accepts:** Pharmacy or pharmacist who initially dispensed the medication. **Donated to:** Pharmacists, hospitals, health care facilities or practitioners. **Restrictions:** Requires the office of Medicaid policy and planning (office) to review the process of returning unused medication. **Program Status:** Statute Sec. 1 - 6 effective 07/01/04; Program *not* operational as of August 2009.
Indiana HB 1017 (2011)	**What Rx:** Unused medication **Who can donate:** A county jail or a Department of Corrections facility **Who accepts:** The pharmacy which dispensed the medication **Special provisions:** Also allows entity to return unused medical devices or medical supplies that are used for prescription drug therapy. Allows a pharmacist or pharmacy to negotiate a fee for processing returns. Allows the use of an electronic prescription for certain controlled substances. **Program Status:**
Iowa HF 724 Human Resources (2005)	**What Rx:** Prescription drugs and supplies. **Who can donate:** Any person may donate prescription drugs and supplies. **Who accepts:** Medical facilities or pharmacies that elect to participate in the program and meet the requirements established by the department. Don to: Drugs may be donated to individuals or may be distributed to another eligible medical facility or pharmacy for use. **Eligibility:** Iowans at or below 200% of the federal poverty level as well as individuals who are uninsured or under-insured are eligib receive donated drugs. Any organization or individual in the country can donate medications in their original sealed container or in tamper-evident packaging. Any pharmacy or medical facility with authorization to dispense per State of Iowa administrative rules may re-dispense donated medicatior **Restrictions:** Must be inspected to assure the prescription drug or supplies have not been adulterated or misbranded. The drug must be in its original sealed and tamper-evident packaging. **Program Status:** The bill was approved and signed by the governor on May 3, 2005. NABP reports "rules in development establishing a Drug Donati Repository." as of 12/07. Dept. of Public Heath Regulations ARC 5563B (Chapter 109) Effective March 2007; Program is currently Operational and re $5,896,000 worth of drugs donated to 26,800 eligible residents as of 2012. The Iowa Prescription Drug Corporation is a not-for-profit organization that administers programs designed to help ease the financial burden of the hig of prescription medications for uninsured and under-insured Iowans. The corporation contracts with the Iowa Dept. of Public Health to operate the low Prescription Drug Donation Repository Program. Web site: Toll Free: 1-866-282-5817 The Iowa Prescription Drug Donation Repository Program Website [updated Feb. 2014]
Kansas HB 2578 House Appropriations Comm.	**What Rx:** Unused medications; excludes controlled substances. **Who can donate:** Residents of adult care homes and donating entities that volunteer to participate in the program. **Who accepts:** A qualifying center or clinic in consultation with a pharmacist. **Donated to:** Medically indigent residents of Kansas. **Restrictions:** The medications must come from a controlled storage unit of a donating entity and be in its original packaging or tamper-evident packa

	Drugs purchased under Medicaid or SCHIP do not apply. **Program Status:** Signed into law by governor on March 20, 2008. (KS Article 5/5/09); Program currently operational.
Kentucky SB 23 Sen. Denton (2005)	**What Rx:** Cancer prescription "Legend" drugs or supplies needed to administer such drugs. **Who can donate:** Health facilities and pharmacies. **Who accepts:** Donations can be made on the premises of a health facility or pharmacy that elects to participate in the program and meets requiremer specified by the cabinet by an administrative regulation promulgated by the cabinet. **Donated to:** individuals who meet the eligibility criteria specified by an administrative regulation promulgated by the cabinet or eligible health facility o pharmacy for use under the program. **Restrictions:** The legend drug cannot be classified as a controlled substance. Upon inspection, the drug must be in its original, unopened, sealed, ai tamper-evident unit dose packaging. In addition, the legend drug or supplies must be prescribed by a physician, advanced registered nurse practitione physician assistant and dispensed by a pharmacist. **Program Status:** Signed into law by the governor on March 18, 2005; Program not operational as of August 2009.
Louisiana HB 1402 Rep. Walker (2004)	**What Rx:** Prescription drugs. **Who can donate:** Any person, including a drug manufacturer, hospital, health care facility, or governmental entity. **Who accepts:** Charitable pharmacies. **Donated to:** Appropriately screened and qualified patients. **Restrictions:** Drugs must be in their original sealed and tamper-evident packaging. In addition, donor shall execute a form stating the donation of the The pharmacy should retain that form along with other acquisition records. **Program Status:** A pilot program began in 1998 without statutory authority. HB 1402 Signed into law *as Act 811 of 2004;* Program effective August 15, 2004.
Louisiana SB 19 Sen. McPherson (2006)	**What Rx:** Unused portions of or surplus prescription drugs that are within the expiration date. **Who can donate:** A hospital, health care facility, or governmental entity enrolled in the Medicaid program. **Who accepts:** Charitable pharmacies. **Donated to:** Medically indigent residents of Louisiana. **Restrictions:** Drugs must be in their original sealed and tamper-evident packaging. Pharmacists of the charitable pharmacies should determine if the is not adulterated or misbranded and is safe to dispense. **Program Status:** Signed into law by governor as Act 643 of 2006, 6/29/06; Program currently Operational.
Maine HP 105 Rep. Watson (2005) HP 327/ LD 411 Rep. Perry (2007)	**What Rx:** Unused prescription drugs. **Who can donate:** Drug manufacturers, drug wholesale or terminal distributors, hospitals, health clinics, federally qualified health centers, Indian healtl centers and rural health centers and assisted living facilities licensed by the department. **Who accepts:** Pharmacies, hospitals, health clinics and federally qualified health centers, Indian health centers and rural health centers. **Donated to:** Qualified residents of Maine, which include family income below 350% of the federal non-farm income official poverty level and not receiving benefits f Medicaid or Mainecare. **Restrictions:** The program will only accept prescription drugs that are unopened and packaged in tamper-evident unit dose packages or that are unoj injectable, aerosol or topical medications. **Program Status:** Signed into law by governor as Chapter 20, 5/31/05. A 2007 law, Special Act Chapter 27, signed 6/27/07, provided $300,000 funding for the Maine Drug Enforcement Agency to establish a pilot program f return of unused prescription drugs by mail, "consistent with the Main Drug Return Implementation Group established by Public Law chapter 670 of 2C
Maryland SB 1059 Sen. Teitelbaum (2006)	**What Rx:** Prescription drugs or medical supplies. **Who can donate:** Any person. **Who accepts:** Board approved drop-off sites and/or repositories which meets specified criteria. **Donated to:** A needy patient who is a resident of Maryland, as indicated by the individual's health care practitioner. **Restrictions:** The drugs must be in their original unopened and sealed packaging; or packaged in tamper-evident unit dose packaging and unadultera The donor must sign a statement that indicates the donor is the owner of the drugs and are voluntarily offering them to the program. Controlled dange substances may not be donated. **Program Status:** Signed by governor as Chapter 287, 5/2/06. Effective July 1, 2006; Program currently Operational.
Massachusetts Ch. 111, Section 25I (2004)	**What Rx:** Unused medications. **Who can donate:** Residents or consultant pharmacist in a health care facility. **Who accepts:** Health care facilities. **Donated to:** Eligible residents of Massachusetts. **Restrictions:** The donated medication should be sealed in unopened, individually packaged units and within the recommended period of shelf life. Ex are schedule I or II controlled substances as defined in MA chapter ninety-four C. **Program Status:** Signed by governor in 2004; Program currently Operational. **Opinion article:** Massachusetts: "Opportunity to Save Millions Missed" - Rep. Brad Jones newsletter, 12/30/09.
Michigan Public Act 329 of 2004 Rep. Pumford (2004)	**What Rx:** Drug repository program for corrections. A separate cancer program is referenced in Michigan but may not be operational. **Who can donate:** The Michigan Department of Corrections (DOC) is permitted to return and reuse medications. **Restrictions/Analysis: (Archive information)** The DOC estimates that redistributing unused medications would save approximately $800,000 per y but the actual extent of the savings would depend on both the costs of the redispensed medications and the frequency with which they otherwise woul have been discarded. The DOC's estimate, however, did not assume that only unit packaged medications could be reused. This provision likely would diminish potential savings. Link to analysis of HB 6021	Bill summary by House Fiscal Agency, 2004 **Program status:** HB 6021 by was signed as Public Act 329, effective September 23, 2004. The public program may not be operational.
Minnesota Statute 151.55 (2007)	**What Rx:** Cancer drugs or supplies. **Who can donate:** A pharmacy, medical facility, drug manufacturer, or wholesale drug distributor, can donate if the donated drugs have not been prev dispensed. In addition, any individual over the age of 18 may donate.

	Who accepts: Pharmacies or medical facilities on the premises that volunteer to participate in the program. The medical facilities or pharmacies need licensed and in compliance with all applicable federal and state laws and administrative rules. **Donated to:** Any Minnesota resident who is diagnosed with cancer is eligible to receive drugs or supplies. The drugs will be distributed upon a priority **Restrictions:** Drugs must be in its original, unopened, tamper-evident unit dose packaging and not adulterated or misbranded. The donation must als accompanied by a cancer drug repository donor form that is signed by the person making the donation or that person's authorized representative. **Program Status:** Statute effective 2007; Program Operational as of August 2009. SF 2941 expanding terms for a state repository and reuse of unused drugs program. (Passed Senate; passed House; signed into law as Chapter 327 2008, 5/15/08
Mississippi Miss. Code Ann. § 43-13-503 (2004)	**What Rx:** Prescription drugs. **Who can donate:** The State Board of Pharmacy; the State Department of Health; the Division of Medicaid; any person, including a drug manufacturer health care facility or government entity. **Who accepts:** Any pharmacy, hospital, nonprofit clinic or health care professional. **Donated to:** Individuals who meet the eligibility standards or to other government entities and nonprofit private entities to be dispensed to individuals v meet the eligibility standards. **Restrictions:** Only drugs in their original sealed and tamper-evident packaging may be accepted and dispensed. **Program Status:** The drug repository program shall be fully implemented not later than July 1, 2005; Program *not* operational as of August 2009.
Missouri HB 898, SB 1160 Sen. Shields (2004)	**What Rx:** Sealed and unopened prescription drugs. **Who can donate:** Any person or entity may donate prescription drugs. **Who accepts:** Any pharmacy, hospital, or non-profit clinic that elects to participate in the program. **Donated to:** Eligible Missouri residents. **Restrictions:** Prescription drugs must be in their original sealed and tamper-evident unit dose packaging. Prescription drugs donated by individuals sh bear the manufacturer's lot number and an expiration date that is more than six months from the date the prescription drug is donated. **Program Status:** The act was effective 8/28/04; Program currently operational.
Missouri HB 1687 Rep. Mark Wright (2006)	**What Rx:** Prescription drugs. **Who can donate:** Any person, including but not limited to a prescription drug manufacturer or health care facility, may donate prescription drugs to the prescription drug repository program. **Who accepts:** Any pharmacy, hospital, or nonprofit clinic that elects to participate in the prescription drug repository program and meets the criteria fo participation established by rule of the department pursuant to section 196.994. **Donated to:** People who are residents of Missouri and who meet the eligibility requirements of the program, or to other governmental entities and non private entities to be dispensed to persons who meet the eligibility requirements of the program. **Program Status:** Approved by governor 07/12/2006. Appears to be not yet operational as of 4/09.
Montana SB 288 Sen. Christiaens (2001)	**What Rx:** Unused prescription drugs. **Who can donate:** Long-term care facilities. **Who accepts:** Provisional community pharmacies. **Donated to:** Qualified patients for transfer free of charge or at a reduced charge to those individuals. **Restrictions:** Drugs defined as a dangerous drug or a drug designated as a precursor to a controlled substance cannot be accepted. **Program Status:** This act was effective 10/1/01; it was to be fully implemented by 1/1/05; Program currently operational.
Nebraska LB 756 Sen. McDonald (2003) LB 331 (2005) LB 1116 (2006)	**What Rx:** Cancer drugs. **Who can donate:** Any person or entity, including, but not limited to, a cancer drug manufacturer or health care facility. **Who accepts:** Any physician's office, pharmacy, hospital, or health clinic that elects to participate in the program and meets criteria established by the department for such participation. **Donated to:** Eligible Nebraska residents. **Restrictions:** The drug needs to be in its original, unopened, sealed, and tamper-evident unit dose packaging, except that a cancer drug packaged in unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened. **Program Status:** The Act, RRS Neb. 71-2424 et seq., became operative on 9/15/03. In addition, LB 1116 of 2006 clarified the program, including eliminating a restriction on the number of doses that can be donated; allowing donation of injectable cancer drugs and requiring donation forms to include the name of the original patient. (Signed into law 3/13/06)
Nevada SB 327 Sen. Wiener (2003)	**What Rx:** Prescription drugs. **Who can donate:** A public or private mental health facility may return a prescription drug that is dispensed to a patient of the facility, but will not be us that patient. **Who accepts:** A dispensing pharmacy. **Donated to:** The drug will be used to fill other prescriptions for patients in the pharmacy facility. **Restrictions:** The drug cannot be a schedule II drug specified in or pursuant to chapter 453 of NRS. The drug must be dispensed in a unit dose, in individually sealed doses or in a bottle that is sealed by the manufacturer of the drug. **Program Status:** The act becomes effective on July 1, 2003; Program currently operational.
New Hampshire HB 111 (2011) (State law, N.H. RSA §318.58 authorized a reuse program)	**What Rx:** Manufacturer's samples. **Who Can Donate:** Grants the New Hampshire pharmacy board rule making authority regarding other persons and entities allowed to donate to the pr Who can accept: The New Hampshire donation program for unused prescription drugs. **Program Status:**
New Jersey Title 24	**What Rx:** Prescription drugs. **Who can donate:** Unopened, unexpired prescription drugs dispensed to, but not used by, a patient within a licensed health care facility, may be reuse

Assemblyman Conaway (2007)	the facility in accordance with regulations issued by the State Board of Pharmacy. **Restrictions:** Must be unopened and unexpired. **Program Status:** According to the National Association of Boards of Pharmacy, no program was in operation as of August 2009.
New Mexico SN 82 Sen. Beffort (2009)	**What Rx:** Unused medication **Who can donate:** A corrections facility that has a registered or licensed nurse. **Who accepts:** A pharmacy operated by, or under contract with, the Corrections Department . **Restrictions:** Product "has not been altered, defaced or tampered with and include the identity, strength, expiration date and lot number of the presc drug; and the prescription drug was dispensed in a unit-dose package or unit-of-issue package." **Program Status:** Signed into law by governor as Chapter No. 2009-236, 4/7/2009; Program currently operational.
New Mexico SB 37 (2011)	**What Rx:** Unused and donated prescription drugs. **Who can donate:** Clinics. **Who Accepts:** **Program Status:**
New York S 2803-e Sen. Golden (2007)	**What Rx:** Unused medication. **Who can donate:** A resident or consultant pharmacist or his designee in a residential health care facility. **Who accepts:** The pharmacy from which the medication was purchased. **Donated to:** Eligible New York residents. **Restrictions:** The medication must be unopened in the original manufacturer's packaging and must be in tamper evident packaging. Program Status: The new law was referred to the NY Health Department on 1/9/08.
North Carolina Rules, 21 NCAC 46.2513	**Who can donate:** State does allow a drug repository/Donation program **Who accepts:** State permits the return and use of medication (Source: NABP, 2014)
North Dakota HB 1256 Rep. Weisz (2007)	**What Rx:** Legend drugs, devices, or supplies. **Who can donate:** Any person or entity. **Who accepts:** Practitioners or pharmacies that meets the criteria established for participation in the program. **Donated to:** Eligible patients. **Restrictions:** A drug donated, prescribed, or dispensed under the program must be in the original, unopened, sealed, and tamper-evident unit dose packaging, except a drug packaged in single-unit doses may be accepted and dispensed if the outside packaging has been opened and the single-un package is unopened. **Program Status:** Signed into law by governor in April 2007; Program currently operational. Patients may find out if a prescription is available by visiting www.nodakpharmacy.com. A drug donor form can be printed online find participating pharmacies and available drugs, devices and supplies, residents can visit www.freemedsnd.com, sponsored by the North Dakota Board of Pharmacy and the North Dakota Pharmacists Association.[updated 9/09]
Ohio HB 221 Rep. Schuring (2003)	**What Rx:** Prescription drugs. **Who can donate:** Any person, including a drug manufacturer or health care facility. **Who accepts:** Any pharmacy, hospital, or nonprofit clinic that has elected to participate in the program and meets certain eligibility requirements estal in rules adopted by the Board. **Donated to:** Individuals with a prescription issued by a health care professional authorized to prescribe drugs. **Restrictions:** Drugs must be in their original sealed and tamper-evident unit dose packaging. **Program Status:** Signed by governor 1/6/03; Program currently operational.
Oklahoma HB 1297 Rep. Gilbert (2001) SB 1640 Sen. Johnson (2006)	**What Rx:** Unused prescription drugs. **Who can donate:** Drugs may be transferred from residential care homes, nursing facilities, assisted living centers, public intermediate care facilities fc people with mental retardation (ICF/MR) or pharmaceutical manufacturers. **Who accepts:** Any pharmacies operated by a county, pharmacy operated by a city-county health department or a pharmacy under contract with a city county health department, a pharmacy operated by the Department of Mental Health and Substance Abuse Services or a charitable clinic for the purp distributing the unused prescription medications. **Donated to:** Oklahoma residents who are medically indigent. **Restrictions:** Prescription drugs defined as controlled substances will not be accepted. **Program Status:** This act became effective 11/1/06; Program currently operational.
Pennsylvania SB 638 Sen. Wonderling (2008)	**What Rx:** Unused cancer drugs **Who can donate:** health care facility, health clinic, hospital, pharmacy or physician's office. **Who accepts:** Authorized participating pharmacies, designated by the Cancer Drug Repository Program of the State Board of Pharmacy. **Donated to:** Needy residents, as dedfined in "Income eligibility criteria and other standards and procedures for individuals participating in the program determined by the Department of Public Welfare and the Pharmacy Board. **Restrictions:** Unit dose medication must be maintained by a health care facility, health clinic, hospital, pharmacy or physician's office rather than an individual patient, as "part of a closed drug delivery system." Expiration date must be at least six months in the future. A pharmacy "may charge a han fee", to be determined by the Board of Pharmacy. Regulations to be drafted within 90days of effective date. **Program Status:** signed into law by governor as Act No. 14 on 5/13/08; effective date 7/12/08; Program not operational as of August 2009.
Rhode Island HB 5107 Rep. Sullivan (2005) HB 5850 (2007)	**What Rx:** Unused prescription medication. **Who can donate:** Nursing homes, assisted living centers and prescription drug manufacturers. **Who accepts:** Authorized participating pharmacies. **Donated to:** Medically indigent Rhode Island residents. **Restrictions:** The packaging of the medication should not be opened, except cancer drugs packaged in single-unit doses.

	Program Status: The program was scheduled to begin 1/1/06. In 2007 HB 5850 extended the implementation date to 4/1/07 and required notification nursing homes of the new program; Program not operational as of August 2009.
South Carolina	**Who can donate**: State **does not** allow a drug repository/Donation program. (Source: NABP, 2014) **Who accepts**: State permits the return and use of medication, "with pharmacist's professional judgment."
South Dakota HB 1165 Rep. Glenski (2004)	**What Rx:** Unused unit dose drugs. **Who can donate:** Patients in hospice programs, nursing facilities, or assisted living facilities. **Who accepts:** Hospice programs, nursing facilities, or assisted living facilities. **Donated to:** Eligible patients. **Restrictions:** The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the pharmacy in a hermetically sealed single u dose container. **Program Status:** Signed by governor 2/19/04; Program not operational as of August 2009.
Tennessee HB 3560 & SB 3660 Sen. Haynes (2006)	**What Rx:** Unused prescription medications; controlled substances are excluded. **Who can donate:** Nursing homes or hospice services programs. **Who accepts:** Charitable clinic pharmacies. **Donated to:** Tennessee residents who are indigent. **Restrictions:** Drugs only in their original sealed and tamper-evident packaging should be accepted. **Program Status:** The act took effect 7/1/06; Program currently operational.
Texas SB 1896 Sen. Lucio (2007)	**What Rx**: Unused drugs; controlled substances are excluded. **Who can donate**: A pharmacist who practices in or serves as a consultant for a health care facility or a licensed health care professional responsible administration of drugs in a penal institution. **Who accepts**: Pharmacies. **Donated to**: Eligible patients. **Restrictions**: Drugs must be sealed in unopened tamper-evident packaging and either individually packaged or packaged in unit-dose packaging. **Program Status**: Signed into law by governor 6/15/07; Program currently operational.
Utah 58-17b-503 Rep. Last (2005)	**What Rx:** Unused drugs. **Who can donate:** A pharmacist may accept back and redistribute any unused drug, or a part of it, after it has left the premises of the pharmacy. **Who accepts:** n/a **Donated to:** n/a **Restrictions:** The drug must have been prescribed to a patient in a nursing care facility, an ICFMR, or state prison facility, county jail, or state hospita drug must have been stored under the supervision of a licensed health care provider according to manufacturer recommendations; the drug should be unit pack or in the manufacturer's sealed container; the drug should have been returned to the original dispensing pharmacy; the drug should have init dispensed by a licensed pharmacist or licensed pharmacy intern; and back and redistribution of the drug complies with Federal Food and Drug Administration and Drug Enforcement Administration regulations. **Program Status:** This law became effective on July 1, 2005; Program not operational as of August 2009
Vermont H.711 Rep. Canfield (2005)	**What Rx:** Any unsold or unused prescription drugs and medical supplies that the facility or distributor cannot sell or otherwise use. **Who can donate:** Any health care facility and wholesale drug distributor. **Who accepts:** Any participating pharmacy, hospital, or nonprofit clinic. **Donated to:** Vermont residents who meet the eligibility standards. **Restrictions:** Drugs or medical supplies must be in their original sealed and tamper-evident unit dose packaging to be accepted and dispensed, exce drugs packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed. The board of pharmacy s allow donation of only those drugs bearing an expiration date that is less than six months beyond the date the drug is donated and shall allow drugs tc dispensed only when the expiration date is more than one month from the date of dispensing. **Program Status:** 01/24/2006.
Virginia HB 154 (2002) HB 1854 Del. Eisenberg (2005) HB 2682 Del. Eisenberg (2009)	**What Rx**: Prescription drugs. **Who can donate**: Hospitals are authorized to donate drugs that were originally dispensed to hospital patients, but have been returned. **Who accepts**: Pharmacies. May be redispensed by clinics (2005) and hospitals (as of 2009 law) **Donated to**: Indigent patients, without charge. **Restrictions**: The pharmacist-in-charge at the pharmacy shall be responsible for determining the suitability of the product for re-dispensing. A re-disp prescription shall not be assigned an expiration date beyond the expiration date or beyond-use date on the label from the first dispensing and no prod shall be re-dispensed more than one time. No product shall be accepted for re-dispensing by the pharmacist where integrity cannot be assured. **Program Status**: H 154 signed 4/6/02. *HB 1854* Signed by governor as Chapter 68, 3/24/05; Program currently Operational. 2009 HB 2682 signed as Chapter No. 114, 2/5/09. **Statute:** Va. Code Ann. 54-3411.1
West Virginia	**Who can donate**: State **does** allow a drug repository/donation program **Who accepts**: State permits the return and use of medication (Source: NABP, 2014)
Wisconsin SB 56 Sen. Fitzgerald (2003) **Wisconsin** AB 845	**What Rx**: Prescription drugs. **Who can donate**: State prison pharmacies. **Who accepts**: State prison pharmacies. **Donated to**: Any patients in any state prison. **Restrictions**: The prescription drug should never have been in the possession of the patient to whom it was originally prescribed. The prescription dr returned in its original container. A pharmacist determines that the prescription drug has not been adulterated or misbranded. **Program Status**: Approved by governor 8/20/03.

Rep. Underheim (2004) **Wisconsin** AB 197 Rep. Vukmir (2005)	**What Rx**: Cancer drugs or supplies. **Who can donate:** Any person or entity. **Who accepts:** Medical facilities or pharmacies that elects to participate in the program and meets requirements specified by rule by the department. **Donated to**: Individuals who meets eligibility criteria or to another eligible medical facility or pharmacy for use under the program. **Restrictions**: The cancer drug or supplies needed to administer a cancer drug must be in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging must be unopened. **Program Status**: Enacted April 6, 2004. **What Rx**: Expands Wisconsin's Rx recycling cancer drug repository to include prescription drugs and supplie all other chronic diseases such as diabetes. **Program Status**: Signed into law by governor as Act 16, 7/5/05.
Wyoming HB 194 Rep. Hastert (2005)	**What Rx**: Prescription drugs. **Who can donate**: Any person or entity, including but not limited to a drug manufacturer, physician or health care facility. **Who accepts**: Any physician's office, a pharmacy or health care facility that elects to participate in the program and meets criteria established by the department. **Donated to**: Wyoming residents. **Restrictions**: Drugs shall be accepted or dispensed under the drug donation program only if they are in their original, unopened, sealed packaging or outside packaging is opened, the contents are single unit doses that are individually contained in unopened, tamper evident packaging. **Program Status**: Signed by governor as Chapter 158, 3/2/05; Program currently operational.

Restricted Purpose State Programs or Policies

North Carolina	Specific guidelines are being developed for a drug repository/return program. ♦
Oregon	Repository not permitted. Return and reuse is permitted only in long-term-care pharmacies where drugs have remained in the control of facility staff ar packaged in tamper-resistant containers. ♦
South Carolina	Repository/donation not permitted. Return and reuse of medications are allowed with pharmacist's professional judgment. ♦
West Virginia	Return of unit-dosed non-controlled substance drugs allowed. ♦

Notes:

♦ = Facts confirmed or obtained from National Association of Boards of Pharmacy: 2009 Survey of Pharmacy Law.

Definitions:

Controlled Substances: generally a drug or chemical whose manufacture, possession, and use are regulated by a government. It may include illegal drugs and prescription medications.The federal goverment sets the standard for controlled substances; states may modify regulation by, for example, requiring additional restrictions on certain individua products. For complete lists, refer to the Controlled Substances Act and "Schedules I through V" detailed at Sec. 812. Schedules of controlled substances, online a http://www.usdoj.gov/dea/pubs/csa/812.htm#a

Legend Drugs: any drug that requires a prescription. This may be a controlled substance (narcotic) or a non-narcotic drug.

APPENDIX A:

Resources and Media-related Articles

New York Times

http://www.nytimes.com/2016/03/01/health/waste-in-cancer-drugs-costs-3-billion-a-year-a-study-says.html

http://opinionator.blogs.nytimes.com/2015/03/20/recycling-unused-medicines-to-save-money-and-lives/

Wall Street Journal

http://www.wsj.com/articles/match-com-for-unused-medicine-1443798827

National Public Radio

http://www.npr.org/2015/05/22/408680065/poor-residents-benefit-from-oklahoma-countys-medicine-recyclin

http://www.marketplace.org/2014/12/10/health-care/shocking-cost-wasted-prescription-pills

Kansas Press

http://www.reuters.com/article/mn-optum-idUSnBw096380a+100+BSW20150409

Iowa Press

http://www.nbcnews.com/id/23983062/ns/health-health_care/t/recycled-medications-help-battle-rising-costs/#.Vwb5sBIrLBI

http://www.foxnews.com/story/2008/04/06/states-recycling-prescription-drugs-for-poor-uninsured.html

Wyoming Press

http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=3174

http://trib.com/news/opinion/blogs/seavey/wyoming-department-of-health-offers-medication-donation-program/article_20588486-f515-5875-aff5-964d165ae53d.html

http://www.wyomingnews.com/news/donation-program-helps-low-income-people-get-medications-in-wyoming/article_a2901824-064e-59ef-9668-c186367aec59.html

Other States

https://nonprofitquarterly.org/2015/05/26/the-next-recycling-frontier-prescription-drugs/

http://www.highlighthealth.com/healthcare/st-vincent-de-paul-charitable-pharmacy-provides-5m-in-medicatic

http://www.thisweeknews.com/content/stories/clintonville/news/2014/12/26/charitable-pharmacy-seeks-generosity-during-holidays.html

http://www.dispatch.com/content/stories/editorials/2010/01/22/charited.ART_ART_01-22-10_A10_18GC6I2.

http://www.reviewjournal.com/life/health/pharmacies-balk-giving-donated-drugs-patients

NEWS ARCHIVES (2005-2014)

http://theadvocate.com/news/14376514-123/after-150-years-society-of-st-vincent-de-paul-still-fulfilling-mission-tc help-the-poor-in-baton-ro

http://www.nytimes.com/2005/05/18/health/old-pills-finding-new-medicine-cabinets.html

NCSL Article: "Donating Unused Drugs" - State Legislatures Magazine, July/August 2008.

Kansas sets up program to redistribute unused meds, AP news article: May 5, 2009.

Hurdles Facing Unused Prescription Drug Repositories: State-legislated programs for the donation of unused drugs have seen limited succes Scientific American, January 29, 2009.

Massachusetts: "Opportunity to Save Millions Missed" - Rep. Bard Jones newsletter, 12/30/09.

Oregon looks to Oklahoma for Re-use program example, 210/2009

EPA issues guidelines on proper drug disposal (Wednesday, September 8, 2010)

U.S. EPA released draft guidelines today for the proper disposal of unused pharmaceuticals by hospitals and other health care facilities. The 43-page document describes techni for reducing or avoiding pharmaceutical waste, practices for identifying and managing types of unused pharmaceuticals, and applicable disposal regulations.

U.S. EPA released draft guidelines September 8, 2010 for the proper disposal of unused pharmaceuticals by hospitals and other health care facilities. The 43-page document de techniques for reducing or avoiding pharmaceutical waste, practices for identifying and managing types of unused pharmaceuticals, and applicable disposal regulations. EPA is s public comment on the draft until Nov. 8 and expects to publish a final draft later in 2010.

Sewage- and water-treatment plants that are often located just up or downstream from one another are generally not equipped to block or filter trace concentrations of pharmace Scientists fear such concentrations may have long-term effects on people and animals, accounting in part for fish that have both male and female sex organs. "All of this stuff, thi soup of pharmaceuticals, is ending up in our drinking water," said Mae Wu, an attorney for the nonprofit Natural Resources Defense Council. "What is the effect of taking these si doses every day? Who knows?"

EPA has research under way to investigate the health effects. Since 2008, EPA has launched or helped fund six studies to better understand the sources and occurrence of pharmaceuticals in wastewater discharges, human waste disposal and fish tissues. By focusing on health care facilities, the draft document concentrates on a single but prolific s of drug waste.

The report includes recommendations for improving inventories, tightening purchasing and dispensing practices, and arranging for the return, donation or segregation of unused for proper disposal. Except in cases where state or federal hazardous waste laws apply, the report generally recommends sending excess drugs to a reverse distributor or othen segregating nonhazardous, noncontrolled drugs from other waste and sending them to a landfill or incinerator. Click here to read the draft.

Kansas sets up program to redistribute unused meds
AP News: Kansas article, May 5, 2009

KANSAS CITY, Mo. (AP) -- A new effort in Kansas to redirect some types of unused medications to safety net clinics is off to a slow start, but supporters are confident it will even benefit patients and the state.

Under a program approved by the Legislature in 2008, adult care homes, mail service pharmacies and medical care facilities can donate unused prescription drugs to clinics and centers that serve the uninsured and poor.

When the law took effect in January, the state joined at least 37 states with similar laws or programs, according to the National Conference of State Legislatures. The organizatio success of those programs vary widely. A program started in Missouri in 2004 never got off the ground.

The Kansas program got its first donation in April, when Prescription Solutions of Overland Park, a mail-order pharmacy, gave about $250,000 of unused medicines that will even go to 36 clinics in 30 cities.

So far, the focus has been on notifying qualified donors and clinics and organizing the logistics, said Robert Stiles, director of primary care for the Kansas Department of Health a Environment. The state also is trying to arrange clearinghouses where drugs could be stored.

"We are hearing a lot of interest," Stiles said. "It's still early. But it's such a great idea, to use medicines that are usually thrown away. I think it will be popular."

Authors: Richard Cauchi, Program Director; Karmen Hanson, Program Manager; for the NCSL Health Program, Denver. *--Reviewed 6/27/2016--*

Mr. Knittles:

I am responding to the proposed changed to the drug dispensing regulations. I have noted that section 11.5.8 addressing prohibition is use of returned drugs; my comments refer to that section.

Background. In 2003, under the Bush Administration, the Medicare Modernization Act was passed. This act led to a change in the manner in which cancer chemotherapy drugs were reimbursed. It has had several unintended effects:

1. Instead of cost of drug and mark up, practitioners were reimbursed average sales price +6%. Average sales price was determined by a CMS analysis. This had the impact of leading to closure of private oncology practices around the country which could no longer afford the overheads associated with intravenous chemotherapy administration (purchasing, mixing, administration of drug, support staff, etc) and shifted the practice of oncology to hospital based practices. Hospitals are the only institutions able to sustain the overhead costs of cancer care.

2. Second, the law forbid CMS, the largest purchaser of drugs, from negotiating prices with pharmaceutical manufacturers. The impact from this aspect of the law is that here has been a **dramatic increase** in the cost of cancer drugs which has far exceeded the rate of inflation during the time frame since passage of the law. The costs of these **oral drugs** is commonly between $10 and $20,000 a month.

Intravenous chemotherapy drugs are reimbursed by Medicare Part B. **Oral chemotherapy drugs are not reimbursed** unless the patient has Part D; many patients do not have Part D and of those who do have it, many Part D plans require co pays of 10 – 20%.

The highest incidence of cancer occurs in individuals living social security who have a fixed income i.e. over age 65. Since Medicare **does not pay for oral drugs** and many patients rely upon the Part D, supplemental drug policy, if they have such a policy at all. The copays vary from one carrier to the next; a common formula is 20% co pay. Thus, if a drug were to cost $10,000 per month, most patients cannot afford a co pay of 20% or $2000 a month if they live on a fixed income. Therefore, even if a patient were to have Part D insurance, many cannot afford to pay for the drug.

An **"authorization"** by an insurance company does not mean the patient will receive drug. The inability to afford the co pay has led to proliferation of **"foundations"** set up to help with co pay assistance. Many of these foundations require submission of financial records by the patient, in order for the foundation to justify providing assistance. This process can take weeks.

If the foundation were to "approve" the patient for co pay assistance, another hurdle then needs to be addressed i.e. **source of drug**. Many manufacturers have set up **"specialty pharmacies"** to dispense these drugs. Therefore, most patients cannot walk into a local commercial pharmacy (CVS, Rite Aid or Wal Mart) and procure the prescribed cancer drug.

Comment 8

The same impact has been felt in other subspecialties such as Rheumatology, Infectious Disease and soon, in Cardiology. These subspecialties are also using oral dugs which run thousands of dollars per month.

By the time the patient has been put through insurance authorization, co pay foundations, financial records and specialty pharmacies, the **procurement of the drug can be as long as two months or more from prescription written to procurement by the patient.** This process leads to significant delays in starting a prescribed course of care by the practicing physician. While it would be defensible, **delay in treatment** is one of the prime areas for attorneys to attack physicians.

MEDICAL COMMUNITY RESPONSE

Because of the costs and difficulties in procurement of these drugs, the medical community around the country has responded in several ways. First, there has been a proliferation of articles in medical journals and the new term "**financial toxicity**" has been introduced into the literature. Such references can be provided upon request. The problem has also garnered the attention of the Congress.
In February 2016, Congress held public hearings with several pharmaceutical executives demanding an explanation for the high costs of oral cancer chemotherapy drugs.

These above noted articles and Congressional hearings demonstrate that the prolonged process and associated costs have led to:

1. Financial burden occurs in 30 – 40% of such patients
2. Is associated with a worse quality of life, especially in cancer patients
3. Cancer patients are more likely than others to declare bankruptcy
4. Some reports indicate that up to 25% of patients discontinue or do not comply with taking their therapy due to financial hardship
5. One study reported that patients from a single institution avoided (19%) or did not fill at all (24%) their prescriptions due to the costs. From the same study, 17% of patients discontinued taking their drug at all.
6. Two major caner centers (Memorial Sloan Kettering and MD Anderson) have refused to stock some drugs on formulary due to the costs and have made it very public via editorials to the New York Times.

As the public has become aware of this issue, more and more families donate unused drugs to Oncology practices, Rheumatology practices and Infectious disease practices. It has, therefore, become a common

practice around the country for physicians to accept donated drug and provide these to patients in order to fill the two month gap which can occur in care of the patients while working through the process outlined above.

In the current environment of high cost, this proposal by the Board of Medicine is contrary to how practitioners help patients

As outlined previously, many specialty drugs are extremely costly. I have outlined previously the $10 – 15,000 per month cost of some oral cancer drugs. The problem is not restricted to oncology. Infectious disease physicians use Harvoni for hepatitis C at a cost of $30,000 per month. Untreated hepatitis C has major financial burdens to society (attached articles) . A similar issue exists in cardiology with the recently approved drug for cardiac failure (Entresto) which retails for $500 - $1000 per month. The average social security check is $1000 / month. The largest group potentially affected by this proposed change would be the rheumatogists who use drugs for collagen vascular disorders which also run in the tens of thousands.

I echo Dr Jones' statements that this is a common practice in neighboring states and has been ongoing for many years. To prohibit this in WV would have an adverse effect on patient care, forcing some patients to go without treatment or drive many miles to a neighboring state. We are, for instance, currently sending some patients 30 miles to Winchester, Va to obtain oral cancer drugs that were donated. Some have refused to go due to lack of transportation. It could also have the impact of having some physicians not wishing to practice in this state.

I am uncertain as to the motivation for the change by the Board and can only assume that it may be related to issues of safety. If that is the issue, then a compromise solution is to have the patient sign an **informed consent acknowledging that the drug has been returned** and is being given on a temporary basis while they procure their own supply. That procurement of these oral drugs can take months for the reasons outlined above; in the current environment, for example, procurement of Harvoni used to treat Hepatitis may worsen. Two prominent retail pharmacies (Express scripts and CVS Caremark) have announced their intention not to pay for it at all.

The elements of **informed consent are contained within the CFR: 21**. and could easily be applied to this particular circumstance; INFORMED CONSENT could be incorporated into the process of how to handle returned drugs that have-NOT been opened and have NOT expired. Since other states permit to this practice but do not require informed consent, this approach would serve as a model for other states which would permit the practice but put into place procedures that maximize safety and obtain patient consent while working through this lengthy 1 – 3 month process to procure drug which has been prescribed by the practitioner.

Thank you for allowing my input.

Eric Bonnem MD

Hepatitis C Virus (HCV)
Economic burden of HCV Backgrounder

Fast facts:

- Hepatitis C virus (HCV) is a serious global health issue, dubbed a 'viral time bomb'[1] by the World Health Organization (WHO) due to its high prevalence, long term unpredictable disease progression, aging population, low diagnosis and treatment rates.
- HCV is entirely preventable and can be successfully treated using antiviral therapy,[2] but the economic burden of the disease remains high as healthcare costs continue to rise.
- Approximately 150 million people are estimated to be living with HCV, leaving them at risk of developing liver cirrhosis and/or liver cancer.[2]
- The disease has a pro-longed time-course, as individuals develop cirrhosis within 20 years and so the disease burden of HCV is increasing now.[3]
- The economic burden of HCV is high due to the management of its long-term consequences, including cirrhosis, liver cancer and liver transplantation.[3]

Economic Burden in Patients Who Go Untreated or Fail Treatment

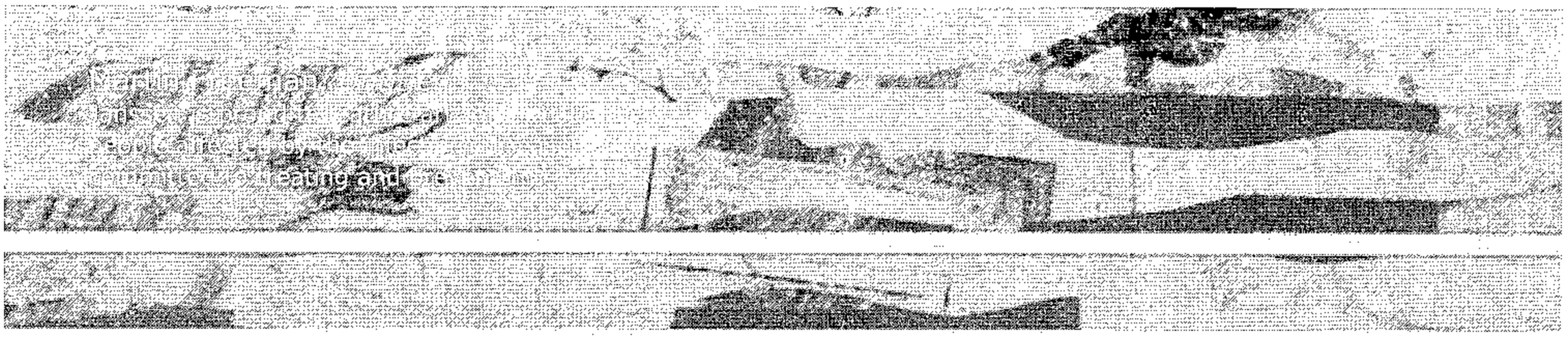
- Due to significant limitations (including complex regimens and the cost of treatment) many diagnosed patients around the world are left untreated or undertreated.[4]
- The previous standard of care for HCV, pegylated interferon and ribavirin, is successful in only approximately 40 to 50% of patients with genotype 1 HCV.[5]
- Those who go untreated or fail treatment are at risk of developing severe liver problems or primary liver cancer, which can require a liver transplant, or other treatments and procedures.[6]

Cost of Receiving Treatment

- Cost analysis, including the cost of complications, shows that the median lifetime cost for treating one patient with dual therapy (pegylated interferon and ribavirin) is between €7,517 and €21,229 depending on the virus genotype.[3]
- Cost effectiveness analyses for treating chronic HCV with triple therapy costs an additional USD 70,100 per quality-adjusted life year (QALY) (mild fibrosis) and USD 36,300 QALY (advanced fibrosis) compared with dual therapy.[3]

Indirect Costs of HCV

- HCV begins to exact a cost before end-stage conditions kick in.[4]
    - A 2010 study drawing on US employment records found that the cost of sick days and lower productivity per HCV infected employee was US$8,352 per year.[4]



- A US survey by the American Gastroenterological Association (AGA) indicated that the cost for outpatient physician services connected to the more than 300,000 outpatient visits for HCV in 1998 amounted to $24 million.[7]

'End-Stage Conditions' Costs

- HCV is the leading cause of liver transplant operations worldwide.[4]
  - Average cost of transplant in US is $139,000 and topped at $400,000.[4]
  - In Europe, there are 30,000 people on the transplant waiting list, but only 12,000 procedures per year.[4]

Clinical and Economic Impact of HCV Continues to Grow

- Despite the fact that HCV infection rates are decreasing, the clinical and economic impact of chronic HCV infection is expected to grow considerably in the next decade as a large population of individuals who acquired the virus in the 1960s through to the 1980s begin to develop health issues associated with the disease.[8]

As these numbers continue to grow, effective HCV treatment and care become more crucial in addressing the financial implications currently associated with the disease.

For more information on HCV, please go to http://www.stop-hepatitis-c.info.

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Oncology Times

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25 July 2016 - Volume 38 - Issue 14 - p 30–31
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News

Solutions to Meet Global Challenge of Rising Cancer Costs

Eastman, Peggy

Free Access

The worldwide costs of cancer care are unsustainable not only for the U.S., but also for other countries; they are projected to mount to $458 billion by the year 2030, according to speakers at a news briefing sponsored by *Health Affairs*. By way of comparison, the global costs of cancer care were estimated at $290 billion in 2010.

cancer costs. cancer...

cancer costs. cancer...

Image Tools

Given the rapid pace of discovery in the development of new cancer therapies and the emphasis on precision

medicine, it is no surprise that policy makers are grappling internationally with ways to deliver high-quality cancer care while keeping a lid on costs, said Egbert Schillings, CEO of the World Innovation Summit for Health (WISH), a project of the Qatar Foundation in Doha.

Indeed, cancer is the "emperor of all metaphors" when it comes to climbing health care costs, said Schillings, who moderated a panel on cancer care at the briefing. For example, data presented at the briefing show that the share of global oncology drug costs allocated specifically to targeted therapies grew from 11 percent in 2003 to 46 percent in 2013. Schillings warned that "these are very sophisticated issues" which must be discussed carefully, since patients are sensitive to anything regarding costs that "smacks of rationing," and have been led to believe that "more is better" when it comes to cancer care.

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Policy Recommendations

The high costs of cancer care create financial toxicity for patients and undermine the effectiveness of care by fostering noncompliance, said Ryan Callahan, a Senior Associate at McKinsey & Company, former Director of Analytics at COTA (Cancer Outcomes Tracking Analysis), and former policy fellow in the Centre for Health Policy at the Institute for Global Health Innovation at Imperial College London.

Callahan co-authored an analysis and commentary on cancer care distributed at the briefing as a special selection from *Health Affairs* and written with Lord Ara Darzi, KBE, HonFREng, FmedSci, holder of the Paul Hamlyn Chair of Surgery at Imperial College London and the Institute of Cancer Research. Darzi is Director of the Institute of Global Health Innovation at Imperial College London, Vice Chair of the UK Government All Party Parliamentary Group on Global Health, and Executive Chair of WISH. In their paper, "Five Policy Levers to Meet the Value Challenge in Cancer Care" (***Health Aff (Millwood) 2015;34:1563-8***), Callahan and Darzi make five specific policy recommendations to meet the challenges of providing high-quality, affordable care globally.

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The five global cancer care policy solutions recommended are as follows:

1. Governments should define common standards for value-based decision-making. The authors cite the standard for "meaningful outcome" of the American Society of Clinical Oncology as an example of an attempt through consensus to define a standard for the adoption of a new drug into clinical practice, which policymakers could and should support. ASCO considered four cancer patient populations in its meaningful outcome improvement standard, and found that the standard translated into a minimum 25 percent improvement in baseline median overall survival using the current standard of care. This approach at setting value-based standards "deserves buy-in from policymakers," the authors stated.

2. Governments should be information brokers. Through cancer registries, many of which are supported by governments, the tracking of patient outcomes has contributed to an increased understanding of the epidemiology of cancer, Callahan and Darzi noted. "Even greater potential exists in systematically tracking the costs and benefits of therapies in a real-world setting." Governments can take action to promote transparency of collected data, as the U.S. Centers for Medicare & Medicaid Services (CMS) did in releasing provider payment data and as the United Kingdom's Systemic Anti-Cancer Therapy Dataset does in allowing comparisons of treatment delivery.

3. Governments can be strategic purchasers. As publicly funded health systems, governments can introduce new models of financing to produce better value-based decision making, thus serving as "the first mover in testing transparency and accountability in purchasing in oncology," according to the authors. CMS is testing new models of care delivery with the Oncology Care Model, for example.

4. Governments can engage their populace in "deliberative democracy" to participate in setting cancer spending priorities. Callahan and Darzi noted that such a process has been used in New Zealand regarding cancer screening policy and in British Columbia on the allocation of cancer treatment resources. In New Zealand, for example, a citizens' jury listened to opposing expert testimony on implementing free mammography screening

for women ages 40-44, and on the basis of what they heard the citizens voted against funding the screening.

5. Governments can serve as community educators. The authors recommend that governments generate knowledge about high-value cancer care through collaborative networks. They cite the online community "**PatientsLikeMe**" as such a knowledge network; this group recently partnered with Genentech to conduct research on the patient experience with cancer therapy. According to the authors, "grassroots participation in transparency and accountability" will be "essential to overcome political barriers to policy change."

Callahan and Darzi found that the burden of cancer care on public finances is a serious concern for policymakers worldwide as more people develop cancer, as standards for high-quality care have risen, and as more patients are surviving and requiring longer-term care. They also found that higher spending on cancer care at the population level may not necessarily translate into a "reliably positive" impact on patient outcomes. In fact, they found that, although international comparisons show significant variations in overall outcomes, these variations do not seem to be explainable by variations in spending. "The effectiveness of high cancer spending in improving survival and reducing mortality remains questionable," explained Callahan and Darzi.

While progress in new cancer care technologies has accelerated, this acceleration has only widened the variations in outcomes—not narrowed inequalities. "Once the latest diagnostic and therapeutic technologies become available to the oncology community, overdiagnosis, overtreatment, and treatment that produces only minimal benefit are widely suspected," Callahan and Darzi wrote. "However, the root of the issue is the fact that clinicians, payers, and policymakers seem not to understand the care being provided well enough to make confident decisions about value."

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Role of Physicians

While policymakers are grappling with cancer care costs on a broad system's level, it is up to the individual physician to help reign in costs by educating patients about what is realistic and appropriate for their care,

emphasized Murray F. Brennan, GNZM, MD, Vice President for International Programs; holder of the Benno C. Schmidt Chair in Clinical Oncology; and Director of the Bobst International Center at Memorial Sloan Kettering Cancer Center, New York, N.Y.

"The cost of U.S. cancer care is absolutely unsustainable," said Brennan, former Director of the American Board of Surgery, former Chairman of the American College of Surgeons Commission on Cancer and former President of the Society of Surgical Oncology, among other surgical leadership positions.

"We've got to stop treating people who won't benefit; we treat for marginal benefit," he stressed, adding that unsustainable expenses cannot be blamed solely on the high cost of cancer drugs. "We do not seek realistic expectations" in patients, Brennan said, noting that nothing is more costly than paying for care that does not change outcomes. "We need to talk about individualized, meaningful outcomes...I tell my fellows, cancer care is about setting expectations."

Brennan emphasized that it is up to the clinician, in an individual relationship with each cancer patient, to accept the responsibility of serving as an educator. This education process should start at the very beginning of a cancer diagnosis; the physician should describe accurately and fully what the patient can expect realistically in terms of benefit from an individual treatment and what will provide no benefit. Through this education process, according to Brennan, it is possible to reduce over diagnosis, over investigation and overtreatment—thus saving the health system money.

Asked by *Oncology Times* what the physician should do if the patient is so terrified of the diagnosis that he or she has difficulty thinking logically, has unrealistic expectations, and wants everything possible done, Brennan said, "What I am saying is that the physician must take the time to educate the patient"—a process that may take a while in the doctor/patient relationship. What the physician should not do is to order tests and prescribe a drug or treatment regimen when there is very little chance these will have any effect on outcome, he concluded.

Peggy Eastman is a contributing writer.

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The Burden of Untreated Hepatitis C Virus Infection: A US Patients' Perspective.....

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HCV+ reported greater work impairment (26% vs 16%), more activity impairment (42% vs 23%)....more emergency room visits, hospitalizations & physician visits, greater direct health costs ($22 mill vs $12 mill: ER visits/hospitalization, physician visits) & indirect costs (($10 mill vs $5 mill: work absenteeism/presenteeism), greater productivity losses: $23,000 per patient year, approximately $10,000 more than for average survey respondent & about $7500 more than for matched controls.....Average incremental cost for each untreated HCV infected patient was approximately $9,000 compared with matched controls. It is important to remember these costs do not include the cost of HCV treatment, or the adverse events associated with it.

Dig Dis Sci (2012)

Antoine C. El Khoury · Jeffrey Vietri · Girish Prajapati
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Authors Conclusions:

Untreated HCV infection is a costly illness, both economically and in terms of quality of life. The economic cost to society of impaired work productivity and increased use of healthcare resources is substantial, and there is a significant impact on both mental and physical health. The results of this study highlight the economic and humanistic burden that HCV can cause to patients and society if left untreated.

Aims - To estimate the impact of untreated HCV infection on work productivity. daily activity, healthcare use, economic costs, and health-related quality of life (HRQoL).

Methods Respondents to the 2010 US National Health and Wellness Survey (n = 75,000) reporting physician diagnosis of HCV infection but not current or previous treatment (patients) were matched to respondents without HCV infection (controls) by use of propensity scores.....Self-reported work impairment, activity impairment, healthcare resource use, and HRQoL were compared between patients and controls.

Indirect and direct costs were estimated.

Results: A total of 306 patients met inclusion criteria. Patients were more impaired at work than controls, with overall work impairment of 26 % versus 15 %, respectively (P<0.001), mostly because of presenteeism in both groups. Annual productivity losses were estimated at $10,316 per employed patient compared with $5,469 per control (P<0.001). Patients used more healthcare, with all-cause healthcare costs estimated at $22,818 per patient annually, compared with $15,362 per control (P\0.001). HRQoL and activity impairment were also worse among patients than controls.

Treatment-naõve HCV infected patients reported significantly impaired work productivity, greater impairment of non-work activity, more healthcare resource utilization, higher estimated costs, and worse health-related quality of life compared with unmatched and propensity-matched subjects without HCV infection. Overall work impairment averaged more than 25 %, well above the 15 % figure for non-HCV controls. The average employed untreated HCV infected patient loses over $10,000 worth of productivity because of ill health, nearly double that lost by either the average patient in the NHWS without HCV or propensity matched controls. Healthcare resource use was also greater, especially for outpatient physician visits, which were nearly 50 % more frequent than for the matched controls.

Direct costs were even larger than the productivity losses, averaging nearly $23,000 per patient per year, approximately $10,000 more than for the average survey respondent, and approximately $7,500 more than for matched controls. Average incremental cost for each untreated HCV infected patient was approximately $9,000 compared with matched controls. It is important to remember these costs do not include the cost of HCV treatment, or the adverse events associated with it.

HCV patients differed in a variety of ways from unmatched non-HCV controls.....

- HCV patients versus non-HCV subjects were older (53 vs. 48 years old, P\0.001),

- more likely to be male (64 vs. 48 %, P\0.001), and

- less likely to be heterosexual (86 vs. 91 %, P\0.01) or to live with a partner (46 vs. 60 %, P<0.001).

- less likely to have graduated from high school (95 vs. 97 %, P\0.05),
- less likely to be employed (40 vs. 55 %, P\0.001), or
- less likely to have health insurance (73 vs. 83 %, P<0.001) than non-HCV subjects in the NHWS, and

- tended to have lower household income.

- They also had poorer health habits, being less likely to be normal weight (23 vs. 31 %, P<0.01) and
- more likely to be obese (37 vs. 33 %, P<0.05),
- smoke cigarettes (44 vs. 19 %, P<0.001), and

- less likely to exercise (57 vs. 65 %, P<0.01).

- They were less likely to drink alcohol (56 vs. 65 %, P<0.001), although more than half reported doing so.

- They also suffered from more non-liver co-morbid health conditions (0.78 vs. 0.37, P<0.01). As expected, they were also much more likely to suffer from cirrhosis (3.9 vs. 0.1 %, P<0.001) or liver cancer (0.7 vs. 0.0 %, P<0.001).

Treatment-naõve HCV infected patients had....

- greater presenteeism,
- overall work impairment, and activity impairment (Table 2), and
- used more healthcare resources (Table 3).
- estimated costs were significantly higher for untreated HCV infected patients than for the unmatched control group.

- lower HRQoL than matched controls on all three SF-12 metrics (Table 5). Differences on MCS (43.72 vs. 48.62, P<0.01) and PCS (40.20 vs. 44.89, P\0.01) were more than four points lower than for those without HCV, suggesting a clinically important difference

- Health utilities were 0.08 point lower (0.65 vs. 0.73, P\0.001), which would also be considered clinically meaningful

HCV1.gif

HCV2.gif

"Consistent with previous studies of chronic HCV infection, we found HCV diagnosis had a significant impact on a range of outcomes. The magnitude of these effects was comparable with those in other studies which relied on different data sources or inclusion criteria. Our analysis of self-reported work productivity found that absenteeism was approximately 80 % higher for untreated HCV infected patients, similar to a recent analysis of the Human Capital Management Services Research Reference Database, although the values for the patients and controls were half of those reported in that study [19]. Absenteeism figures reported here are also similar to those in an analysis of the 2009 NHWS data that did not exclude HCV patients on the basis of treatment status [18]. Our results for presenteeism and overall work impairment show a greater [20] decrement in the HCV group than the 2009 data, however, perhaps because of the inclusion of successfully treated

patients in that analysis. We are not aware of another study estimating the indirect costs of work productivity loss, which were substantial among the employed patients. The impact of HCV on direct costs reported here is consistent with a recent analysis of untreated HCV infected patients in the Ingenix database, which found all-cause medical expenditure to be approximately $19,000 per year in 2007 dollars, not including pharmacy costs [9]. It is, however, higher than another recent analysis, which is, in part, likely to be because of the inclusion of patients achieving SVR in that sample [12]. The HRQoL burden is slightly larger than that reported in previous studies of HCV infected patients which did not exclude currently or previously treated patients [24], suggesting that studies which include treated patients may underestimate the impact of HCV infection. Although these analyses revealed an impact of HCV on a broad range of health outcomes, not every metric was significantly affected. Treatment-naõve HCV infected patients were much more impaired while at work, but did not miss significantly more work than controls. Part of this could be lack of sensitivity of the WPAI, because the recall period is only seven days, and even those who miss a substantial amount of work per year are relatively unlikely to miss work in a given week. A previous study using an employer database revealed a significant, but relatively subtle, impact of HCV on work attendance, and a larger impact on productivity [19]. Likewise, untreated HCV infected patients had more physician visits and use of the ER. The difference in hospitalizations was not statistically significant, although the magnitude of the difference-68 % higher among patients than controls-suggests this null result may be because of small sample size and the resulting lack of statistical power rather than comparable rates of hospital admission."

"The advent of new direct-acting antiviral agents will shorten treatment duration, likely increase the number of people offered treatment, and improve HCV cure rates (final two steps of the HCV treatment cascade) [15], [35]. However, educating providers and the general public about HCV prevention, care, and treatment; ensuring access to providers skilled in the treatment of HCV infection; and addressing the high cost of these agents will be critical to maximizing the benefits of these new therapies [14], [39]. In a recent cost-effectiveness simulation evaluating birth-cohort HCV screening and subsequent treatment of HCV-infected adults, Rein and colleagues [http://www.natap.org/2012/HCV/022212_04.htm] note that birth-cohort screening followed by HCV treatment including direct-acting antiviral agents will increase quality-adjusted life-years (QALYs) by $532,200 and medical costs by $19.0 billion, for an incremental cost-effectiveness ratio of $35,700 per QALY saved (95% credible interval, $28,200 to $47,200) [40]. While these simulations accounted for common HCV-associated complications, funders, public health administrators, and providers should be aware of the financial burden of untreated HCV infection. Using data from the 2010 U.S. National Health and Wellness Survey, El Khoury et al. note that persons with untreated HCV infection had significantly ($p<0.001$) higher annual productivity losses ($10,316 vs. $5,459 per employed person) and annual all-cause healthcare costs ($22,818 vs. $15,362 per person) compared to HCV-uninfected individuals. [41] Evaluating the trade-off between the benefits and costs of these new agents will be critical to scaling up HCV treatment [35].....

Khoury et al.- Table 1 shows that the demographic characteristics of treatment-

naõve HCV patients differed in a variety of ways from unmatched non- HCV controls. HCV patients versus non-HCV subjects were older (53 vs. 48 years old, P\0.001), more likely to be male (64 vs. 48 %, P\0.001), and less likely to be heterosexual (86 vs. 91 %, P\0.01) or to live with a partner (46 vs. 60 %, P<0.001). HCV infected patients were also less likely to have graduated from high school (95 vs. 97 %, P\0.05). to be employed (40 vs. 55 %, P\0.001), or to have health insurance (73 vs. 83 %, P<0.001) than non-HCV subjects in the NHWS, and tended to have lower household income. They also had poorer health habits, being less likely to be normal weight (23 vs. 31 %, P\0.01) and more likely to be obese (37 vs. 33 %, P<0.05), smoke cigarettes (44 vs. 19 %, P<0.001), and less likely to exercise (57 vs. 65 %, P<0.01). They were less likely to drink alcohol (56 vs. 65 %, P<0.001), although more than half reported doing so. They also suffered from more non-liver co-morbid health conditions (0.78 vs. 0.37, P<0.01). As expected, they were also much more likely to suffer from cirrhosis (3.9 vs. 0.1 %, P<0.001) or liver cancer (0.7 vs. 0.0 %, P<0.001).

"The employed HCV group (n = 121) reported an average of 23 % impairment while at work, approximately 10 percentage points greater than employed controls (n = 141; 13 %, P\0.001). Overall work impairment was also greater than that reported by those without HCV infection (26 vs. 15 %, P\0.001), although untreated HCV infected patients did not report missing more hours of work than matched controls (5.0 vs. 2.8 %, P = 0.09). Activity impairment also was higher among untreated HCV infected patients, with 42 % impairment in non-work activity on average, compared with 27 % among matched controls (P\0.001).....

....Greater use of healthcare resources was also reported among treatment-naive HCVinfected patients compared with matched non-HCV subjects (Table 3). Untreated HCV infected patients went to the ER more often (0.76 vs. 0.54 times per year, P\0.05) and made more annual visits to traditional healthcare providers (12.24 vs. 8.22, P\0.001). There was also a trend for untreated HCV infected patients to have more hospitalizations on average (0.42 vs. 0.25), although this did not reach statistical significance (P = 0.07).

.....Estimated costs are presented in Table 4. These were also significantly higher among the untreated HCV infection group than matched controls. For employed treatment-naõve HCV infected patients, productivity impairments were worth $10.316 per patient per year, compared with $5,469 for matched controls (P\0.001). Indirect costs were primarily because of productivity lost to presenteeism in both groups, which was significantly higher among untreated HCV infected patients ($8,209 vs. $4,424, P\0.001). Annual incremental costs were approximately $400, $3,100, and $3,950 dollars more for ER visits, hospitalizations, and physician visits, respectively, for untreated HCV infected patients than for matched controls. Total direct costs were $22.818 for untreated HCV infected patients and $15,362 for matched controls (P\0.001). The direct costs estimated here do not include outpatient pharmacy costs, which can be substantial for HCV infected patients undergoing treatment. The average total costs were nearly $27,000 per untreated HCV infected patient per year, approximately 150 % of the total costs of the matched controls. This is an incremental cost of $9,017 per patient per year....

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BELINGTON COMMUNITY MEDICAL SERVICES ASSOCIATION, INC.

70 N. Sturmer Street, Belington, West Virginia 26250 (304) 823-2800 FAX: (304) 823-2703

August 10, 2016

Robert S. Knittle, M.S.
Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, WV 25311

Reference:
Proposed Legislative Rules on administering/dispensing medication

Dear Mr. Knittle,

We respectfully request that the Board consider a change to the proposed Rule. We believe the proposal unintentionally penalizes those facilities that only administer medication. Our clinic, as many others, does not dispense medications in any form to include professional drug samples. We only administer medication to patients during a routine clinic visit. This would include such injectable medication as allergy immunotherapy, ketorolac for pain, antibiotics and vaccines. We administer oral medication such as diphenhydramine, acetaminophen and ibuprofen. Additionally, we administer, without charge, first dose oral antibiotics for patients who otherwise would have to wait until the end of the day to obtain their prescriptions.

The proposed rule requires any practitioner who administers a controlled substance to be a "registered controlled substance dispensing practitioner". We request the Board consider changing this requirement to those practitioners who administer Schedule II or Schedule II and III controlled substances. Our clinic currently stocks two Schedule IV medications which are diazepam (Valium) and butalbital (Donnatal). The diazepam is in our secure emergency crash cart. The butalbital is administered with Maalox/Xylocaine for severe nausea. Donnatal, though controlled, is actually on the DEAs "Exempted Prescription Products List". As proposed, the rule would require our three physicians and three PAs to register. With due respect to the Board, we believe this is burdensome. Our suggestion, which amounts to permitting administering single doses of Schedule IV and V drugs, would not adversely affect the public or the intent of the overall proposed rule changes.

Thank you for your Consideration

Sincerely Yours,

John Henderson, M.D.
Medical Director

Comment 9

August 10, 2016

Robert Knittle, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311
Robert.C.Knittle@wv.gov

Dear Mr. Knittle:

The WVSMA appreciates the opportunity to comment on the proposed amendment to 11 CSR 5, Dispensing of Legend Drugs by Practitioners.

We recognize that the purpose of the amendment is to update the rule, which has not been reviewed since 1989. We thank you for your effort to clarify the language and to ensure that it corresponds to current law. We are grateful that you have not proposed any additional requirements, other than those mandated by statute. We are particularly grateful that the Board has not proposed an increase to the fees associated with the rule, especially at a time when physicians are facing declining reimbursements, as well as a substantial assessment related to the closure of the Patient Injury Compensation Fund.

One very minor change that we recommend, in order to correlate more precisely with current law, is that practitioners need not access the WV Controlled Substance Monitoring Program (CSMP) database for Schedule V medications. Under §11-5-3 of the proposed rule, practitioners would be required to register with the Board of Medicine to access the CSMP if they dispense or administer "any controlled substance," which by definition in §11-5-2 includes Schedule I, II, III, IV, and V medications. In contrast, WV Code §60A-9 requires the WV Board of Pharmacy to implement the CSMP as a central repository for information regarding Schedule II, III, and IV medications.

In order to be consistent with the WV statute and the corresponding Board of Pharmacy rule, we respectfully request that you modify the proposed rule to stipulate that practitioners are only required to register with the Board to access the CSMP if they dispense or administer Schedule II, III, or IV medications.

Again, thank you for modernizing and clarifying the requirements of the rule.

Sincerely,

PF Taylor MD

Paula F. Taylor, RPh, MD,
President

Brian O. Foy,
Executive Director

Comment 10

4307 MacCorkle Avenue, SE, Charleston, West Virginia 25304
Phone: 304-925-0342 Toll Free: 800-257-4747 Fax: 304-925-0345

Knittle, Robert C

From: Rudolph, Karen <KRudolph@wvumedicine.org>
Sent: Wednesday, August 10, 2016 2:07 PM
To: Knittle, Robert C
Subject: Rule 11CSR5

Dear Mr. Knittle:

I am a physician practicing Internal Medicine and Geriatrics in Berkeley County, WV. I am writing to protest the inclusion of section 8.9 "A practitioner may not dispense, administer, or reuse any returned or surrendered drug" in proposed Rule 11CSR5.

I can certainly appreciate the need for safeguards and record keeping. However, being barred by law from giving an unopened and appropriately labelled package of a medication which has been returned to me by a patient, or family of deceased patient, for whom the medication is no longer needed with a request to pass it along to another patient who could use it seems unnecessary and ill-advised. Examples would be inhalers, some of which are quite expensive and often not covered by prescription plans. I am hearing from my oncology, infectious disease, and pulmonology colleagues that this is also a concern for their practices. The impact of this restriction on our free clinics must also be considered.

I would hope that the WV Board of Medicine would strike section 8.9 from the proposed rule, and focus on more appropriate ways to protect patient safety.

Sincerely yours,

Karen J. Rudolph, M.D.

University Internal Medicine
1002 Sushruta Dr.
Martinsburg, WV 25401

Comment 11

HID

August 11, 2016

Robert Knittle, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311

Dear Mr. Knittle:

HID Global, a worldwide leader in secure identity solutions, supports the proposed rules change that would require the Board of Medicine to develop rules to control the dispensing of controlled substances.

Controlled substances account for nearly 12 percent of those prescribed each year. Statistics show that every day, 44 people die as a result of prescription opioid overdose. Deaths from prescription drug overdose continue to sky-rocket, creating a public health epidemic which requires increased focus on the need for compliance and safety. As policymakers, doctors and pharmacists struggle to mitigate this growing epidemic, they are enlisting the help of health IT professionals to use existing technology for better control of dispensing controlled substances.

As an example, requiring prescribers to use two-factor authentication would improve security standards and auditing activity. Such technology helps to address the problem of forged or stolen prescriptions. This would also help to reduce the number of prescription errors and paper prescription forgeries. Additionally, technology would help both providers and pharmacies to integrate and manage prescriptions into other records. Ultimately, this leads to increased efficiency while also reducing overall costs.

We commend the Board of Medicine for its thoughtful approach to address this growing public health concern. Thank you for your time and attention. Please contact me at 512.998.3154 if you would like more information.

Sincerely,

Wendy Reilly
Manager, Government Affairs, HID Global

CC: Kathleen Carroll, Vice President,
Government Affairs, HID Global

Comment 12

Knittle, Robert C

From: Roacsinc <roacsinc@gmail.com>
Sent: Wednesday, August 10, 2016 9:40 PM
To: Knittle, Robert C
Subject: RE: 11 CSR 5

Dear Mr. Knittle,

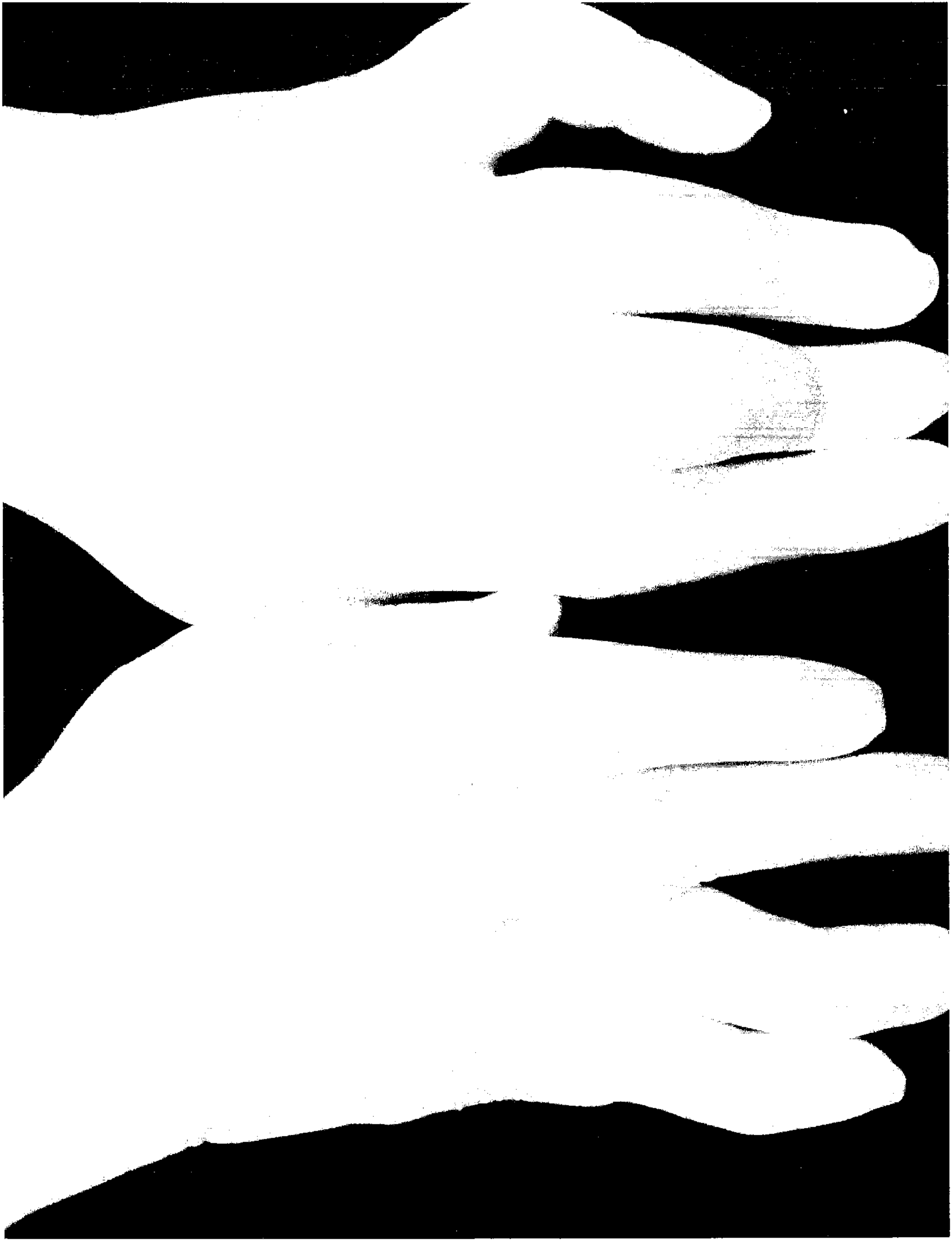
My name is Michael Rezaian and I am a rheumatologist in Martinsburg, WV.

The proposed amendments included in 11 CSR 5 specifically "8.9. A practitioner may not dispense, administer or reuse any returned or surrendered drug." should have an exception for biologic drugs.

Biologic drugs are extremely expensive and out of reach of small but significant population of rheumatology patients in the state of West Virginia. These drugs are refrigerated, mostly individually wrapped and cost thousands of dollars.

To simply discarding these drugs will be a tragedy. These drugs have saved thousands of people from becoming disabled. With the use of these drugs we have moved from here:

Comment 13



to here:

Please make sure that an exception for biologic drugs is placed in the final bill.

We certainly have enough headaches with insurance companies becoming more difficult every year and drug companies keep raising their prices monthly.

Sincerely,

Michael M. Rezaian, MD

Rural Outreach Arthritis Center

Consultant in Adult and Children with Arthritis and Rheumatic diseases

Board Certified in Rheumatology and Clinical Immunology

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August 11, 2016

Robert C. Knittle
Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, WV 25311

Re: Comments Regarding Proposed Amendments to Dispensing of Legend Drugs by Practitioners Rule 11 C.S.R. 5

Dear Mr. Knittle:

MedExpress Urgent Care, Inc. – West Virginia ("MedExpress") submits the following comments regarding the Proposed Amendments to Dispensing of Legend Drugs by Practitioners Rules, 11 C.S.R. 5. MedExpress is a physician-owned practice and operates urgent care centers throughout West Virginia. In order to fulfill its dedication to providing extraordinary care to patients at an affordable rate, MedExpress utilizes Advanced Practitioners, such as Nurse Practitioners and Physician Assistants that are closely supervised by MedExpress physicians.

The proposed changes to the Board of Medicine's Rules for Dispensing of Legend Drugs by Practitioners raise a number of issues that MedExpress appreciates the opportunity to address and/or seek clarification.

- **Section 11-5-5.1**. The proposed language of 11-5-5.1 states, "Drug dispensing practitioners may not fill prescriptions written by other practitioners." Given that the proposed definition of "practitioner" would include both physicians and physician assistants, it is unclear whether this provision would prevent a physician from filling prescriptions written by physician assistants. Given the increased cost associated with only permitting physician assistants to dispense prescriptions they write and to increase the efficiency and promptness of the services provided to patients, MedExpress would suggest a revision to 11-5-5.1 that would permit drug dispensing physicians to fill prescriptions written by a PA under a physician supervision that practices in the same location as the dispensing physician.

Comment 14

- **Section 11-5-5.5**. The proposed language of 11-5-5.5 states, "A drug dispensing practitioner may administer those drugs to a patient ***under his or her care***, which are, in the practitioner's medical judgment, therapeutically beneficial or necessary for the patient's treatment and in keeping with approved use of the medication." MedExpress's concerns articulated above regarding the increased cost of preventing physicians from administering drugs under the care of PAs practicing at the same location as the dispensing practitioner and the impact on the patient apply to this proposed language as well.

  As you know, West Virginia law and Board regulations provide that a physician assistant shall perform only under the supervision and control of a supervising physician. Thus, when a patient is evaluated by a physician assistant, that patient is, by law, "under the care" of a physician. *See* W. Va. § 30-3-16(a)(5) (defining "supervising physician" as a doctor "permanently and fully licensed in this state without restriction or limitation who assume[s] legal and supervisory responsibility for the work or training of any physician assistant under his or her supervision"); *see also* West Virginia Code of State Rules § 11-1B-2.1(i) (defining "supervision" as "the opportunity or ability of the physician to provide or exercise control and direction over the services of physician assistants.").

  Accordingly, MedExpress proposes that this subsection be amended to reflect that a patient is considered under a physician's care when the patient is evaluated and a prescription prescribed by a PA practicing at the same location as a dispensing physician.

- **Section 11-5-6**. The language of proposed section 11-5-6 provides that legend drugs must be stored in a "secure area" to prevent access when the dispensing practitioner is not present in the office." This mirrors the current regulatory requirement on securing legend drugs, which similarly prevents access "when the dispensing physician is not present in the office." W. Va. 11 C.S.R. § 5.4.6.

  However, the proposed section 11-5-6 also includes language mandating controlled substances to be stored in an "environmentally controlled, locked safe" with only the controlled substance dispensing practitioner having the access code or key. Undoubtedly well intentioned, this change would add unnecessary complexity to the practice of dispensing practitioners, while doing little to enhance the security of controlled substances.

  Currently, in addition to dispensing practitioners, nurses under the supervision and control of a physician may have access to the controlled substances in order to permit them to assist the dispensing practitioner in

fulfilling their duties more efficiently. The proposed section would benefit from a modification that would continue to permit lawfully licensed nurses designated by the dispensing practitioner to retain access to controlled substances.

In addition, the use of the term "safe" is unclear, at least insofar as it would exclude the use of other secure cabinets that would not be included within the common definition of a "safe." Currently, many dispensing practitioners store controlled substances in secure and locked cabinets that would not be considered "safes." Presumably, the Board did not intend this proposed language to prohibit the use of such secure cabinets in favor of actual fireproof safe cabinets.

In practice, such a requirement would be impractical. A safe large enough to store these medications would be so heavy that it would have to be placed on the floor and would likely be visible to patients and visitors alike. A more feasible – and secure – approach would be modify the proposed language to require medications to be stored in a "separately locked, climate controlled area with only the controlled substance dispensing practitioner(s) and/or their professionally licensed designee having the access code or key."

- **Section 11-5-6.11**. The proposed language of 11-5-6.11 states that the packaging on a container for controlled substances must include all of the information required in "subsection 6.8." Subsection 6.8 only indicates that labels for dispensed medications must be legible. This reference appears to be a typographical error and the Board intended to reference the detailed list of required information set forth in subsection 6.9.

Again, MedExpress appreciates the opportunity to provide comments on the Proposed Rule. If you have any questions or require additional information, please feel free to contact me at 304-346-7000.

Sincerely,

Carte P. Goodwin

cc: Frank W. Alderman, M.D., CEO (Via E-Mail)

Augustr 11, 2019

Dear Robert Knittle,

Thank you for the alert regarding the proposed rule change 11CSR5.

I agree that revising the 1989 Rule is due and many of the revisions are valuable but I have 3 major disagreements:

- The Board should not prohibit physicians from redistributing unused medication from one patient to another
- The process for developing this rule should be much more open and involve the governed entities (practitioners and their patients) much earlier. (You know by the people and for the people)
- The rules which have the force of law inhibit innovation and continue a stagnant enforcement approach rather than moving towards a process of improving the quality of medical care.

§11-5-8. Returned or Surrendered Drugs; Authorization and Procedures for Destruction; Prohibition on Reuse

8.9. A practitioner may not dispense, administer or reuse any returned or surrendered drug.

This hidden item is a great surprise. It seems that this prohibition of a long accepted practice has come out of nowhere. My concerns regarding this prohibition apply only to medicines that are not controlled medicines.

For the first time introduces a restritction of a common patient care I strongly disagree with the major insertion of rules regarding a method for a physician to provide patient care. This criminalizes a common-sense charitable act involving patients and their personal physician. A caring professional, expert receives unused medications from a patient or family member who no longer need them and wish to make them available to another person in need.

What are these medicines and why are they given to doctors?

Patients who no longer need these medicines often have unused syringes or unopened bottles that they give to the doctor rather than throw away. These are then available to be used in special situations. Delay of a few days treatment can lead to progression of disease (as in the case of an untreated venous thrombosis resulting in a pulmonary embolism)

Comment 15

Specialty medicines are now exorbitant with prices of $10,000 per month. Though eventually many of these medicines can be obtained through insurance with prior approval this takes time and then when the patient find out their copay is $2,000 they are in tears and give up. There are Prescription Assistance Schemes for most of these medicines (worth a whole separate investigative journalism expose) but it usually takes a few weeks to get this worked out.

Unfortunately patients need to stop medications due to side-effects or die and there are unused extremely expensive medications that patients or surviving family members do not want to waste. These patients/families are well aware of the difficulty obtaining the medications and the fear and frustration they previously experienced waiting for these medicines to be approved and arrive.

Anticoagulants are now effective as oral medicines that work almost immediately and prevent hospitalization. Though insurance may cover the insurance usually needs to prior approve which often takes more than 24 hours. Patients do not fill medicines which cost $400 out of pocket even if strongly recommended by doctor.

They trust their physician to properly distribute the medication to appropriate patients and volunteer these medications. I am not aware of physicians soliciting patients to provide these medicines for other patients. It is great to have the medicines on hand so that treatment can be started immediately when it has been determined that a patient could benefit from the medicine.

Is redistribution of medicines a problem?

Some regulators not involved in actual patient care as a physician this may seem to address a dangerous medical practice. Though one can imagine multiple ways that this could result in a less than perfect outcome I am not aware of an epidemic of poor practices resulting in harm to the patients in this State.

This act of providing medical care is similar to most aspects of patient care that involve a complex consideration of individual patient physical and psychological problems, consideration of whether a therapy will benefit the patient, the patient's ability to tolerate a proposed therapy, , and social aspects (including timely availability and affordability).

Prior to instituting such a rule the Board should establish that there is actually a real public health care problem. Such evidence should be openly reviewed and discussed and other means to control dangerous practices should be attempted before rules are instituted. If guidelines rather than rules are developed the affected

Looking at a problem from a narrow point of view can be harmful. Providing the best care for an individual patient involves consideration of multiple considerations The main concern that I have heard supporting the need to prohibit redistribution of surrendered medications is the chain of custody "How do we know if drug is still safe?" Indeed the simplest way to not have to deal with this concern is to prohibit physician involvement in redistributing unused medications. While this will free those who worry about this imperfect chain of custody issue it does not help to deliver care for the patient.

Many medications are expensive (several hundred dollars a month) and not covered by a patients insurance (if they have one) or require prior approval and such approval can take days to obtain. Certain medications need to be started immediately and a few day wait for an insurer to approve payment to a pharmacy is too long. Other mediations, even if approved by the insurer cost thousands of dollars a month (cancer and rheumatology drugs are commonly now in the range of $10,000 a month) and the 20% patient co-pay is not affordable by the patient. Though Prescription Assistance Foundations exist these are fraught with difficulties for the patient and prescriber and if assistance is granted it can take weeks to obtain this assistance

Having small supplies of donated unused medications has helped many patient obtain necessary medicines before the other systems of care (pharmacies, insurance companies, assistance programs, etc.) can act. To remove this small item removes yet another strand from the Safety Net that we try to provide for our patients.

Protection of the public requires more than enacting regulations and inspecting. What can seem to a regulator to perfectly address a concern raises multiple other problems.

This will lead to further waste. The State and private companies and individuals are State already paid for medicine, drug company made money, what is the motivation to prevent use of the surrendered medicines. In few other areas do we require that purchased items be discarded.

What happens if physicians cannot give unused medicines to patients

By removing the physician as an honest broker for this transaction will NOT eliminate the concern regarding distribution of unused medicines. . The physician has no monetary gain and the donating patient has no monetary gain. To close this option invites patients to turn to other means of distributing unused medications worth thousands of dollars on the Black Market. This occurs worldwide and leads to criminal activity, theft, counterfeiting, etc. The internet and different lists on the internet have enhanced the ability for buyers and sellers Protect confidentiality

If the patient /families cannot give these medications to the doctor other options could be for the doctor to act as a broker introducing patient with pills to others who need them. Another scenario is for people to sell these $5400 or 10,000 packages on the internet for a drastic discount. This encourages such unregulated distribution system with all the problems known with expensive items from Rolex watches to AIDS and intravenous cancer medications including distribution of counterfeit medications. Such concerns are not a problem when patients are donating the drugs to their persona l physician. There are some patients from whom the physician may decide not to redistribute the medications (just as we might chose not to eat some home prepared food that certain patients might bring us).

My trust in the Board of Medicine has been diminished by the introduction of this significant rule change in the middle of the Summer with announcement to physicians coming only the week before comments are due.

This is a major change that has not been discussed by the medical community or the patients we care for. Since it may be another 27 years until the Board of Medicine looks at this law there is no need for the Board to add this extensive new addition to the rules.

I recommend the comment period be lengthened and input from Oncology, Hematology, Rheumatology and Infectious Disease specialists be sought.

Terrence Reidy, MD, MPH
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Bunker Hill, WV 25413