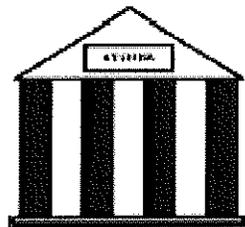
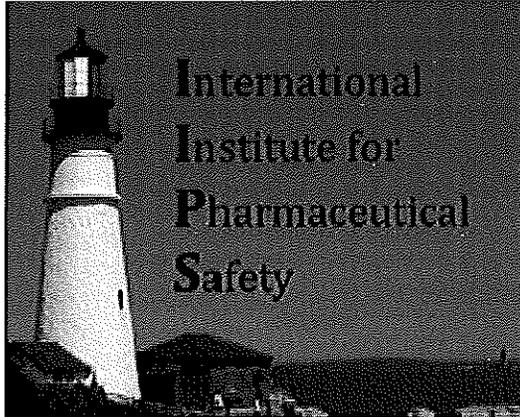


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Gressit, Stevan and Jayne Harper
(2011) Ongoing Medication
Collection Activities Throughout
Maine.



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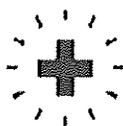
UNE UNIVERSITY OF
NEW ENGLAND

**On-going
Medication
Collection
Activities
throughout
Maine**

A report for Task
Force 3,
Legislative Study
Group for LD 1501

November 30, 2011

Prepared by
Stevan Gressitt
and Jayne
Harper



Your resource for life.
MaineGeneral Health



**DRUG
DISPOSAL**



Six Reasons for Paying attention to consumer drug disposal:

THE ATHENS DECLARATION was unanimously voted on August 3rd, 2007 at the 2nd International Conference on Environment in the City of Athens Cultural Center is as follows:

We, an international group, support the following six reasons to address citizen unused drug disposal:

1. To curtail childhood overdoses
2. To restrict household drug theft
3. To limit accumulation of drugs by the elderly
4. To protect our physical environment
5. To restrain improper international drug donations
6. To eliminate waste in the international health care systems of all countries

We call upon governments, NGOs, and citizens everywhere to correct policies and practices that foster waste in the health care systems of all countries and endanger humans, animals, and our physical environment.

We call upon all countries to renew their support of WHO Guidelines on Drug Donations and the WHO Guidelines on Drug Disposal, and strive to improve on these.

We call upon health care providers worldwide to appropriately prescribe medicines to patients in the most effective form and quantity.

We call upon health care organizations to refrain from policies that promote excessive dispensing.

We call upon patients worldwide to recognize the need for medicine to be taken as intended if it is to be effective.

We call upon governments, NGOs, and citizens worldwide to refrain immediately from improper drug donations either as humanitarian aid following disasters or in general practice.

We call upon others to endorse these principles with us for the betterment of the health of the environment and patients worldwide.



12-26-2004

**Athens,
Greece
August 3rd,
2007**



**DRUG
DISPOSAL**

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Types of drug return

There are four methods of collecting unused drugs from the community: drop off, event driven, pickup, and mailback. Maine leads the nation in the mailback area and serves as a model for both Federal legislation and replication under appropriate Federal regulations and law. Maine has led the nation for

amount collected by weight per capita during each of the three DEA-sponsored community collections too. From these data, this is an issue that requires attention in order to create a permanent solution for proper medication disposal.

Community Event and Drop off

A request for medication collection activities was made among contacts from the Healthy Maine Partnerships throughout Maine. The table below shows a sample of activities taking place in the state although not every coalition is represented here. There may be additional actions going on in other geographic regions that are not highlighted below. The funding source for Community Events is noted in the column to the right of the event for the geographic locations providing these activities since additional resources were needed prior to the National DEA-sponsored collections that included costs of disposal. It is understood the National DEA covers the disposal costs associated with drop-off and pick-up activities and the local law enforcement agencies provide in-kind services of staff time and storage of medications. The mail-back envelope program is described in more detail in a subsequent section.

At present, medication disposal costs have been shifted to the DEA. Prior to this arrangement, a few communities cobbled together funds from grants provided to local Councils of Governments, applied small amounts of funds from Federal Drug Free Communities Grants (in the Maine communities that receive these grants), obtained small grants, and solicited local businesses and citizens for donations to cover costs associated with disposal. This is a precarious set-up because staff who do the work to piece together these funding schemes are typically grant funded and may not be in these positions from year-to-year.

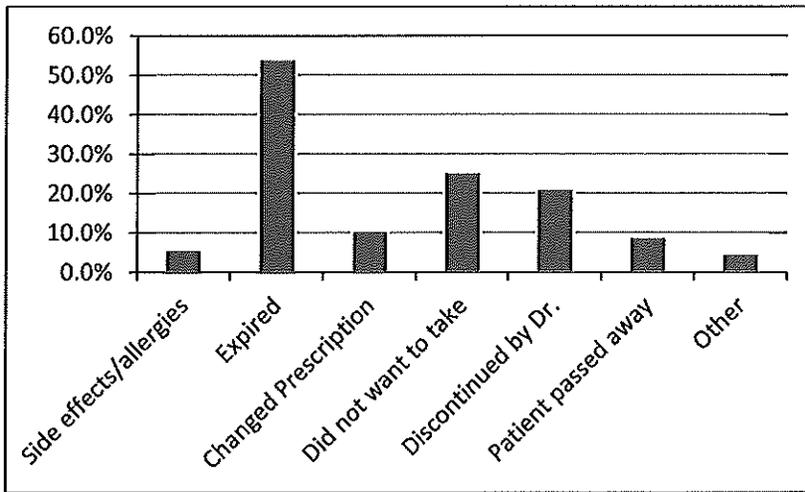
Service Area	Community Event	Collection/Disposal Funding Source	Drop-Off (at LEA)	Pick-Up (by LEA)	Mail-back Envelopes
Healthy Androscoggin: Androscoggin County	Spring/Fall Community Collection Events in Lewiston; 3 DEA-Sponsored Events at LEA's	Fall 2007, Spring 2008- donations from businesses, DFC Grant; Fall 2008- Spring 2010-SSHS Grant + starting in Fall 2010 DEA paid for disposal	Since 2010 DEA-sponsored events		Yes
Choose to be Healthy: Berwicks, Eliot, Kittery, Lebanon, Ogunquit, Wells, York	3 DEA-Sponsored Events at LEA's	DEA paid for disposal	Since 2010 DEA-sponsored events. Plans to purchase 4-5 secure boxes for local police depts (DFC funds for boxes)		Yes
Bangor Region Public Health and Wellness:	3 DEA-Sponsored Events at LEA's	DEA paid for disposal	Since 2010 DEA-sponsored events. Secure boxes at Bangor Police Dept, Veazie Police Dept, Orono Police		Yes

Service Area	Community Event	Collection/Disposal Funding Source	Drop-Off (at LEA)	Pick-Up (by LEA)	Mail-back Envelopes
(continued)			Dept, Brewer Police Dept		
Healthy Lincoln County:	3 DEA-Sponsored Events at LEA's	DEA paid for disposal	Since 2010 DEA-sponsored events: Lincoln Sheriff's Office & Damariscotta Police Dept. collect medications during business hrs		Yes
Partnership for a Healthy Northern Penobscot:	3 DEA-Sponsored Events at LEA's	DEA paid for disposal	Since 2010 DEA-sponsored events. Secure boxes at Lincoln Police Dept, E. Millinocket Police Dept, Millinocket Police Dept		Yes
Healthy Aroostook & Power of Prevention: Aroostook County	2008 & 2009 Medication Disposal as part of Household Hazardous Waste Collection Events; 3 DEA-Sponsored Events at LEA's	Grant funds covered costs of 2008-2009 events (not funded in 2010); starting Fall 2010, DEA paid for disposal	Since 2010 DEA-sponsored events, all police depts. in the county accept unused medications (store until DEA event for disposal)	Yes – Caribou Police Dept	Yes
Access Health: Sagadahoc County, Harpswell, Brunswick area	2005: First community take-back (Topsham, Brunswick, W Bath); 2006-2010: annual events in June & November (Topsham, Brunswick, W Bath; Richmond joined in 2007, Phippsburg joined 2010); 3 DEA-Sponsored Events at LEA's (all sites listed + Harpswell joined 2011)	Grants obtained to help with disposal costs 2005-2010; starting in Fall 2010, DEA paid for disposal	By late 2011, secure boxes will be available at: Topsham Police Dept, Brunswick Police Dept, Bath Police Dept, and Sagadahoc Sheriff's Office. (funds from DFC & Davenport Trust to purchase boxes)		Yes
Planned Approach To Community Health (PATCH), Healthy Communities of the Capital Area; Healthy	2008-2010: Medication Disposal as part of Household Hazardous Waste Collection Events annually in Augusta, Jackman, Pittsfield, Skowhegan, Waterville, Unity; 3	Grants from Kennebec Valley Council of Governments and DFC to help with disposal costs 2005-2010; starting in Fall 2010, DEA paid for disposal	Since 2010 DEA-sponsored events; Secure boxes located at Augusta Police Dept, Gardiner Police Dept, Kennebec Sheriff's Office, Oakland Police	Yes – Kennebec Sheriff's Office	Yes

Service Area	Community Event	Collection/Disposal Funding Source	Drop-Off (at LEA)	Pick-Up (by LEA)	Mail-back Envelopes
(continued) Sebasticook Valley, & Greater Somerset Public Health Collaborative: Kennebec and Somerset Counties	DEA-Sponsored Events at LEA's		Dept, Waterville Police Dept, Winslow Police Dept, Winthrop Police Dept, Fairfield Police Dept, Madison Police Dept, Pittsfield Police Dept, Skowhegan Police Dept, Somerset Sheriff's Office (2011 DPS funds to purchase boxes)		

In Androscoggin County, people dropping off medications at community collection events are asked to complete a short, anonymous survey about why they are disposing of the medications. The chart below shows responses from participating community members from the two events held in 2011.

Oct. 2011 WHY WERE DRUGS RETURNED



What was returned in Maine during the April 2011 DEA Take Back statewide by sample:

Top 10 Therapeutic Class, Wastage by Pill Count

Therapeutic Class	Original Amount	Returned Amount	Waste (%)
Cardiovascular	12350	9344	75.7
Hormone & Hormone Replacement	4201	2601	61.9
Diuretic	2537	1703	67.1
Anticonvulsant	1983	1684	84.9
Antibiotic	1797	1487	82.7
Antidepressant	1692	1280	75.7
Antineoplastic	1966	1144	58.2
Anticoagulant	1567	1116	71.2
Gastrointestinal	1069	968	90.6
NSAID	962	572	59.5

11

Environmental hazard of drugs collected (all were assessed)

PharmEcology® review of returns for environmental hazard*

- No controlled drugs were hazardous wastes
- Seven OTC drugs were RCRA hazardous or potentially hazardous (alcohol content not documented)
- Of Rx drugs, only 15 were RCRA hazardous waste

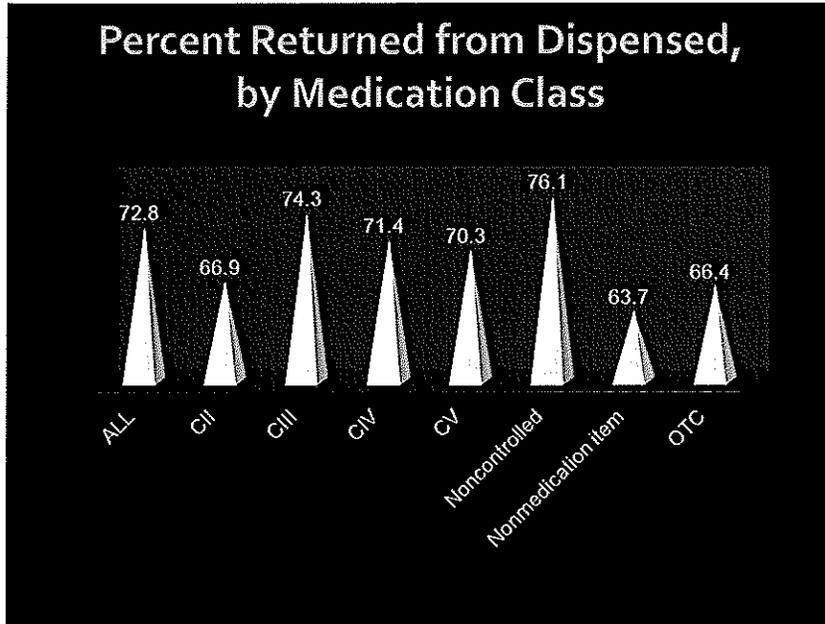
*Analysis performed manually by PharmEcology Services, WM Healthcare Solutions, Inc. based on available data

Maine Take-back Waste Analysis

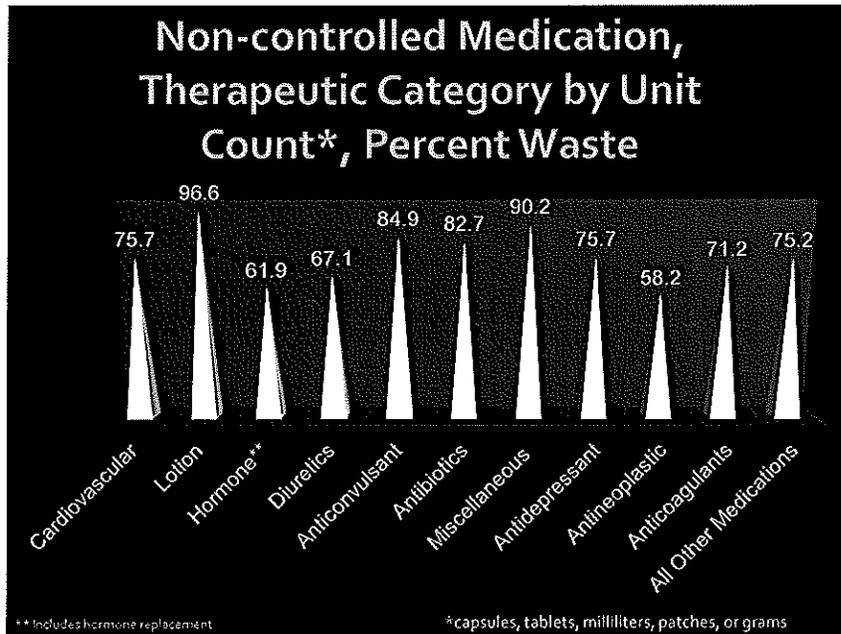
Waste Type	Controlled Substances	Non-Controlled Rx	OTC	Summary	Summary Percentages
RCRA Hazardous	0	15	7	22	4%
PharmE Hazardous	0	25	0	25	4%
Non-hazardous	75	284	195	554	92%
Total	75	324	202	601	100%

Manual analysis performed by PharmEcology Services, WM Healthcare Solutions, Inc. PharmE Hazardous® is a proprietary category developed by PharmEcology Services to identify drugs that are potentially as hazardous as wastes currently "listed" under RCRA, but are not RCRA hazardous wastes (i.e. many chemotherapy drugs).

Wastage by Schedule:



Non-controlled drug wastage for comparison:



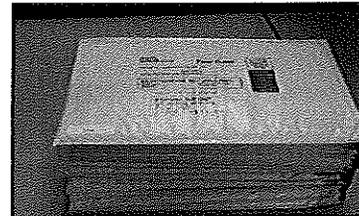


Pickup

The third method, pickup, is exemplified by the Chief of Caribou Police and the Kennebec County Sheriff's Office (KSO). A consumer makes a call to the station and a car is dispatched to retrieve the unused medication and brought to the station. In 2010, deputies from the KSO started asking citizens if they had any unused medications in their homes to dispose of during all calls to homes for any law enforcement need.

It is understood the National DEA covers the disposal costs associated with drop-off and pick-up activities and the local law enforcement agencies provide in-kind services of staff time and storage of medications. This funding stream will end after the last scheduled DEA-sponsored collection.

Mailback



www.benzos.une.edu

www.safemeddisposal.com

Unused medication of consumers and long term care facilities falls under a number of different Federal and State agencies with no harmonization between any States and varying recommendation across Federal agencies. Maine was the first state to enact enabling legislation in 2004 (see: <http://www.maine.gov/legis/opla/drugrpt.pdf>) to facilitate the return of consumer medication. This enabled application for a 2007 US EPA Grant # CH-83336001-0 now completed, see <http://www.epa.gov/aging/RX-report-Exe-Sum/>. Data from that project was instrumental in formulating the MaineCare 15-day rule which limited first prescriptions of opiates, some antidepressants and some antipsychotics, nicotine replacement, and anti-spasmodics to an initial fill of 15 days. Savings has been made and potential for waste diminished. Further review of other drugs based on known adherence and wastage may lead to improvements in pharmacy management and patient outcome. CMS is currently calling for comment based in part on experience in Maine.

The current mailback program in Maine is the only authorized mailback program able to handle controlled drugs from the consumer. Failure of any program to address controlled drugs is simply ineffective.

Initially four colleges, now five [University of Maine Center on Ageing, Husson University College of Pharmacy, UNE College of Pharmacy, UNE College of Osteopathic Medicine, and Marshall University College of Pharmacy] created the International Institute for Pharmaceutical Safety to address all aspects of safe medicine use and disposal from cradle to grave. The Institute is responsible for the oldest continuous prescription drug abuse conference in the State and the oldest continuous drug disposal conference in the world. Stemming from this are models for long term care facility drug disposal which have been demonstrated to various officials in Maine in the past month. In addition the Institute is engaging in exploring methodology for real time fraud detection which in turn might simplify the stability of MaineCare payment systems, not just for pharmaceuticals. An International Association is under formation to improve best practices in all communities dealing with drug disposal. By providing research that compares the relative rate of controlled drug return from event driven takebacks and mailback the Institute was able to present to the Central DEA Office of Diversion that events brought back 8% and mail brought back 17% controlled drugs.

During the period of October 2009 – November 2011, approximately 29,833 envelopes have been distributed to individuals and distribution sites.

During the period of October 2009 – November 2011, approximately 17,095 envelopes containing medicines have been returned through the program.

From 2008 – November, 2011, approximately 21,993 envelopes containing medications have been returned through the program.

Total pounds of medicines disposed of from 2008 to November, 2011, have been approximately 7,170.

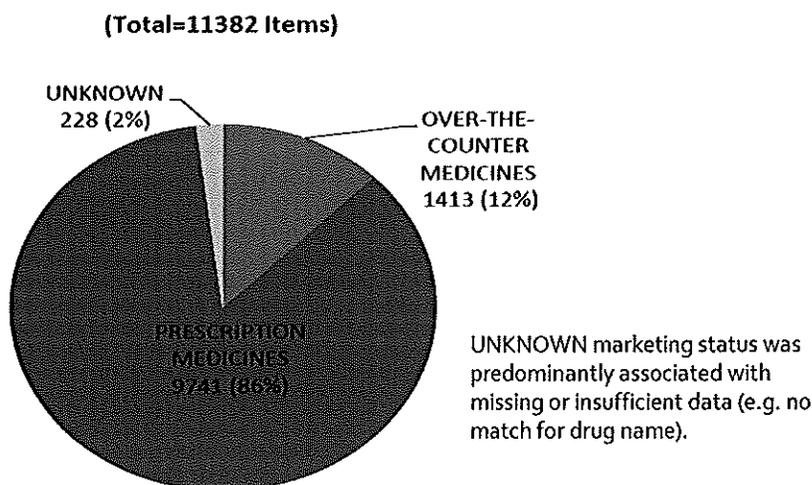
Reasons given on survey for medications being waste:

Participant Survey Results: Top Reasons for Medication Collection in Patient Homes

- A physician told the patient to stop taking the medication or gave the patient a new prescription. (27.3%)
- Medicine belonged to a deceased family member. (19.6%)
- The person felt better or no longer needed the medicine. (18%)
- The person had a negative reaction or allergy to the medicine. (11.9%)

What was returned:

Marketing Status of Returned Medication



Future events and proposals

At some point in the next few months, the US DEA will be issuing proposed final regulations in response to S3397 which directs the US DEA to promulgate regulations to make it easier for the public to dispose of their unused medication. These Federal regulations will supersede State regulations and so there is a natural hold period for initiating any new program other than those above which we have been told will all be permitted to continue.

In addition CMS currently has a request for comment pending and open:

(see lower left column below)

<http://www.gpo.gov/fdsys/pkg/FR-2011-10-11/pdf/2011-25844.pdf>

of an enrollee's medications upon his or her request, and we seek specific comment as to this possibility, as well as to any issues we may need to address to facilitate this possibility. For instance, in order for sponsors to be able to monitor the prevalence and appropriateness of the dispensing of prescriptions in shorter than 30 days supply to ensure that a pharmacy does not dispense a 30-day prescription in stages in order to increase dispensing fees, we urge the industry to develop coding to be used by network pharmacies to communicate to sponsors whether a less than 30 day fill is to align refill dates, or for that matter, is an initial fill of a new medication, or in the case of the LTC setting, is to communicate the dispensing methodology employed.

We believe that realized savings from the daily cost-sharing rate requirement may be partly offset by additional dispensing fees, administrative and programming costs, and additional initial fills of more expensive drugs. We assume additional dispensing fees would result when a trial fill of a medication is dispensed and the enrollee returns to the pharmacy for the remainder of the month's supply (or more) if the medication were successful, or when an enrollee chooses to synchronize medications. Thus, over a year, there would be up to 12 dispensing events for medication continued after a trial fill as opposed to up to 12 Part D sponsors may also incur some costs to program their systems to establish and apply a daily cost-sharing rate to prescriptions dispensed to enrollees with less than a 30-day supply, as well as administrative costs to administer the trial fill requirement we propose here. Finally, we expect some additional costs due to more initial fills of brand drugs that enrollees previously declined to try due to the cost of a full month's supply when the brand drugs are known for significant side effects and/or to be frequently poorly tolerated.

We considered proposing a requirement similar to the Fifteen Day Initial Script program introduced in Maine in the summer of 2009. In this program, specific medications that were identified by the MaineCare program with high side effect profiles, high discontinuation rates, or frequent dose adjustments, were phased in by class and must be dispensed in a 15-day initial script to ensure cost effectiveness without wasting or discarding of dispensed, but unused, medications. We have learned through representatives of the program that MaineCare has achieved overall savings for two

consecutive State fiscal years with respect to both brand and generic drugs through this program, despite the additional dispensing fees. The representatives have also reported that there has been very good acceptance of the program and very little confusion upon implementation. While we acknowledge the savings benefits of the mandatory MaineCare approach, we believe that leaving the decision to obtain less than a month's supply of a prescription with the enrollee and his or her prescriber and pharmacist may be a better approach in light of the voluntary nature of the Medicare Part D program.

A previous review of 2009 PDE data by CMS suggested that just under 32 percent of approximately 78.6 million first fills for maintenance medications are not refilled by Medicare Part D enrollees. Maintenance medications are used for diseases when the duration of therapy can reasonably be expected to exceed one year, and we assume for purposes of estimating savings to the Part D program that the lack of refills indicates the prescribed medications were discontinued. The estimated total cost of these discontinued medications was approximately \$1.6 billion (70 percent for brands and 30 percent for generics). However, this review did not distinguish between community and institutional settings. Thus, to estimate the costs of discontinued medications in community settings only, since the daily cost-sharing rate requirement proposed here does not further change the dispensing requirements in the long-term care setting effective January 1, 2013, we reduced the total costs by approximately 13 percent in accordance with CMS data on gross drug costs in the Part D program in 2009 in the community and institutional settings to remove a proportion representing long-term care expenses. Consequently, the adjusted total estimated cost of 2009 community-based discontinued first fills of chronic medications was estimated at roughly \$1.4 billion.

Potential savings of a daily cost-sharing requirement on Part D sponsors would come from a reduction of these costs which would be offset by some additional dispensing fees. In order to estimate the savings, we must make assumptions about how many first fills will be dispensed in quantities of less than a 30-day supply, and what the average quantity of such first fills will be. It should be pointed out that these assumptions are highly uncertain, because it is very difficult to predict enrollees' behavioral response. Having noted this caveat, we assume 20 percent of first fills in 2013 will be for a supply of less than 30 days, trending to 50

percent by 2018, and that the average of such fills will be for a 15-day supply. Assuming 32 percent of these first fills are discontinued, we estimate the potential savings to the Part D program to be \$180 million in 2013 alone, and over \$2.5 billion by 2018.

We recognize that certain medications are universally accepted in the health care community as not suitable to be dispensed in amounts less than a 30-day supply (for example, lotions and other drugs not in solid form). Therefore, we propose to further limit the requirement that sponsors establish and apply a daily cost-sharing rate to drugs similar to those to which the Medicare Part D long-term care dispensing requirements apply. That is, the daily cost-sharing rate requirement would apply to solid oral doses of drugs, except antibiotics or drugs which are dispensed in their original containers as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, steroid dose packs). However, unlike the long-term care dispensing requirements which apply only to brand drugs, we are proposing here that the daily cost-sharing rate requirement would apply to both brand and generic drugs.

We also understand that, while there may be additional waste generated by multiple fills when medications are continued or synchronized (for example, more plastic bottles and paper inserts, additional trips to pharmacies), the harmful effects on the environment from unused drugs, particularly the biological implications, likely have a much greater impact on the environment than additional recyclables. We seek specific comments as to this assumption.

In light of the foregoing, we propose to define "daily cost-sharing rate" in § 423.100. "Daily cost-sharing rate" would mean, as applicable, the established monthly—

- Copayment under the enrollee's Part D plan divided by 30 or 31 and rounded to the nearest lower dollar amount or to another amount but in no event to an amount which would require the enrollee to pay more for a month's supply of the prescription than the enrollee would have paid if a month's supply had been dispensed; or

- Coinsurance rate under the enrollee's Part D plan applied to the ingredient cost of the prescription for a month's supply divided by 30 or 31. We solicit comment on whether we should establish specific rounding rules so that sponsors are consistently calculating

Within the State however there are some clear and definite points that need to be addressed.

1. Immediate reversal of DEP refusal to grant waivers for in-state as has been done in NH and Wisconsin and which were presented to a previous Commissioner of DEP.
2. Rewrite of DHHS Licensing and Regulatory Affairs regulations regarding Long Term Care Facility disposal of all drugs but particularly controlled drugs such that drugs are disposed of in a timely, secure, and environmentally conscious way.
3. Consideration of development of a return program for sealed unused drugs from closed distribution pharmacy sites for use within MaineCare, as has been done in Georgia since 1997, and now passed in 38 states, see: <http://www.ncsl.org/default.aspx?tabid=14425>.
4. Identification of an agency or collaborative of agencies that follows through on the mission of obtaining funds to continue the successful statewide mailback program. Leadership may be provided by the International Institute for Pharmaceutical Safety or District Coordinating Councils within Maine's public health structure.

5. OSA to encourage the private and community partners across the state to harmonize approaches and best practices by providing support for meetings and communication.
6. DHHS to fund research in to the lessons to be learned from what drugs are returned, why, and how to prevent the waste in the first place.
7. Recruit research academic to conduct evaluation studies of medication disposal patterns and methodologies to bring notoriety, credibility, and on-going funding for the work being done in Maine.
8. Support the collaboration of State agencies local and regional collaborative and universities to identify resources to address the needed education for the public and professionals on the changes the DEA pending regulations will bring to this complex field.
9. DEP should be encouraged to address certifying scientific claims regarding drug disposal.

Acknowledgement and Contact

This presentation includes information collected and compiled by the *Pharmaceutical Collection Monitoring Group* through use of the *Pharmaceutical Collection Monitoring System™*

<http://medicationcleanout.com/DataCollectionProject.aspx>

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