MARYLAND
TASK FORCE ON THE ESTABLISHMENT OF A PRESCRIPTION DRUG REPOSITORY PROGRAM

FINAL REPORT
TO THE GENERAL ASSEMBLY

July 1, 2006

MARYLAND TASK FORCE ON THE ESTABLISHMENT OF A PRESCRIPTION DRUG REPOSITORY PROGRAM

FINAL REPORT

TABLE OF CONTENTS

WORKGROUP PARTICIPANTS

American Cancer Society
Arnold L. Amass, Pharm. D.

Pharmacy Representative
Lynette R. Bradley-Baker, R.Ph., Ph.D.

Nursing Home Representative
Elizabeth R. Bowerman

Community Health Center
Howard C. Cohen

House of Delegates
Delegate Donald B. Elliott
Delegate David D. Rudolph

Maryland Board of Pharmacy
Donald W. Taylor, Chairman of the Task Force and Board of Pharmacy Member

Pharmaceutical Industry
Philip D. Noguchi, M.D.

Office of Health Care Quality
William Vaughan

University of Maryland, School of Pharmacy
Francis Palumbo, Esquire, Ph.D.

Maryland Medical Assistance Program
Frank Tetkoski

Board of Pharmacy Staff
LaVerne G. Naesea, Executive Director
Anna D. Jeffers, Acting Legislative and Regulations Manager

EXECUTIVE SUMMARY

This is the final of three reports promised to the Maryland General Assembly on the establishment of a prescription drug repository program in Maryland. The First Interim Report was submitted for January 1, 2006 in accordance with Senate Bill 441 (SB 441), passed during the 2005 legislative session. That report discussed the types of programs that have been legislated or established in 21 other states. It also provided reference information specific to the experiences of those programs. The First Interim Report is incorporated into this Final Report and is attached as Appendix I.

The Second Interim Report was submitted February 28, 2006. That report discussed the feasibility of establishing a prescription drug repository in Maryland and provided specific recommendations regarding the areas outlined in SB 441. After exploring several approaches to establishing a prescription drug repository program, the Task Force unanimously agreed that it is feasible to implement a program in Maryland. The Task Force, however, recommended that safeguards must first be in place to ensure patient safety, protect against liability, ensure proper collection, storage, and dispensing of previously dispensed medications, and to ensure that the program is not exploited or misused.

The Second Interim Report also addressed each of the eleven (11) issues in order of mention in SB 441. Two issues, the types of drug that may be donated to the program and the types of drugs that may not be donated to the program, were discussed jointly in the first section. A total of 16 recommendations are made under the 10 specific issues raised in SB 441. Eight additional recommendations are provided under the catch-all category entitled other matters. That section recommends approaches regarding such issues as: costs for operating a central repository, destruction of drugs, feasibility of tax credits, the program sunset, etc. Each set of recommendations was followed by discussions of points that led to the recommendations. The Second Interim Report is incorporated into this Final Report and is attached as Appendix II.

With the passage and signing of SB 1059 Prescription Drug Repository Program, 2006, Chapter 287, this Final Report will provide an overview of the proposed regulations, based on the rationale discussed in the Second Interim Report.

INTRODUCTION

SB 441 – Task Force on the Establishment of a Prescription Drug Repository Program was passed to study and make recommendations regarding the establishment of a Prescription Drug Repository Program in Maryland. The Maryland Board of Pharmacy (the "Board) staffed the Task Force for the Department of Health and Mental Hygiene (the "Department"). The Task Force submitted a First Interim Report, for January 1, 2006 to comply with SB 441.

The Task Force submitted a Second Interim Report on February 28, 2006 that included recommendations that could be considered for use in related proposals for legislation during the 2006 Legislative Session. The Second Interim Report was used as a basis for HB 1689 and SB 1059, Prescription Drug Repository Program. Both bills passed and SB 1059 was signed into law on May 6, 2006 as Chapter 287.

The Task Force continued to work through June 2006 to develop recommendations for regulations that may be used to support implementation of a Prescription Drug Repository Program in Maryland.

FINAL RECOMMENDATIONS

The Task Force met several times during and after the 2006 Legislative Session to draft regulations for promulgation by the Maryland Board of Pharmacy. The proposed regulations were based on the recommendations set forth in the First and Second Interim Reports. The Maryland Board of Pharmacy will review the recommendations and begin the promulgation process for the proposed regulations in July 2006.

SUMMARY OF RECOMMENDED REGULATIONS

The intent of the regulations recommended by the Task Force was to set forth the structure of the Drug Repository Program and add details as required by SB 1059, Prescription Drug Repository Program. Significant regulatory recommendations are discussed below.

Eligible and Ineligible Drugs

The Task Force proposed that any drugs shall be accepted at designated drop-off sites, but only those drugs donated in their original unopened and sealed packaging would be eligible for re-dispensing. The types of drugs determined ineligible addressed concerns related to potency, quality and the threat to public health. In general, the types of drugs recommended as ineligible for redispensing are those drugs that:

- Bear an expiration date that is less than 90 days from the date the drug is donated;
- Have been adulterated, according to the standards of Health-General Article, § 21-216, Annotated Code of Maryland;

- Are designated as controlled dangerous substances by the U.S. Drug Enforcement Administration, which has determined that controlled dangerous substances may not be donated under a repository program;
- Require refrigeration; or
- Have been previously compounded because compounded prescription drugs require specific handling or specific ingredients that may not be applicable to the new patient**.**

Designated Drop-Off Sites and Donation Procedures

Designated drop-off sites may be a pharmacy or other health care facility that is in good standing with their respective licensing board. Once a donor or a donor's representative makes the decision to donate prescription drugs or medical supplies, they may only donate at designated volunteer drop-off sites. At the drop-off site, the donor will complete a donor form and then donate the prescription drugs or medical supplies.

A pharmacist or other health care practitioner at the drop-off site will place the donated items in a sealed bag with the signed donor form, labeled with a control number and placed in a secure box designated for donated prescription drugs or medical supplies. The drop-off site will then forward the sealed bags of donated prescription drugs or medical supplies to a repository at least every two weeks. The drop-off site may not dispense donated prescription drugs or devices, resell them, or charge a fee for the donations.

Designated Repositories and Repository Acceptance, Storing and Dispensing Procedures

The repository must be a pharmacy that is in good standing with the Maryland Board of Pharmacy. The repository will accept and dispense the donated prescription drugs or medical supplies. The repository will designate a pharmacist to accept and inspect the donated prescription drugs and medical supplies. If the donated prescription drugs are ineligible drugs, then the repository will dispose of them. The designated pharmacist will also obliterate patient specific information from the prescription labels of donated prescription drugs or medical supplies. Repositories may not resell donated prescription drugs or medical supplies or establish or maintain a waiting list. A repository may charge a fee of not more than $10 per dispensed prescription.

The standards and procedures for safely storing donated prescription drugs or medical supplies shall be in accordance with State and federal laws and regulations, except that donated prescription drugs or medical supplies must be stored in a secure location separate from other inventory. The standards and procedures for dispensing, shipping and disposing of donated prescription drugs or medical supplies will also be the same standards and procedures currently set for in State and federal laws and regulations.

Patient Eligibility for Donated Drugs

Patient eligibility will be determined by the patient's health care practitioner with prescribing authority based on the financial need of the patient. Recipients must be residents of Maryland. Recipients will be required to sign a Board approved recipient form before receiving the prescription drug or medical supply to confirm that the recipient understands the prescription drugs or medical supplies have been donated and that entities involved in the program are immune from liability.

Accountability, Recordkeeping, and State Review

The drop-off sites shall forward the completed donor form and donated drugs to a designated repository in sealed individual bags. Drop-off sites will be reviewed by the Division of Drug Control or the Office of Health Care Quality inspection agents during routine inspections.

Repositories shall maintain separate inventories for donated prescription drugs or medical supplies; store donated items in a secure location; maintain separate prescription files for patients receiving donated prescription drugs or medical supplies; and submit annual reports on its activities to the Maryland Board of Pharmacy. Finally, record keeping requirements consistent with the standard prescription record keeping requirements will be in place for both the drop-off sites and the repositories. All related documents will be reviewed during routine inspections.

CONCLUSION

The primary goal of the Task Force, as requested by the legislature, was to find a way to eliminate the waste of unused medications and assist appropriate individuals in obtaining the medications they desperately need. It is the hope of the Task Force that the passage of SB 1059 Prescription Drug Repository Program, 2006, Chapter 287 and the promulgation of the subsequent regulations will accomplish that goal.

The implementation of this program, however, is not without obstacles. The only potential repository that has been identified is Medbank of Maryland, Inc. (Medbank). Although willing to apply to be a designated repository, Medbank has not secured adequate funding as of the date of this Final Report. Private funding of Medbank, or another interested pharmacy, unfortunately, will determine the success of this program. Drop-off sites, as well, will need a funding source or mechanism for delivering donated prescription drugs or medical supplies to the designated repositories. There are "pony" systems available, but not for all potential drop-off site locations. Various non-profit organizations have expressed interest in privately funding aspects of the program. It will be crucial that an adequate funding source steps up to the plate.

The implementation of a Prescription Drug Repository Program is a national trend and Maryland can be proud that it is among the states that have tackled this issue. Maryland's Prescription Drug Repository Program, however, is not a panacea for connecting unused prescription medications with needy patients. Unfortunately, the majority of unused

prescription medications are not eligible for donation into this program. If a bottle of medication has been opened, no matter how expensive or medically valuable to those in need, it is ineligible for the program.

The Task Force recommendations for Maryland's Prescription Drug Repository Program introduce both a concept and a method for allowing the donation of unused prescription drugs or medical supplies to less fortunate individuals. The establishment of this program illustrates a continued commitment by Maryland to improve healthcare access for all Marylanders.

ACKNOWLEDGEMENTS

The Task Force has successfully fulfilled its mandate to explore and craft a prescription drug repository program for Maryland. This achievement would not have been possible without the support of all of it members. The Task Force would like to take this opportunity to thank the legislature for its vision in pursing a prescription drug repository program in Maryland; in particular Senator Leonard H. Teitelbaum, Delegate David D. Rudolph and Delegate Donald B. Elliott who provided encouragement and demonstrated patience with the Task Force as it worked to craft a program that met the legislative intent.

The Task Force is also especially grateful to Medbank of Maryland, Inc. who shared their perspectives, expertise and thoughts during its deliberations.

The work of the Task Force encompassed hours of meetings, extensive research, review of three reports, review of proposed legislation, testimony at the bill hearings, and the drafting of proposed regulations under the leadership of Board Member and Designated Task Force Chair, Donald Taylor. Mr. Taylor's knowledge base and thoughtful guidance greatly facilitated the Task Force's ability to meet legislative mandates and deadlines.

Finally, the hard work and support provided by Anna Jeffers, who staffed the Prescription Drug Repository Task Force is acknowledged. She is commended for her tireless research, note taking and coordination of activities undertaken during the Task Force work.

APPENDIX I

MARYLAND
TASK FORCE ON THE ESTABLISHMENT OF A PRESCRIPTION DRUG REPOSITORY PROGRAM

FIRST INTERIM REPORT TO THE GENERAL ASSEMBLY

January 1, 2006

MARYLAND TASK FORCE ON THE ESTABLISHMENT OF A PRESCRIPTION DRUG REPOSITORY PROGRAM

FIRST INTERIM REPORT

TABLE OF CONTENTS

INTRODUCTION

SB 441 – Task Force on the Establishment of a Prescription Drug Repository Program was passed to study and make recommendations regarding the establishment of a Prescription Drug Repository Program in Maryland. With the increasing costs of medications in Maryland and the current disposal of unused expensive medications, the legislature has convened this Task Force in the hopes of determining an appropriate method to dispense unused medications to those who could benefit the most.

Pursuant to SB 441 the Task Force will consist of various stakeholders in healthcare, both from State Government and private industry. These stakeholders include two members of the Senate of Maryland, two members of the House of Delegates, the Secretary of the Department of Health and Mental Hygiene or the Secretary's designee, the Executive Director of the State Board of Pharmacy, or the Executive Director's designee, and the Executive Director of the Maryland Health Insurance Plan, or the Executive Director's designee. The Task Force will also include a representative from the American Cancer Society, a hospital, a nursing home, a community health center, a pharmacy and the Medbank Program. The Maryland Board of Pharmacy will staff and coordinate the Task Force.

GOALS OF THE TASK FORCE

The Task Force has been charged to study and make recommendations regarding the establishment of a Prescription Drug Repository Program. Those recommendations shall include:

- Types of drugs that may be donated to the Program;
- Types of drugs that may not be donated to the Program;
- Who may donate drugs to the Program;
- Entities that may receive drugs for distribution;
- Standards and procedures for accepting, storing, and dispensing donated drugs;
- Eligibility requirements for individuals wishing to receive
- Donated drugs;
- Standards and procedures for inspecting donated drugs;
- Appropriate entity to operate the Program;
- Liability issues;
- Fees; and
- Any other matter relating to the establishment of a Prescription Drug Repository Program.

The Task Force was requested to report its findings and recommendations to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly, on or before January 1, 2006. The Task Force shall continue to exist for a period of 1 year until June 30, 2006. The Task Force only met once on December 15,

2006 because most members were appointed in late fall 2005. During the interim, the Maryland Board of Pharmacy performed background research on 21 different states to determine how they have addressed this issue, and posted relevant citations and links to those states' activities on its web site.

During the initial meeting, the Task Force considered the feasibility of accelerating its work in order to complete recommendations for key components of a program that could be considered for use in any related proposals for legislation during the 2006 Legislative Session. The Task Force agreed to meet January 10th, 24th, and February 7th and 14th and proposes to provide a Second Interim Report to the legislature early during the 2006 Legislative Session. The Task Force's focus during the four meetings will be to develop recommendations regarding the following five (5) questions:

- Is it feasible to implement a Prescription Drug Repository Program in Maryland;
- Which entity would run the Program;
- Which entities would be eligible to receive donated drugs;
- What type of drugs would be accepted; and
- What type of fees would be imposed?

It was further determined at the initial meeting that most of the other areas outlined in SB 441 could be addressed by regulations. The Task Force will also review cost/revenue considerations, including possible co-pays. The Task Force will continue to meet between March and June 2006 to address issues and provide recommendations regarding requirements that may be addressed by regulations prepared by the administering agency.

REVIEW OF OTHER STATES' ACTIVITIES

The concept of a drug repository is a relatively new one. Thus, many states are still exploring through legislation how best to implement such a program. The following is an overview of activities undertaken in those states who have passed legislation for prescription drug repository programs.

Entities that Regulate and Operate Programs

States have been quite creative in designating which entities will regulate and operate programs. For example, California authorizes a county to establish a repository and distribution program. Colorado designated the Department of Public Health and Connecticut and Kentucky designated the State Departments of Social Services. Still, Kansas and Indiana appointed the Board of Pharmacy to regulate their programs. One state, Michigan, designated pharmacies operated by the Department of Correction or a county jail to accept donated prescription drugs. Regarding operations in other states, health care facilities, medical clinics, hospitals, wholesale distributor and/or pharmacies seem to be the primary entities allowed to operate programs.

Standards and Procedures

Some states charge a minimum-handling fee to the recipient of a donated drug. Louisiana requires the name and prescription number be obliterated on the original prescription label to comply with HIPAA regulations. A few states issue identification cards to individuals eligible to receive donated drugs.

Eligibility Requirements

Most states have limited eligibility to persons in need of financial assistance, the uninsured and the underinsured. For example, one state determines eligibility by a certain percentage of the federal poverty level. Also, some states limit eligibility to special illness populations (such as cancer patients).

Types of Drugs Donated to Programs

All prescription drugs are acceptable in most programs, under certain conditions. However, a few states limit drugs donated to those drugs used to treat specific illnesses or to a predetermined list. Also, some states do not allow the acceptance of donated controlled dangerous substances. Almost all states require that the donated drugs be sealed in the originally packaged units with qualifiers regarding the expiration dates. Drug that are sensitive to light or heat are not acceptable in some states. Some states also require a repository donor form accompany the donation.

Who May Donate

A patient or a patient's family, drug manufacturers, nursing homes, long-term care facilities, and health care facilities are examples of the types of donors that are acceptable by the states' programs. In Nebraska, any person or entity may donate cancer drugs.

INTERIM RECOMMENDATION

The approach that the Task Force will take in developing its recommendations will include outside research by Task Force members, invited speakers with expertise in this area, and an in-depth review of similar programs in other states. Based on the limited time that the Task Force has had to deliberate on the important issue of a Prescription Drug Repository Program in Maryland, the following recommendations are offered:

1. Provide a Second Interim Report on February 28, 2006 that includes recommendations that could be considered for use in related proposals for legislation during the 2006 Legislative Session; and

2. Continue work through June 2006 and submit a Final Report on July 1, 2006 that provides recommendations for regulations that may be used to support implementation of a Prescription Drug Repository Program in Maryland.

APPENDIX A

Prescription Drug Repository
Task Force Directory

Member	Organization in Statute
Arnold L. Amass, Pharm.D. American Cancer Society 41 Fitzhugh Avenue Westminster, MD 21157 (Work) 410-848-3326 (Fax) 410-876-8434 Arnoldams@adelphia.net	American Cancer Society
Lynette R. Bradley-Baker, P.Ph. Manager CVS/pharmacy Severn, MD 21144-6810 (Work) 301-572-2814 (E-Fax) (401) 652-1396 Voicemail: 1-866-222-9438 ext 18776 lbbaker@cvs.com	Pharmacy Representative
Elizabeth R. Bowerman, CEO Keswick Multi-Care Center 700 West 40th Street Baltimore, MD 21211 (Work) 410-235-8860 Bowermanl@Keswick-multicare.org	Nursing Home Representative
Howard C. Cohen, COO People's Community Health Centers 2204 Maryland Avenue Baltimore, MD 21218 (Work) 410-467-6040 x20 (Cell) 410-382-0101 (Fax) 410-735-5897 hcohen@peopleschc.org	Community Health Center
Delegate Donald Elliott Maryland House of Delegates Annapolis, MD 21041 Donald.Elliott.house.state.md.us	House of Delegates

Member	**Organization in Statute**
Delegate David Rudolph Maryland House of Delegates Annapolis, MD 21041 David.Rudolph@house.state.md.us Phone: 301 858-3424 Fax: 410 841-3242	House of Delegates
Donald Taylor Maryland Board of Pharmacy 30410 W. Rustic Drive Salisbury, MD 21804 (Work) 410-543-0446 dtaylor@shore.intercom.net	State Board of Pharmacy
Philip D. Noguchi, M.D. Director Regulatory Affairs Amgen's Global Government Affairs 555-13th Street, N.W. Washington, DC 20005 (Work) 202-585-9628 pnoguchi@amgen.com	Pharmaceutical Industry
William Vaughan Chief Nurse Office of Health Care Quality Spring Grove Center Bland Bryant Building 55 Wade Avenue Catonsville, MD 21228 (Work) 410-402-8140 (Cell) 410-440-1503 wvaughan@dhmh.state.md.us	Office of Health Care Quality

Member	**Organization in Statute**
Francis Palumbo, Esquire, Ph.D. Executive Director University School of Pharmacy 515 W. Lombard Street 2nd Floor Baltimore, MD 21201 (Work) 410-706-2303 (Fax) 410-706-5394 fpalumbo@rx.umaryland.edu	University School of Pharmacy
Frank Tetkoski Maryland Pharmacy Assistance Program 201 W. Preston Street Room 409 Baltimore, MD 21201 (Work) 410-767-1460 or 410-767-1455 (Fax) 410-333-5398 tetkoskif@dhmh.state.md.us	Maryland Medical Assistance Program

APPENDIX B

UNOFFICIAL COPY OF SENATE BILL 441
J1 (5lr1518)
ENROLLED BILL
-- *Finance/Health and Government Operations* --
Introduced by **Senators Teitelbaum, Astle, Della, Dyson, Exum, Gladden, Haines, Hollinger, Hooper, Kelley, Lawlah, Middleton, Pipkin, and Ruben**
Read and Examined by Proofreaders:
_____
Proofreader.
_____
Proofreader.
Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____M.
_____
President.
CHAPTER_____
AN ACT concerning
Task Force on the Establishment of a Prescription Drug Repository Program
FOR the purpose ~~of requiring Medbank of Maryland, Inc., in collaboration with the State Board of Pharmacy, to establish a Prescription Drug Repository Program to accept and dispense prescription drugs donated for the purpose of dispensing to certain individuals; providing that the Program may only accept and dispense drugs in certain unit dose packaging; providing for a certain exception; prohibiting the Program from accepting or dispensing drugs that bear a certain expiration date or may be adulterated; authorizing any person to donate prescription drugs to the Program; specifying that drugs may only be donated to certain entities that participate in the Program; requiring an entity that seeks to participate in the Program to apply to Medbank of Maryland, Inc. in the form and manner required; specifying the persons who can receive drugs donated through the Program; requiring a drug donated through the Program to be~~

13 of this Act; and generally relating to a Task Force on the Establishment of a
14 Prescription Drug Repository Program.
~~15 BY adding to~~
~~16 Article - Health - General~~
~~17 Section 15-124.3~~
~~18 Annotated Code of Maryland~~
~~19 (2000 Replacement Volume and 2004 Supplement)~~
20 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
21 MARYLAND, That ~~the Laws of Maryland read as follows:~~
~~22 **Article - Health - General**~~
~~23 15-124.3.~~
~~24 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS~~
~~25 INDICATED.~~
~~26 (2) "HEALTH CARE FACILITY" MEANS:~~
~~27 (I) A HOSPITAL;~~
~~28 (II) A HOSPICE CARE PROGRAM;~~
~~29 (III) A NURSING HOME;~~
~~30 (IV) A HOME HEALTH AGENCY;~~
~~31 (V) AN INTERMEDIATE CARE FACILITY FOR THE MENTALLY~~
~~32 RETARDED;~~
~~33 (VI) A FACILITY THAT PROVIDES TREATMENT OR OTHER SERVICES~~
~~34 FOR INDIVIDUALS WHO HAVE MENTAL DISORDERS; OR~~
~~35 (VII) AN ASSISTED LIVING PROGRAM.~~

~~(3) "HEALTH CARE PRACTITIONER" MEANS AN INDIVIDUAL LICENSED OR CERTIFIED UNDER THIS ARTICLE TO PROVIDE HEALTH CARE.~~
~~(4) "NONPROFIT CLINIC" MEANS A PUBLIC OR PRIVATE NONPROFIT ORGANIZATION THAT PROVIDES PRIMARY OR SPECIALTY OUTPATIENT HEALTH CARE SERVICES TO INDIGENT AND UNINSURED INDIVIDUALS FOR FREE OR AT REDUCED COST.~~
~~(5) "PRESCRIPTION DRUG" HAS THE MEANING STATED IN § 21-201 OF THIS ARTICLE.~~
~~(6) "PROGRAM" MEANS THE PRESCRIPTION DRUG REPOSITORY PROGRAM.~~
~~(B) MEDBANK OF MARYLAND, INC., IN COLLABORATION WITH THE STATE BOARD OF PHARMACY, SHALL ESTABLISH A PRESCRIPTION DRUG REPOSITORY PROGRAM TO ACCEPT AND DISPENSE PRESCRIPTION DRUGS DONATED FOR THE PURPOSE OF DISPENSING TO INDIVIDUALS WHO ARE RESIDENTS OF THE STATE AND MEET ELIGIBILITY REQUIREMENTS ESTABLISHED FOR THE PROGRAM.~~
~~(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, THE PROGRAM MAY ONLY ACCEPT AND DISPENSE DRUGS IN THEIR ORIGINAL UNOPENED, SEALED, AND TAMPER-EVIDENT UNIT DOSE PACKAGING.~~
~~(2) THE PROGRAM MAY ACCEPT AND DISPENSE DRUGS PACKAGED IN SINGLE UNIT DOSES WHEN THE OUTSIDE PACKAGING IS OPENED IF THE SINGLE UNIT DOSE PACKAGING IS UNDISTURBED.~~
~~(3) THE PROGRAM MAY NOT ACCEPT OR DISPENSE DRUGS THAT:~~
~~(I) BEAR AN EXPIRATION DATE THAT IS LESS THAN 6 MONTHS FROM THE DATE THE DRUG IS DONATED; OR~~
~~(II) MAY BE ADULTERATED ACCORDING TO THE STANDARDS OF § 21-216 OF THIS ARTICLE.~~
~~(D) (1) ANY PERSON, INCLUDING AN INDIVIDUAL, A DRUG MANUFACTURER, OR A HEALTH CARE FACILITY, MAY DONATE PRESCRIPTION DRUGS TO THE PROGRAM.~~
~~(2) DRUGS MAY ONLY BE DONATED AT A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT PARTICIPATES IN THE PROGRAM.~~
~~(E) (1) A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC SEEKING TO PARTICIPATE IN THE PROGRAM SHALL APPLY IN THE FORM AND MANNER REQUIRED~~

~~34 BY MEDBANK OF MARYLAND, INC.~~
~~35 (2) A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT PARTICIPATES~~
~~36 IN THE PROGRAM MAY ONLY DISPENSE DRUGS DONATED THROUGH THE PROGRAM~~

~~1 TO INDIVIDUALS WHO ARE RESIDENTS OF THE STATE AND MEET THE ELIGIBILITY~~
~~2 STANDARDS ESTABLISHED BY MEDBANK OF MARYLAND, INC.~~
~~3 (3) A DRUG DONATED THROUGH THE PROGRAM MAY ONLY BE~~
~~4 DISPENSED ON A PRESCRIPTION ISSUED BY AN AUTHORIZED PRESCRIBER.~~
~~5 (4) A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT ACCEPTS~~
~~6 DONATED DRUGS SHALL:~~
~~7 (I) COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND LAWS OF~~
~~8 THIS STATE PERTAINING TO STORAGE AND DISTRIBUTION OF DANGEROUS DRUGS;~~
~~9 AND~~
~~10 (II) INSPECT ALL DRUGS BEFORE DISPENSING TO DETERMINE~~
~~11 THAT THE DRUGS ARE NOT ADULTERATED.~~
~~12 (5) THE PHARMACY, HOSPITAL, OR NONPROFIT CLINIC MAY CHARGE~~
~~13 INDIVIDUALS RECEIVING DONATED DRUGS A HANDLING FEE ESTABLISHED IN~~
~~14 ACCORDANCE WITH REQUIREMENTS ESTABLISHED BY MEDBANK OF MARYLAND,~~
~~15 INC.~~
~~16 (6) DRUGS DONATED TO THE PROGRAM MAY NOT BE RESOLD.~~
~~17 (F) (1) THIS SUBSECTION APPLIES TO:~~
~~18 (I) MEDBANK OF MARYLAND, INC.;~~
~~19 (II) THE STATE BOARD OF PHARMACY;~~
~~20 (III) THE SECRETARY OF HEALTH AND MENTAL HYGIENE;~~
~~21 (IV) ANY PERSON THAT DONATES DRUGS TO THE PROGRAM; AND~~
~~22 (V) ANY PHARMACY, HOSPITAL, NONPROFIT CLINIC, OR HEALTH~~
~~23 CARE PRACTITIONER THAT ACCEPTS OR DISPENSES DRUGS UNDER THE PROGRAM.~~
~~24 (2) FOR MATTERS RELATED TO DONATING, ACCEPTING, OR DISPENSING~~
~~25 DRUGS UNDER THE PROGRAM, A PERSON DESCRIBED IN PARAGRAPH (1) OF THIS~~
~~26 SUBSECTION THAT ACTS IN GOOD FAITH MAY NOT BE SUBJECT TO:~~
~~27 (I) CRIMINAL PROSECUTION;~~
~~28 (II) LIABILITY IN TORT OR OTHER CIVIL ACTION FOR INJURY,~~
~~29 DEATH, OR LOSS TO PERSON OR PROPERTY; OR~~
~~30 (III) DISCIPLINARY ACTION BY A PROFESSIONAL LICENSING BOARD.~~
~~31 (3) A DRUG MANUFACTURER ACTING IN GOOD FAITH MAY NOT BE~~
~~32 SUBJECT TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL~~
~~33 ACTION FOR INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR MATTERS~~
~~34 RELATED TO THE DONATION, ACCEPTANCE, OR DISPENSING OF A DRUG~~

~~1 MANUFACTURED BY THE DRUG MANUFACTURER THAT IS DONATED BY ANY PERSON~~
~~2 UNDER THE PROGRAM, INCLUDING LIABILITY FOR FAILURE TO TRANSFER OR~~
~~3 COMMUNICATE PRODUCT OR CONSUMER INFORMATION OR THE EXPIRATION DATE~~
~~4 OF THE DONATED DRUG.~~
~~5 (G) (1) ON OR BEFORE OCTOBER 1, 2006, AND IN CONSULTATION WITH THE~~
~~6 STATE BOARD OF PHARMACY AND THE SECRETARY, MEDBANK OF MARYLAND, INC.~~
~~7 SHALL ESTABLISH REQUIREMENTS FOR THE PROGRAM.~~
~~8 (2) THE REQUIREMENTS SHALL INCLUDE:~~
~~9 (I) PARTICIPATION REQUIREMENTS FOR PHARMACIES,~~
~~10 HOSPITALS, AND NONPROFIT CLINICS TO ACCEPT AND DISPENSE DONATED DRUGS~~
~~11 UNDER THE PROGRAM;~~
~~12 (II) STANDARDS AND PROCEDURES FOR ACCEPTING, SAFELY~~
~~13 STORING, AND DISPENSING DONATED DRUGS;~~
~~14 (III) STANDARDS AND PROCEDURES FOR INSPECTING DONATED~~
~~15 DRUGS TO DETERMINE THAT:~~
~~16 1. THE ORIGINAL UNIT DOSE PACKAGING IS SEALED AND~~
~~17 TAMPER-EVIDENT; AND~~
~~18 2. THE DRUGS ARE UNADULTERATED, SAFE, AND SUITABLE~~
~~19 FOR DISPENSING;~~
~~20 (IV) ELIGIBILITY STANDARDS BASED ON ECONOMIC NEED FOR~~
~~21 INDIVIDUALS TO RECEIVE DRUGS;~~
~~22 (V) A MEANS, SUCH AS AN IDENTIFICATION CARD, BY WHICH AN~~
~~23 INDIVIDUAL WHO IS ELIGIBLE TO RECEIVE DONATED DRUGS MAY DEMONSTRATE~~
~~24 ELIGIBILITY TO THE PHARMACY, HOSPITAL, OR NONPROFIT CLINIC DISPENSING THE~~
~~25 DRUGS;~~
~~26 (VI) A FORM THAT AN INDIVIDUAL RECEIVING A DRUG FROM THE~~
~~27 PROGRAM MUST SIGN BEFORE RECEIVING THE DRUG TO CONFIRM THAT THE~~
~~28 INDIVIDUAL UNDERSTANDS THE IMMUNITY PROVISIONS OF THE PROGRAM;~~
~~29 (VII) A FORMULA TO DETERMINE THE AMOUNT OF A HANDLING FEE~~
~~30 THAT PHARMACIES, HOSPITALS, AND NONPROFIT CLINICS MAY CHARGE TO DRUG~~
~~31 RECIPIENTS TO COVER RESTOCKING AND DISPENSING COSTS;~~
~~32 (VIII) 1. A LIST OF DRUGS THAT THE REPOSITORY WILL ACCEPT;~~
~~33 2. A LIST OF DRUGS THAT THE REPOSITORY WILL NOT~~

~~34 ACCEPT, INCLUDING A STATEMENT AS TO WHY THE DRUG IS INELIGIBLE FOR~~
~~35 DONATION; AND~~

~~3. FOR AN INDIVIDUAL DONOR, A FORM EACH DONOR MUST SIGN STATING THAT THE DONOR IS THE OWNER OF THE DRUGS AND INTENDS TO VOLUNTARILY DONATE THEM TO THE PROGRAM; AND~~
~~(IX) ANY OTHER STANDARDS AND PROCEDURES MEDBANK OF MARYLAND, INC. CONSIDERS APPROPRIATE.~~
~~(a) There is a Task Force on the Establishment of a Prescription Drug Repository Program.~~
~~(b) The Task Force consists of the following members:~~
~~(1) two members of the Senate of Maryland, appointed by the President of the Senate;~~
~~(2) two members of the House of Delegates, appointed by the Speaker of the House;~~
~~(3) the Secretary of Health and Mental Hygiene, or the Secretary's designee;~~
~~(4) the Executive Director of the State Board of Pharmacy, or the Executive Director's designee;~~
~~(5) the Executive Director of the Maryland Health Insurance Plan, or the Executive Director's designee; and~~ *one representative of the Board of Directors for the Maryland Health Insurance Plan, as determined by the Chairman of the Board of Directors;*
(4) one representative of the State Board of Pharmacy, as determined by the President of the State Board of Pharmacy;
(5) the following two members, appointed by the Secretary of Health and Mental Hygiene:
(i) one representative of the Maryland Medical Assistance Program in the Department of Health and Mental Hygiene; and
(ii) one representative of the Office of Health Care Quality in the Department of Health and Mental Hygiene; and
(6) the following six *eight* members, appointed by the Governor:
(i) one representative of the American Cancer Society;
(ii) one hospital representative;
(iii) one nursing home representative;
(iv) one representative of a community health center;

(v) one pharmacy representative; and

(vi) one representative of the Medbank Program*;*

(vii) one representative of the pharmaceutical industry; and

(viii) one representative of the University of Maryland School of Pharmacy.

(c) The members shall elect a chair from among the members.

(d) The Department of Health and Mental Hygiene shall provide staff for the Task Force.

(e) A member of the Task Force may not receive compensation.

(f) The Task Force shall:

(1) study and make recommendations regarding the establishment of a Prescription Drug Repository Program in the State, including:

(i) types of drugs that may be donated to the Program;

(ii) types of drugs that may not be donated to the Program;

(iii) who may donate drugs to the Program;

(iv) entities that may receive drugs for distribution;

(v) standards and procedures for accepting, storing, and dispensing donated drugs;

(vi) eligibility requirements for individuals wishing to receive donated drugs;

(vii) standards and procedures for inspecting donated drugs;

(viii) the appropriate entity to operate the Program;

(ix) liability issues;

(x) fees; and

(xi) any other matter relating to the establishment of a Prescription Drug Repository Program; and

(2) report its findings and recommendations to the Governor and, in accordance with § 2-1246 of the State Government Article, the General Assembly, on or before January 1, 2006.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October~~ July 1, 2005. It shall remain effective for a period of 1 year and, at the end of June 30, 2006, with no further action required by the General Assembly, this Act shall be abrogated and of no further force and effect.

APPENDIX C

WEB SITE ADDRESSES FOR THE SUMMARY OF DRUG REPOSITORY PROGRAMS

California

http://www.leginfo.ca.gov/pub/bill/sen/sb_0751-0800/sb_798_bill_20050913_enrolled.html

http://www.pharmacy.ca.gov/laws_regs/legislation.htm

Colorado

http://www.leg.state.co.us/clics2005a/csl.nsf/billsummary/

Connecticut

Information was faxed from Emily Piddock at the State of Connecticut, Department of Social Services.

Delaware

http://www.legis.state.de.us/LIS/LIS143.nsf/Legislation

Georgia

http://www.legis.state.ga.us/legis/2005_06/search/hb430.htm

Indiana

http://www.ai.org/legislative/ic/code/title25/ar26/ch20.html

http://www.in.gov/legislative/ic/code/title25//ar26/ch13.html

Iowa

http://coolice.legis.state.ia.us/Legislation\Bills\HouseFiles\Introduced\HF245.html

Kansas

http://www.kslegislature.org/legsrv-billtrack/searchBills

Kentucky

http://www.lrc.ky.gov/KRS/194A00/CHAPTER.HTM

http://www.lrc.ky.gov/record/04rs/HB86.htm

Louisana

http://www.labp.com/

Maine

http://www.mainelegislature.org/legis/bills/chapters/PS20-1.asp

http://janus.state.me.us/legis/LawMakerWeb/summary.asp?LD=129

Massachusetts

http://www.mass.gov/legis/bills/house/ht02/ht02702.htm

http://www.mass.gov/legis/184history/h02702.htm

Michigan

http://www.legislature.mi.gov

Minnesota

http://www.phcybrd.state.mn.us/hf139.pdf

Mississippi

http://www.mscode.com/free/statutes/43/013/0501.htm

http://www.mscode.com/free/statutes/43/013/0503.htm

http://www.mscode.com/free/statutes/43/013/0505.htm

http://www.mscode.com/free/statutes/43/013/0507.htm

http://www.mscode.com/free/statutes/43/013/0509.htm

Missouri

http://www.dhss.mo.gov/DrugRepository/

http://www.moga.mo.gov/statutes/C100-199/1960000970.HTM

http://www.senate.state.mo.us/04INFO/bills/SB1160.htm

Nebraska

http://www.hhs.state.ne.us/cancerdrugs/index.htm

http://www.hhs.state.ne.us/cancerdrugs/71-2422.pdf

http://www.sos.state.ne.us/business/regsearch/Rules/Health_and_Human_Services_System/Title-181/Chapter-6.pdf

Ohio

http://pharmacy.ohio.gov/RulesEffec040101-DR-Nw.htm

Oklahoma

http://www.ok.gov/OSBP/documents/law04.pdf

Rhode Island

http://dirac.rilin.state.ri.us/BillStatus

http://www.rilin.state.ri.us/Billtext/BillText05/HouseText05/H5561.pdf

Wisconsin

http://folio.legis.state.wi.us/cgi-bin/om_isapi.dll?clientID=26736853&advquery=Cancer%20Drug%20Repository%20Program&headingswithhits=on&infobase=code.nfo&record={1E1E2}&recordswithhits=on&zz=

APPENDIX D

SUMMARY OF STATES DRUG REPOSITORY PROGRAM EFFORTS
(Effective, Passed & Failed State Legislation)

California - Passed

Title: **Prescription Drugs: Collection and Distribution Program, SB 798 was enrolled in September 2005**

This legislation authorizes a **county** to establish a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill limits the program to pharmacies owned by or contracting with the county. It requires a county that elects to establish a repository and distribution program to establish procedures for, at a minimum, 1) establishing eligibility for medically indigent patients who may participate; 2) ensure that eligible participants are not charged; 3) develop a formulary of appropriated medications; 4) ensure proper safety and management of any medications collected; and 5) ensure the privacy of individuals for whom the medication was originally prescribed.

No controlled dangerous substances may be donated. Medications may not have been adulterated, misbranded, or stored improperly. The donated medications shall not have been in the possession of a patient or member of the public, and in the case of medications donated by a skilled nursing facility, shall have been under the control of staff of the skilled nursing facility.

Colorado - Passed

Title: **Colorado Cancer Drug Repository Program, SB 165, 2005, Effective 8/9/05**

This legislation established the Colorado Cancer Drug Repository Program for the purpose of allowing a cancer patient or the patient's family to donate unused cancer drugs and medical devices to uninsured and underinsured cancer patients. The program is administered by the **Department of Public Health and Environment.**

A cancer patient or the patient's family may donate unused cancer drugs or medical devices to a health care facility, medical clinic, or pharmacy that elects to participate in the program. A pharmacist may accept and dispense cancer drugs and medical devices donated under the program to eligible patients if all of the following requirements are met: (a) the cancer drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit-dose packaging is unopened; (b) the cancer drug bears an expiration date that has not expired; (c) the cancer drug or medical device is not adulterated or misbranded; and (d) the cancer drug or

medical device is prescribed by a practitioner for use by an eligible patient and is dispensed by a pharmacist.

A cancer drug or medical device donated under the program may not be resold. A health care facility, medical clinic, or pharmacy may charge an eligible patient a handling fee, which fee may not exceed the amount specified in rule by the state board.

Connecticut - Passed

Title: **Nursing Home Drug Return Program, Section 37A and B of Public Act 00-2 of the June Special Session, Effective January 1, 2001.**

The **Commissioner of the Department of Social Services** has established a program by which long-term care facilities return unused patient medications to the dispensing pharmacy and the Connecticut Medical Assistance Program will be credited for the returned medication. Every pharmacy provider supplying drugs to long-term care facilities will be required to participate.

In order for a prescription to be returned it must meet the following criteria: 1) the credit for the ingredient cost of the prescription must be greater than $10.00; 2) the returned product must be one of the 50 drug products listed in an appendix provided by the Department; 3) not a controlled substance; 4) the product must be sealed in individually packaged units; and 5) no expired products may be returned and the date of return can be no longer than 3 months from the date of packaging if packaged by the vendor pharmacy.

Delaware - Failed

Title: **An Act to Amend Title 16 of the Delaware Code Relating to Creation of a Prescription Drug Repository Program, Senate Bill No. 77, did not pass.**

The bill created a prescription drug repository program established by the **Board of Pharmacy** for the purpose of safely accepting and dispensing donated, unused, unopened prescription drugs. This program would be available to eligible residents of the State with a valid prescription from an authorized prescriber. The program may only accept and dispense drugs in their original unopened, sealed, and tamper-evident unit dose packaging. The program may accept and dispense drugs packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed. The program may not accept or dispense drugs bearing an expiration date that is less than 6 months from the date the drug is donated or that may be deemed adulterated

Any person, including an individual, a drug manufacturer, or a health care facility, may donate prescription drugs to the program. Drugs may only be donated at a pharmacy, hospital, or nonprofit clinic that participates in the program. A pharmacy, hospital, or nonprofit clinic that participates in the program may only dispense drugs donated through the program to eligible individuals and government entities and nonprofit private entities to be dispensed to eligible individuals. The pharmacy, hospital, or nonprofit clinic may

charge individuals receiving donated drugs a handling fee. A means, such as an identification card, would be issued to individuals eligible to receive donated drugs.

Georgia - Failed

Title: **Pharmacists and pharmacies; drug repository, "Karon's Law." HB 430, 2005_06 Session, did not pass.**

In HB 430, introduced in the last legislative session in Georgia, the **Board of Pharmacy** would establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who meet eligibility standards. 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 dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated. Unused drugs dispensed for purposes of the Medicaid program may be accepted and dispensed under the drug repository program.

Any person, including a drug manufacturer or any health care facility, may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program and meets criteria for participation in the program established in rules adopted by the board. A handling fee may be charged. A means, such as an identification card, would be issued to individuals eligible to receive donated drugs.

Indiana – Effective

Title: **Regional Drug Repository Program, IC 25-26-20**

The **Board of Pharmacy** organizes a voluntary regional drug repository program to collect and redistribute drugs to nonprofit health clinics. A regional drug repository may be a pharmacist, pharmacy, wholesale drug distributor, hospital, health care facility or nonprofit health clinic. A regional drug repository may not receive compensation for participation in the program.

Donations may only be accepted if: 1) originally dispensed to a patient in an institution or hospice; 2) properly stored and securely maintained; 3) returned unopened; 4) dispensed by the same pharmacy as the pharmacy accepting the return; 5) not expired; 6) not a controlled dangerous substance; and 7) prescribed for a Medicaid patient AND the Medicaid program has been credited for the product cost of the drug.

Iowa - Failed

Title: **Current regulations located at 657-6.15(124,126) Return of drugs and other items.**

A bill was introduced in the Iowa 2005 session, HF 245, establishing a cancer drug repository program in the Iowa **Department of Public Health.** It did not pass out of committee. The bill allowed for the donation of a cancer drug or supplies needed to administer a cancer drug for use by an individual who meets eligibility criteria. Donations may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets requirements established by the department. The medical facility or pharmacy may charge an individual who receives a cancer drug or supplies needed to administer a cancer drug a handling fee that may not exceed an amount established by the department. A medical facility or pharmacy that receives a donated cancer drug or supplies needed to administer a cancer drug may distribute the cancer drug or supplies to another eligible medical facility or pharmacy. The bill provides that a cancer drug or supplies must be in their original, unopened, sealed, and tamper-evident unit dose packaging or in unopened single-unit-dose packaging, and must bear an expiration date later than six months after the date the drug was donated. The bill provides that the cancer drug or supplies must not be adulterated or misbranded, as determined by a licensed pharmacist, that the cancer drug or supplies must be prescribed by a health care practitioner for use by an eligible individual and dispensed by a pharmacist, and that they may not be resold.

Kansas - Passed

Title: **House Bill No. 2077, The State Board of Pharmacy, establishing a cancer drug repository program. Approved by the Governor 4/12/05 and effective 07/01/05.**

The cancer drug repository program will be established under the **State Board of Pharmacy.** Any person, including a drug manufacturer or health care facility, could donate prescription cancer drugs at a physician's office, pharmacy, hospital, or nonprofit clinic that elects to participate in the program. The drugs would then be dispensed to persons who meet eligibility standards established by the Board of Pharmacy. The donated drugs could not be resold, but a handling fee approved by the Pharmacy Board could be charged.

Only cancer drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that cancer drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. A cancer drug that bears an expiration date that is less than six months after the date the cancer drug is being donated shall not be accepted for donation. A drug shall not be accepted for donation if there is reason to believe that it is adulterated or misbranded.

A special license for organizations dispensing the drugs would have to be developed by the Board. With an increase in licensees, the Board would have more inspections to

complete. The Board would be responsible for inspecting the drugs to see that they meet standards or original unit dose and tamper proof packaging.

Kentucky

Title: Legend Drug Repository Program, KRS Chapter 217, 194A.450

The **Cabinet for Health and Family Services** shall establish and maintain a legend drug repository program to support the donation of a legend drug or supplies needed to administer a legend drug for use by an individual who meets the eligibility criteria. Donations may be made on the premises of a health facility or pharmacy that elects to participate in the program. The health facility may charge a handling fee to an individual who received a legend drug or supplies under the program, except that the fee shall not exceed the amount established by an administrative regulation promulgated by the cabinet. A health facility or pharmacy that receives a donated legend drug under the program may distribute the legend drug or supplies to another eligible health facility or pharmacy for use under the program.

The repository program shall: 1) not accept any controlled substance; 2) only accept the legend drug is in it is original, unopened, sealed, and tamper-evident unit dose packaging; 3) not accept the legend drug if adulterated or misbranded; and 4) accept a legend drug that has been prescribed by a physician, advanced registered nurse practitioner, or physician assistant and dispensed by a pharmacist.

Louisiana - Effective

Title: Charitable Pharmacy, Title 37, Part D, 1226.2 and Administrative Code Title 46, Chapter 21

Louisiana has 11 Charitable Pharmacies that are 501(c)(3) non-profit organizations. They receive a Charitable Pharmacy Permit from the **Board of Pharmacy**. They are usually associated with free medical clinics and dispense free medications. They obtain their medications from donated samples and donations from Nursing Homes and Long-Term Care facilities. The pharmacist in charge may accept the donations. Controlled dangerous substances may not be donated. When the medications are donated the name and prescription number must be obliterated on the label to comply with HIPAA regulations, but the remaining information must remain. The patient also must consent to the donation. Redispensing may occur only one time.

Maine - Passed

Title: Unused Prescription Drug Program, 22 MRSA § 254-C, Effective Date May 31, 2005.

This new law provides for the **Department of Health and Human Services** to establish an unused prescription drug program under which unused prescription drugs are accepted

and dispensed to low-income persons. To be eligible for the program a person must have a family income below 350% of the federal poverty level, may not be receiving MaineCare prescription drug benefits and must have a valid prescription for the drug to be dispensed. The program may accept unused and unopened prescription drugs from drug manufacturers, drug wholesale and terminal distributors, hospitals, health clinics, federally qualified health centers, Indian health centers and rural health centers and assisted living facilities licensed by the Department of Health and Human Services.

The program may accept unused prescription drugs that are unopened and packaged in tamper-evident unit dose packages or that are unopened injectable, aerosol or topical medications. It may accept unused prescription drugs from an entity donating under this subsection if: 1) the entity is the owner of the prescription drug; or 2) the entity has maintained custody of the prescription drug for an individual and donation of the prescription drug is accompanied by signed consent to the donation from the individual or authorized representative of the individual.

The program may accept unused prescription drugs that are controlled substances as defined by 21 Code of Federal Regulations, Part 1308 and regulations adopted by the federal Department of Justice, Drug Enforcement Administration as allowed by federal law and regulation.

The program may not accept unused prescription drugs that have been opened, tampered with or compromised in any way; that are within 6 months of their expiration date; or that have been held in the custody of the person to whom the prescription drug was originally dispensed. A fee charged under this paragraph may not exceed the co-payment charged for a similar prescription drug under the MaineCare program.

Massachusetts

Title: **Drug Repository Program, House, No. 2702, Hearing Held September 21, 2005.**

Legislation is currently pending in Massachusetts to establish a drug repository program. **The Department of Public Health and the Board of Registration in Pharmacy** will establish the program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who meet eligibility standards.

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 dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated.

Any person, including a drug manufacturer, health care facility, or government entity, may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital, or a nonprofit clinic. The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee. A means, such as an identification card, would be issued to individuals eligible to receive donated drugs.

Michigan - Effective

Title: **333.17766d Pharmacy operated by department of corrections or under contract with county jail; resale of redistribution of prescription drug; definitions.**

A pharmacy operated by the **Department of Corrections** or under contract with the department of corrections or a county jail may accept for the purpose of resale or redispensing a prescription drug that has been dispensed and has left the control of the pharmacist if the prescription drug is being returned by a state correctional facility or a county jail that has a licensed physician's assistant, a registered professional nurse, or a licensed practical nurse, who is responsible for the security, handling, and administration of prescription drugs within that state correctional facility or county jail if certain conditions are met.

Minnesota

Title: **Cancer Drug Repository Program, 151.55**

Passed in 2005, the Minnesota Cancer Drug Repository Program will be established and maintained by the **Board of Pharmacy**. Any person may donate a cancer drug or supply for use by an individual who meets certain eligibility criteria. Donations may be made on the premises of a medical facility or pharmacy that elects to participate. An individual or a pharmacy, medical facility, manufacturer or distributor may donate on the premises of a cancer drug repository to a person designated by the repository. A drop box may not be used to deliver or accept donations.

Donations must 1) be accompanied by a repository donor form; 2) have an expiration date that is at least 6 months later than date of donation; 3) be in the original, unopened package; and 4) not be adulterated or misbranded. No controlled dangerous substances may be donated.

Charge to recipient of a handling fee of no more than 250% of the medical assistance program dispensing fee.

Mississippi

Title: Drug Repository Program, Mississippi Code, Sec. 43-13-501 and 509

The **State Board of Pharmacy and the State Department of Health** jointly shall establish a plan for a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who meet the eligibility standards. The plan shall be submitted to the Chairmen of the Public Health and Welfare Committees of the Mississippi House of Representatives and Senate for review. Under the drug repository program: 1) Only drugs in their original sealed and tamper-evident packaging may be accepted and dispensed; 2) 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 dose packaging is undisturbed; 3) The drugs must have been properly stored such that the integrity of the medicine remains intact; 4) A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated; and 5) Subject to the limitation specified in this subsection, unused drugs dispensed for the purposes of the Medicaid program may be accepted and dispensed.

Any person, including a drug manufacturer, any health care facility or government entity, may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital, nonprofit clinic or health care professional that elects to participate in the drug repository program and meets criteria for participation in the program established in rules adopted by the board in consultation with the State Department of Health. A handling fee may be charged. A means, such as an identification card, would be issued to individuals eligible to receive donated drugs.

Missouri - Effective

Title: Prescription Drug Repository Program, Title 19 Department of Health and Senior Services, Division 20 Division of Environmental Health and Communicable Disease Prevention, Chapter 50 Prescription Drug Repository Program. Missouri Revised Statutes, Chapter 196.970.

The Prescription Drug Repository will be established by the **Department of Health and Senior Services** to provide access to unused prescription drugs for persons who have economic need. Drugs that have been donated by individual patients may be provided by healthcare facilities such as nursing homes or hospitals to pharmacies; hospitals or non-profit clinics that agree to dispense the drugs to eligible recipients. For safety reasons, donated drugs must have been under the control of a healthcare facility or healthcare professional, and cannot have been in the possession of the individual owner. The owner of the drugs is the patient for whom the drugs were prescribed and dispensed, regardless of the method of payment.

Participating dispensers may charge recipients a limited handling fee to cover stocking and dispensing costs. This handling fee may be no more than 200% of the standard Missouri Medicaid dispensing fee. The standard Missouri Medicaid dispensing fee is $4.09, so repository sites may charge no more than $8.18 per dispensing.

Controlled substances such as narcotics and many medications to treat nervousness and insomnia may not be donated. Drugs that are sensitive to light or heat may not be

donated. Other drugs may be donated if they are packaged in original sealed and tamper-evident packaging such as blister-cards and have an expiration date that will not be reached for at least six months. The program went into effect on January 1, 2005.

Nebraska - Effective

Title: Cancer Drug Repository Program, Title 181, Chapter 6, Nebraska Health and Human Services Regulation and Licensure, Neb. Rev. Stat. §§ 71-2422 to 71-2429.

The Cancer Drug Repository Program is a voluntary program for accepting donated cancer drugs and dispensing them to Nebraska residents. The **Department of Health and Human Services Regulation and Licensure** is responsible for establishing and maintaining the program and will provide information to any person or entity wishing to donate or receive cancer drugs through the program. In 2005, LB 331 created a Participant Registry that identifies those who accept donated cancer drugs.

Any person or entity may donate cancer drugs to the program. Cancer drugs may be donated at a participating physician's office, pharmacy, hospital or health clinic. The following cancer drugs are acceptable for dispensing under this program: 1) if it is in its original, unopened, sealed, and tamper-evident unit dose packaging; 2) if packaged in single unit doses, if the outside packaging is opened; 3) if dispensed under the medical assistance program; or 4) if it does not require refrigeration, freezing, or other special temperature requirements. Controlled substances may not be donated. The expiration date must also be more than 6 months before donation.

A handling fee may be charged by a person or entity with a valid dispensing license, so long as the handling fee does not exceed the Medicaid provider dispensing fee.

Ohio

Title: Drug Repository Program, Administrative Code (AC) Chapter 4729-35, Ohio Revised Code 3715.87 – 3715.873.

The **Board of Pharmacy** shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of this state and meet eligibility standards. A pharmacy, hospital, or nonprofit clinic may elect to participate in the drug repository program. A licensed terminal distributor of dangerous drugs, a licensed wholesale distributor of dangerous drugs or a person who was legally dispensed a dangerous drug pursuant to a patient-specific drug order may donate a dangerous drug. A person electing to donate shall not have taken custody of the drug prior to the donation. A person who resides in an institutional facility, or a person designated by durable power of attorney, a guardian or other individual responsible for the care and well-being of a patient, and was legally dispensed a dangerous drug pursuant to a patient-specific order, may elect to sign and date a donor form prior to donating a drug.

All dangerous drugs, except controlled substances and drug samples, may be donated if the: 1) drugs are in their original packages; 2) drugs have been in the possession of a licensed healthcare professional and not in the possession of the ultimate user; 3) drugs have been stored according to FDA requirements; 4) drugs have an expiration date of six months or greater; 5) drugs do not have any physical signs of tampering or adulteration; and 6) drug packaging does not have any physical signs of tampering.

Oklahoma - Effective

Title: Unused Prescription Drug Program for Oklahoma's Medically Indigent. Rules found in Title 535, Subchapter 12.

The rules of this chapter describe a statewide program under the **Board of Pharmacy** to take unused prescription drugs from nursing homes, assisted living centers; and donated drugs from pharmaceutical manufacturers and utilize them for dispensing to medically indigent Oklahoma residents. The rules further describe the eligibility to donate, the eligible prescription drug formulary, the eligible recipients, and the protections for participants. They describe pharmacies eligible to accept and dispense such drugs, the requirements for eligible pharmacies, and the responsibilities for pharmacist managers. The rules also describe safe handling of medications to protect drug integrity, tracking, sanitation, security and dispensing requirements for these unused prescription drugs. Finally the rules describe confidentiality requirements as well as violations.

No controlled dangerous substances or compounded drugs may be donated.

Rhode Island - Failed

Title: **Drug Repository Program, House Bill No. 5561, 2005, Continued on 3/16/2005, did not pass.**

This legislation required the **State Board of Pharmacy** to establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who meet eligibility standards. 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 dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than 6 months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if a reasonable person would believe that it is or may have been adulterated. Unused drugs dispensed for purposes of the Medicaid program may be accepted and dispensed under the drug repository program.

Any person, including a drug manufacturer or any health care facility may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital or other health care facility that elects to participate in the drug repository program and meets criteria for participation in the program. A handling fee

may be charged. A means, such as an identification card, would be issued to individuals eligible to receive donated drugs.

Wisconsin - Effective

Title: Cancer Drug Repository Program, Chapter HFS 148 under Department of Health and Family Services

Wisconsin has a cancer drug repository program under which unused cancer drugs and cancer supplies may be donated and dispensed to any Wisconsin resident who as been diagnosed with cancer. A pharmacy or a medical facility may be eligible to accept donated drugs by notifying the **Department of Health and Family Services**. An individual or a pharmacy, medical facility, manufacturer or distributor may donate on the premises of a cancer drug repository to a person designated by the repository. A drop box may not be used to deliver or accept donations. No controlled dangerous substances may be donated.

Donations must 1) be accompanied by a repository donor form; 2) have an expiration date that is at least 6 months later than date of donation; 3) be in the original, unopened package; and 4) not be adulterated or misbranded.

Charge to recipient of a handling fee of no more than 300% of the Medicaid dispensing fee or no more than $15, whichever is less.

APPENDIX II

MARYLAND
TASK FORCE ON THE ESTABLISHMENT OF A PRESCRIPTION DRUG REPOSITORY PROGRAM

SECOND INTERIM REPORT TO THE GENERAL ASSEMBLY

February 28, 2006

MARYLAND TASK FORCE ON THE ESTABLISHMENT OF A PRESCRIPTION DRUG REPOSITORY PROGRAM

SECOND INTERIM REPORT

TABLE OF CONTENTS

WORKGROUP PARTICIPANTS

American Cancer Society
Arnold L. Amass, Pharm. D.

Pharmacy Representative
Lynette R. Bradley-Baker, R.Ph., Ph.D.

Nursing Home Representative
Elizabeth R. Bowerman, CEO

Community Health Center
Howard C. Cohen, COO

House of Delegates
Delegate Donald B. Elliott
Delegate David D. Rudolph

Maryland Board of Pharmacy
Donald W. Taylor, Chairman of the Task Force and Board of Pharmacy Member

Pharmaceutical Industry
Philip D. Noguchi, M.D.

Office of Health Care Quality
William Vaughan

University of Maryland, School of Pharmacy
Francis Palumbo, Esquire, Ph.D.

Maryland Medical Assistance Program
Frank Tetkoski

Board of Pharmacy Staff
LaVerne G. Naesea, Executive Director
Anna D. Jeffers, Acting Legislative and Regulations Manager

EXECUTIVE SUMMARY

This is the second of three reports promised to the Maryland General Assembly on the establishment of a prescription drug repository in Maryland. The first Interim Report was submitted January 1, 2006 in accordance with Senate Bill 441 (SB 441), passed during the 2005 legislative session. That report discussed the types of programs that have been legislated or established in 21 other states. It also provided reference information specific to the experiences of those programs. This second report was to discuss the feasibility of establishing a prescription drug repository in Maryland and, if determined feasible, to provide specific recommendations regarding the areas outlined in SB 441.

After exploring several approaches to establishing a prescription drug repository, the Task Force unanimously agreed that it is feasible to implement a program in Maryland. The Task Force, however, recommends caution so as not to develop a program on as grand a scale as had been originally envisioned. Safeguards first must be in place to ensure patient safety, protect against liability, ensure proper collection, storage, and dispensing of previously dispensed medications, and to ensure that the program is not exploited or misused.

The report outline addresses each of the eleven (11) issues in order of mention in SB 441. Two issues, the types of drug that may be donated to the program and the types of drugs that may not be donated to the program, were discussed jointly in the first section. A total of 16 recommendations are made under the 10 specific issues raised in SB 441. Eight additional recommendations are provided under the catch-all category entitled other matters. That section recommends approaches regarding such issues as: costs for operating a central repository, destruction of drugs, feasibility of tax credits, the program sunset, etc. Each set of recommendations is followed by discussions of points that led to the recommendations.

With the increasing costs of medications in Maryland and the current disposal of unused expensive medications, the Task Force recommendations in this Second Interim Report are provided to allow a framework for a program to be developed should legislation be proposed to support a program during the 2006 legislative session. By no means is this report a thorough examination of all considerations that should be reviewed in order to ensure implementation of a successful program. The continued work of the Task Force will yield more detailed recommendations for presentation in its final report, due July 1, 2006. The primary goal of the Task Force is to determine an appropriate method to dispense unused medications to those who could benefit the most. The Task Force is committed to accomplishing this goal.

INTRODUCTION

SB 441 – Task Force on the Establishment of a Prescription Drug Repository Program was passed to study and make recommendations regarding the establishment of a Prescription Drug Repository Program in Maryland. The Maryland Board of Pharmacy (the "Board) is staffing this Task Force for the Department of Health and Mental Hygiene (the "Department"). Since many of the Task Force members were appointed in the late fall, the initial meeting of the Task Force took place on December 15, 2005. The Task Force submitted a First Interim Report, on January 1, 2006 to comply with SB 441.

Based on the limited time that the Task Force had to deliberate on the important issue of a Prescription Drug Repository Program in Maryland, the Task Force recommended that it submit a Second Interim Report on February 28, 2006 that would include recommendations that could be considered for use in related proposals for legislation during the 2006 Legislative Session. The Task Force also recommended that it continue to work through June 2006 and submit a Final Report on July 1, 2006 that would provide recommendations for regulations that may be used to support implementation of a Prescription Drug Repository Program in Maryland.

RECOMMENDATIONS THAT COULD BE CONSIDERED FOR USE IN RELATED PROPOSALS FOR LEGISLATION DURING THE 2006 LEGISLATIVE SESSION

A. Types of drugs that may, and may not, be donated to the Program

Recommendation:

- Develop and maintain a negative formulary of prescription drugs, devices and supplies that would not be acceptable for redispensing.
- Include refrigerated medications, durable medical supplies and previously compounded products on the negative formulary list.

Discussion:

Most states with drug repository programs do not accept donated controlled dangerous substances and require that donated medications must be within 6 months of expiration. A written opinion of the DEA has been requested regarding accepting donations of controlled dangerous substances for use in palliative care. The other states are divided on accepting refrigerated drugs. The patient-specific nature of compounded drugs would also necessitate destruction of those donated medications. Injectables would be accepted as long as they do not require refrigeration and are in unopened containers. The exceptions set forth above will become part of the programs "negative formulary."

In addition to prescription drugs, medical supplies can be costly and are needed by indigent populations. Some examples of necessary and expensive medical supplies are under pads and unopened syringes. In the spirit of public health, the program could

accept supplies such as syringes and promulgate corresponding regulations for the destruction or distribution of supplies. It would be better to receive donated syringes than to have them pulled out of the trash and used on the street. Central Repositories could decide what they can and cannot accept based on available storage.

There is a grave safety concern in accepting donations of medications directly from patients or their families after the medications have been dispensed. The integrity of these medications simply cannot be guaranteed. To keep unused medications off the street, the program could accept all donated medications, but many of them will have to be destroyed.

B. Who may donate drugs to the Program?

Recommendation:

- Allow any individual, institution, manufacturer, or organization to donate to the program
- Require all donors to complete a donation form that allows tracking of the handling of the donation from the time it was initially dispensed to the time it is donated.

Discussion:

A patient or family member may donate to the program. Long-term care facilities may not be able to donate unused medications since the medications either belong to the patients or are credited back to medication benefit programs through the affiliated pharmacies. Assisted living clients or their family members would be able to donate.

The program should require a donation form that will indicate the actual ownership of the medications and how the medications have been handled. This would eliminate medications that should be credited back to Medical Assistance or another entity. Once the medication is dispensed to the end user, the end user is considered to be the owner of the medications. Medications in a hospital setting stay in the hospital's inventory. Medications in nursing homes are returned to the pharmacy and they receive a credit from the pharmacy. Private pay patients in a nursing home could choose to donate to the program. The donation form could include language that indicates that some drugs may be destroyed at the discretion of the program, based on the program's rules and regulations.

C. Entities that may receive drugs for distribution

Recommendations:

- Any medical facility or licensed pharmacy that has applied and been approved as an authorized recipient of donated prescription medications may be designated as a Drop-off Site.
- Authorized, licensed pharmacies that are regionally located may be designated as Central Repositories to receive appropriate medications from Drop-off Sites.
- Only Central Repositories can dispense donated medications.

Discussion:
The Task Force recognized there are not only complex issues regarding the entity receiving donated drugs, but also with the entity dispensing donated drugs. These issues include:

- Appropriateness of donation setting;
- Storage, including temperature requirements;
- State regulation of receiving and donating entities;
- Record keeping and tracking of donor forms;
- Inspection of donated medications;
- Availability to specialized populations e.g., LTC and hospital patients receiving the donated medications vs. the general public; and
- Whether there should be a central repository.

An application process for entities receiving donated drugs would assure that the drop-off points would receive and store donated medications appropriately. The application process would also educate the drop-off points regarding acceptable donor forms and how to forward donated medications to a Central Repository. Regulations could be developed that address this application process. The drop-off point should be a location that is already licensed to handle and store medications, thus keeping the donated medications within the normal distribution chain.

Donations of unused medications could be made at any volunteer pharmacy or medical facility that has complied with the application process. These volunteer drop-off points would then send the donated medications to a Central Repository. Central Repositories could be located in each regional area. The Central Repository would not have to be a retail pharmacy, but must be a licensed pharmacy. The Central Repository would have to have a mechanism for identifying a separate inventory for the donated medications. The number of Central Repositories should be limited so that any one Central Repository has enough donated medications to fill complete prescriptions.

D. Standards and procedures for accepting, storing, and dispensing donated drugs;

Recommended Standards:

- Authorized Drop-off Sites
    a. Accepting Donated Drugs
        i. The donor must complete and sign a donor form releasing the medications.
        ii. There must be an authorized pharmacy or licensed practitioner to accept donations.
        iii. Non-authorized pharmacies that have not applied and been approved to be drop-off points may not receive medications.
        iv. Medications from Health Care Facility patients must be sent by the facility with a donor form signed by the patient or patient's family.

v. Opened Vials - The Drop-off site must send open vials to the Central Repository that may forward to a reverse distributor or destroy the donated medication based on regulatory requirements.
vi. Blister Packs - The Drop-off site must send the packs in its original packaging to a central repository

b. Storing Donated Drugs - all donated medications should be placed into a secure donation box until forwarded to the Central Repository

c. Dispensing Donated Drugs - Authorized Drop-off Sites can not dispense donated medications.

- Authorized Central Repositories

a. Accepting Donated Drugs
   i. Drugs may only be accepted from Authorized Drop-off Sites.
   ii. All medications received must be inspected for lot #s and expiration dates.
   iii. Accept only original unopened sealed, and tamper evident unit dose packaging into the donated inventory for redispensing.
   iv. Must inspect for no visible signs of tampering or adulteration.
   v. Must have written and approved procedures for receiving drugs.
   vi. Must have written and approved procedures for inspecting donated drugs and supplies.

b. Storing Donated Drugs
   i. Maintain a separate inventory for donated medications & supplies donated to the drug repository program.
   ii. Accept only expiration dates - 6 months or more at time of donation (for redispensing)
   iii. Must have a secure area for donated drugs.
   iv. Must allow for inspections of donated inventory and the storage area.
   v. Must have written and approved procedures for the destruction of drugs that follows State and federal guidelines and procedures.

c. Dispensing Donated Drugs
   i. Must maintain separate prescription files for patients receiving donated drugs from the Central Repository.
   ii. Must have an accountable inventory for all donated medications and supplies.
   iii. The physician may fax, mail, etc. a form letter indicating the patient's need to the Central Repository
   iv. The Central Repository will only dispense donated medications as new prescriptions
   v. The medication will be labeled with patient specific information including lot numbers and the most recent expiration date

vi. The name and phone number of patient will be retained at the Central Repository; and
vii. HIPAA requirements will be completed at the Central Repository. Patient specific information will be inventoried and blacked out before it goes on the shelves.

Discussion:
Drop-off points should accept all donated drugs and forward them to Central Repositories for further inspection as soon as possible to avoid expired medications. The Task Force suggests that once a medication is donated that it only be redispensed after it has been documented that the receipt, storage and dispensing standards were met and if the medication is still within date and meets the other standards of the program.

E. Eligibility requirements for individuals wishing to receive donated drugs

Recommendation:
- A physician will determine if a patient should be eligible to be a candidate for the repository program.

Discussion:
Since many drug manufacturers provide free or discounted medications based on a physician's determination, it was suggested that the physician make that same determination for the drug repository program. This would allow insured patients with catastrophic illnesses, but limited means, to also benefit from the program. A simple notation e.g. "donation eligible" on the prescription from a physician would allow the patient to qualify. This would benefit the underinsured as well as the uninsured. The drug repository program should be used as a last resort after other avenues of acquiring prescription drugs has been exhausted. Participants in the program should be aware that there may be a delay in patients getting the drugs.

F. Standards and procedures for inspecting donated drugs

Recommendation:
- Adopt the same standards and procedures that were set forth in the original SB 441 for inspecting and accepting donated drugs into the program.
- The program will be subject to State regulations and inspections.

Discussion:
The process for inspecting donated drugs as included in SB 441 before it was amended required that donated medications under consideration for redispensing be inspected to insure that the drugs were: in original unit dose packaging; sealed and tamper-evident; unadulterated, safe, and suitable for dispensing.

G. Appropriate entity to operate the Program

Recommendations:

- The Board of Pharmacy will promulgate regulations based on the recommendations of the Task Force and will monitor the program under established legislation and regulations.
- The Board of Pharmacy will designate geographically located pharmacies to serve as Drop-off Sites and Medbank of Maryland, Inc. (MedBank) will operate the Central Repositories.

Discussion:
There are entities in the community who want to participate in and help with this program. The State would be responsible for developing statutes, promulgating regulations and monitoring programs for operational compliance and allowing interested stakeholders to apply for approval to participate in receiving, inspecting and dispensing donations. Donating drugs should be an easy process for patients and their families.

The Board of Pharmacy would be the appropriate entity to promulgate regulations, inspect repositories and review audits. The Board of Pharmacy may not, however dispense medications or administer a program that it is responsible for regulating and inspecting.

MedBank is a partially State funded program that maintains pharmacies to dispense drugs donated by manufacturers. MedBank has expressed an interest in becoming a Central Repository. They have eight locations throughout Maryland and use mail order delivery.

H. Liability issues

Recommendations:
- All authorized entities in the program should enjoy liability protection.
- Require the Central Repository to provide clear notification at the time the patient receives a drug that the drug comes from the prescription drug repository program.

Discussion:
The original Senate Bill 441 contained appropriate and adequate language limiting the liability of participants in this program. Most states have a donor form that is completed when medications are donated which releases the donor from liability. There should also be liability release forms for patients picking up the prescriptions. Limitation on liability should be placed in the legislation stating that if a patient accepts medications from the program they know they are receiving medications from a repository program. Patients need to be informed that their medication was donated. Any release information forms for patients receiving donated prescriptions should be sent by the Central Repository and not through their physicians.

I. Fees

Recommendation:

- Allow a fee up to $10.00 for each prescription received to cover program administration costs.
- Provide start-up State supplement based on fiscal note over first 5 years.

Discussion:
Most states throughout the country charge some kind of fee to patients receiving donated medications. It is often related to some proportion of the Medicaid dispensing fee paid to the pharmacy providers. In Maryland that fee is $3.69 for brand name and $4.69 for generic in long-term care facilities and $2.69 for brand name and $3.69 for generic in retail pharmacies. Dispensing and mailings have a nominal cost based on experiences of MedBank. The Task Force was in agreement that there is value in paying a nominal fee. Even for multiple prescriptions there are funds available through charities in the community to help cover the cost.

J. Other matters relating to the establishment of a Prescription Drug Repository Program

1. Costs to Central Repository:

Recommendation:
- Drop-off Sites must assume the costs of getting the donated drugs to the Central Repository.

Discussion:
Drop-off points will incur costs in sending donated medications to the Central Repository. A free or inexpensive distribution system may be worked out that would maintain integrity and confidentiality. In many areas there already is a "pony" system between pharmacies, hospitals, labs and physicians' offices. The pick up for donated medications could be incorporated into a pre-existing system. Volunteer drop-off points transferring donated medications to a Central Repository would do so at their expense unless another secure method of transfer can be established. Wholesale distributors could participate by transferring donated drugs to a Central Repository as a tax benefit or for good public relations.

2. Central Repositories as mail order pharmacies and waiting lists:

Recommendations:
- Consider a mail-order option at the Central Repository
- Do not allow "waiting lists" for medications.

Discussion:
It might be preferable to mail the prescriptions due to the illness of the patient or distance that the patient would have to travel to get to the regional dispensing site. If medications were mailed, the State would need fewer Central Repositories. Mailing prescriptions to patients could result in delays in getting donated medications to patients. Patients would have to be informed that delays may occur and that the

Central Repository may not have the drugs they need or that they may receive a partial fill. A waiting list should be avoided because there is no way to guarantee inventory of any specific medication.

3. Destruction of Drugs

Recommendations:

- The Central Repository should be responsible for determining the integrity of donated medications and whether they are outdated or unusable;
- The Central Repository is the only entity that should decide which drugs may be redispensed.

Discussion:

Some compromised medications may be transferred to a reverse distributor who will try to return them to the manufacturer for credit. Many donated medications will have to be destroyed. The destruction of donated drugs will have to follow State and federal guidelines. The Central Repositories should make the determination of the integrity of donated drugs. Central Repositories should have the current knowledge and expertise and a central tracking system to record what is destroyed.

4. HIPAA considerations:

Recommendation:

- Obliteration of patient specific information should occur only at the Central Repository.

Discussion:

Once the medications are donated, the individuals and entities that handle the donated drugs would be bound by HIPAA to keep the information confidential. Donors should not obliterate information because they might obliterate important labeling information.

5. Will donors be eligible for a tax credit?

Recommendation:

- Do not provide tax credits for donated medications to individuals; and
- Provide incentives to encourage manufacturers

Discussion:

It would be very labor intensive for pharmacists at the drop-off points to look up what donated drugs are worth so that donors may receive a tax credit. Most patients will have only paid a "co-pay" for their medications and not the full retail price. Another consideration is whether tax credits should be given for donated medications that will have to be eventually destroyed by the Central Repository. Companies should be encouraged to allow credits to pharmacies that donate to a Central Repository, rather than returning the drugs to the company.

6. Funding

Recommendation:

- Allow charitable donations to be made to entities that accept donated medications; and
- Recognize the Central Repository as a charitable agency.

Even though the program is voluntary on the part of the drop-off pharmacy or the Central Repository, there may be additional costs incurred. It would be appropriate to allow charitable donations be made to entities that accept donated medications.

7. Sunset Provision

Recommendation:

The Task Force recommends that the program be evaluated on a basis determined by the Secretary of DHMH.

CONCLUSION

The Task Force applauds the legislature for pursuing this issue. A properly implemented drug repository program would eliminate the vast waste of unused medications and would assist appropriate individuals in obtaining the medications they need.

Prescription Drug Repository Programs fulfill a gap in this country between excess unused medications and patients in great need, but without the resources to obtain their **much-needed** medications. **Twenty-one** states have either implemented prescription drug repository programs or have recently passed laws and regulations to establish such programs. The concept is simple. The implementation is more complicated.

Given the public protection issue of guaranteeing the safety of the drug supply in Maryland, it is clear that there are many issues still to be resolved regarding the smooth and safe operation of a Prescription Drug Repository Program in Maryland. The Prescription Drug Repository Task Force discussed the integrity of donated medications. Many patients, or families of deceased patients, although well intentioned in their desire to donate leftover medications, may be uninformed regarding the proper storage and handling of those medications. Leaving medications in the trunk of a hot car, while running a day of errands before dropping the medications at a donation center, is a perfect example of how the effectiveness of donated drugs may be compromised. More sinister adulterations of donated drugs can only be imagined. The Task Force continues to struggle with ways this issue may be resolved. Patients and families may donate prescription medications from their homes, but some of those medications may ultimately need to be destroyed. The Task Force understands that this would severely limit the amount of donated medications available under the program, but the overriding safety concerns must be taken into consideration.

Based on the success of the MedBank program in reaching over 30,000 patients and providing over $89,000,000 in free medications, MedBank would be the repository of choice to act as a Central Repository.

MedBank's own research has shown that over 60% of patients have fewer unscheduled hospitalizations after receiving free medications and 64% had fewer emergency room visits. For each emergency room visit it saves over $1,000 and for every unscheduled hospitalization it saves over $8,000 (HSCRC data). Thus, the value of this repository bill is potentially much greater than the cost of the drugs.

Specific questions that require consideration include: How to assure the integrity of donated drugs; how to avoid exploitation of the program; how to monitor to insure that donated drugs are properly destroyed or properly redispensed; and how to enhance patient safety measures for those to whom the drugs will be redispensed. The Task Force's goal for the remainder of its existence is to provide recommendations for regulations that may be used to answer these questions and support implementation of a Prescription Drug Repository Program in Maryland.

Considering the vast issues involved and the problems that other states have encountered in establishing and implementing a drug repository program, the Task Force unanimously agreed that such a program is feasible in Maryland, although not on as grand a scale as had been originally envisioned.