Center for Health Policy Research

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OSU

Health & Medicine Issue Paper

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• Prescription Medicines & Nursing Homes •

A Problem ... A Solution

... that the Oklahoma legislature provide nursing homes and other similar facilities/organizations the authority to capture unused prescription medications; provided that these medications be voluntarily processed and forwarded to designated local dispensing pharmacies for reissue to medically indigent persons only ...

A Perspective

Every month ... in every nursing home in Oklahoma ... a small group of health care professionals will gather to destroy perfectly usable prescription medications. They will spend up to four hours methodically "punching out" pills, one at a time, from blister-packs of prescription medicines. These pills are flushed down toilets, burned in incinerators, or otherwise destroyed. The personnel costs alone of this exercise will likely exceed $1 million. The value of the destroyed drugs is debatable, but is surely in the millions of dollars.

Why are they destroyed? Because nursing homes are complying with existing law. Where do these drugs go? Too often, they are flushed into our public water and sewer systems.

Every year, Oklahomans are asked to contribute to the Oklahoma Low Income Health Care Fund by income tax return checkoff. This appeal has raised less than $40,000 per year. It would take between 50 - 175 years of income tax checkoffs to provide the amount of money that a single change in the law could provide in one year.

Problem Statement

Medications have historically been dispensed in ways to preclude responsible reuse. Contemporary medications are routinely packaged and distributed in ways to preclude tampering, and thus are available for responsible reissuing. The laws and policies governing these practices are clearly out of synch with contemporary packaging and distribution methods. Additionally, the nursing home workers interviewed for this

" ... The FDA has concluded that individual States, which have direct responsibility for regulating pharmacies, nursing homes, and LTCFs, are in a better position to make a determination on a case by case basis for the protection of their citizens ... " Jane E. Henney, M.D., Commissioner of Food and Drugs, August 21, 2000

(see Exhibit 10, Issue Paper Supplement for full text)

• We Conclude •

This proposal is clearly in the public interest and should not conflict with public safety. The FDA suggests that it may be accomplished via a single act of the Oklahoma Legislature.

According to a survey performed by the Texas Medicaid Pharmacy Program, Oklahoma is one of only 12 states that totally prohibits any form of re-use. There are 36 other states that allow some level of drug recycling. Louisiana restricts drug re-use to donations to free clinics, and has a policy similar to that proposed here.

In a single act, the Oklahoma legislature could provide millions of dollars for medically indigent people in Oklahoma communities.

We recommend that the Oklahoma Senate Interim Study Committee craft a proposed law for enactment in the 2001 legislative session.

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paper uniformly expressed dismay with the amount of waste required and expressed support for more creative and appropriate uses of the prescription drugs.

Oklahoma nursing homes and other health care organizations are legally required to destroy millions of dollars of unused prescription medications. Medically indigent Oklahomans may not receive necessary medications because of an individual inability to pay, or the inability of agencies to purchase medications for them. This contradiction would not matter if the wasted sums were small. They are not.

The Tulsa County Medical Society has provided state and national leadership to resolve this contradiction. The Society has received support and encouragement from the Oklahoma legislature, American Medical Association, the federal Food and Drug Administration, a host of Oklahoma-based professional organizations, and others in the development of a contemporary and responsible re-use policy.

Existing bureaucracies and processes have allowed restricted prescrition drug re-use. There are 36 states with restricted re-use policies. There are only 12 ... and Oklahoma is one ... that allows no re-use.

Oklahoma should take immediate advantage of the freedom encouraged by the FDA and create the most flexible and responsible use policies for wasted prescription drugs.

Drugs and Nursing Homes

Few give thought to how prescription medications are obtained and dispensed in nursing homes. It is rare for a nursing home to have an on-site pharmacist available to fill prescriptions. The majority of prescriptions are filled by designated pharmacies that specialize in high-volume packaging, labeling, and distribution.

These pharmacies receive medicines in bulk from pharmaceutical manufacturers. Most medicines are in pill or gel cap form. The pharmacy repackages the medicines in "blister-pack" cards. Normally these medication cards have a one month supply of prescription medicine.

When repackaging these medications, "the blister pack medications are heat sealed. The UPS standard for an expiration date on these medications would be 6 months or 1/4 of the date listed on the original container. " (Exhibit 4).

In the nursing homes, staff will dispense the medicines one dose at a time, while preserving the unused medicine. Upon a change in medication or the transfer/death of a patient, the unused medicines must be destroyed in accordance with existing law, and the policies and procedures of the facility.

It is these medications that could be reused.

Waste vs. Conservation

Our national health policy literature is marbled with laments of excessive and unnecessary waste, high costs, lack of services to the indigent ... and the uncoordinated efforts that cause them. Proposed responses too often require torturing already complex systems to the point of paralysis.

Our public policy practice is littered with outdated and contradictory practices that cause perceived waste, cost increases, and seem to complicate the delivery of services to the indigent. Oftentimes, these practices appear necessary to preserve the greater public good and public safety. Other times, they are simply artifacts of previous generations.

The perceived prohibition of the responsible reuse of prescription drugs is one of these anachronisms.

In the United States, we take great pride in the reuse of human hearts, corneas, livers, and kidneys. We have yet to muster the creativity and procedures to simply reuse perfectly usable prescription drugs in such a manner as to help many and harm no one.

Surely, it can be easily done. Surely, no one must sacrifice revenue or profits. Surely, this can be a win-win proposal. There appears to be no downside.

Pharmacy managers have indicated that the paperwork and tracking of reused drugs need not be complicated, and could likely be easily accommodated within existing control systems.

Table 1
Estimates
Unused Drugs in Nursing Homes

	Oklahoma	National
NH Patient Census	25,000	1,400,000
Value of Unused Drugs	$2.3-7 M	$73-378 M

Table 2
Oklahoma Nursing Homes
Estimated Mix of Destroyed Medications

Category	Percent
Antibiotics	25%
Hypertensives/Cardiac	25%
Analgesics	20%
Gastrointestinal	15%
Diabetes	10%
Other	5%
Total	100%

The Need?

The need for responsible reuse of prescription drugs was a non-issue a generation ago. At that time there were few effective outpatient drugs that made up only a sliver of health care expense. And distribution methods did not lend themselves to reuse models. Today is very different.

There are many powerful drugs that have helped to drastically reduce hospitalizations ... and increase productivity ... of the public. Prescription drugs have become a mainstream therapeutic tool of practitioners. Cardiac care, blood pressure control, diabetes management, disposition control ... are all positively impacted by pharmacology in ways not imaginable 25 years ago. At the same time, delivering necessary care to medically indigent people has become costly and difficult.

There are two ways to fund indigent care services. One is to collect and spend more public revenue. Another is to responsibly redirect wasted resources to indigent care. Consider the political difficulty in raising $7 million dollars to provide needed medications for the medically indigent. It would be politically difficult.

Cost/Savings Estimates

The Center does not have the resources to conduct a real-time study of nursing home drug use and counts. Even if the funds were available, it is unlikely that important proprietary expense/cost information would be shared on a widespread basis. In any event, the exact amounts used/saved are unlikely to be as important as rational policy discussion and a reasonable estimate methodology.

One methodology is to create alternate savings scenarios using the best information available. Table 3 uses waste ratios from 4-15% ... and drug utilization data from the national average of ALL elderly people up to the amounts provided by a dispensing pharmacy manager based upon their sales.

The May 2000 census of Oklahoma nursing homes was 25,021 filled beds (Joe Lamkin, Oklahoma State Department of Health).

Given these assumptions, it is likely that the statewide savings will range from $2.3 million up to $7 million; savings in the Tulsa MSA will range from $350 thousand to over $1 million; and savings in the Oklahoma City MSA will range from over $500 thousand to almost $1.6 million. In reality, localized savings are most relevant as it is likely impractical to recapture all statewide waste.

It is estimated that the statewide personnel costs of this process approach $1.5 million. If four professionals spend up to 4 hours per month destroying these products per 100 nursing home patients, at an estimated cost of $30/hour, $1.44 million will be incurred.

Previous Analyses

There are two reviews of this issue that are recent and relevant. One was conducted by the Texas Health and Human Services Commission per direction of the Legislature. It was released less than one month ago. The second was performed in Oklahoma in 1997 pursuant to HB 1130. The full text is in the Resource Supplement brief. An abstract and analysis of the published final reports are as follows:

Texas Study

The Health and Human Services Commission formed a workgroup to study the feasibility, benefits, costs, and legal issues of recycling unused nursing home drugs. This study was mandated by legislation enacted by the 76th Texas Legislature. The following is quoted verbatim from the study:

Background

The potential waste caused by destroying unused drugs prescribed for nursing home patients has been a public and legislative concern for over two decades. Continuing cost escalation of prescription drugs has promoted a re-evaluation of this multifaceted issue.

Conclusion

With the receipt of the FDA's policy clarification on recycling nursing home drugs, it does not appear to be cost effective for the State of Texas to implement a recycling program. The policy clarification stipulates that only manufacturer's prepackaged products are allowed in a recycling program. This restriction prevents the legal recycling of an estimated 80% of unused nursing home medications. However, it would be beneficial for the State of Texas to have current data on drug waste in LTCFs to determine a true cost/value analysis.

Recommendation

The workgroup recommends the State of Texas find a more comprehensive research study on the topic of recycling unused nursing home medications. This study would provide the additional information that is essential for performing a cost/value analysis. The workgroup recommends the study should:

1) Determine an accurate estimate of the value of unused drugs destroyed annually, including a breakdown by packaging and dosage forms;

2) Evaluate other states experience to determine costs for development and maintenance of recycling programs;

3) Identify selected clinical, administrative, and technological interventions that would reduce the incidence of medication waste and the feasibility of implementing these systems.

This recommendation, if implemented, would serve as an essential preliminary step in determining the feasibility of establishing a cost-effective prescription-recycling program in Texas.

Oklahoma Study
The following is quoted verbatim from the study:

Background
In 1997, the Oklahoma Legislature enacted House Bill 1130 which directed the Oklahoma State Board of Health in concert with the State Board of Pharmacy and the Oklahoma Health Care Authority to conduct a pilot program using anti-ulcer and antiarthritic medications to determine if the use of bubble pack units and the return and reissuance of unadulterated medications is cost-effective and administratively efficient.

Objectives
The purpose of the pilot program is to develop a system to study the number of anti-ulcer and antiarthritic medications destroyed by nursing facilities, to evaluate the costs related to these medications, and to determine the feasibility of returning the medications to the issuing pharmacist for reissue to other residents.

Conclusion
It was the consensus of the participants who evaluated the data, that based on this study, it is not feasible to return the medications to the pharmacy for reissue.

The total impact statewide was figured based on licensed beds rather than occupancy rate. Additional costs are likely to be incurred to maintain a system to ensure the integrity of the medications being returned. Medications returned to the pharmacy with short shelf life remaining may not in some cases be reissued by the pharmacy prior to the expiration date. These factors will reduce the net benefits of the overall effort.

Observation of Texas/Oklahoma Studies
The Texas study was recently completed and released in late August/early September 2000. Correspondence dated August 21, 2000 was included and discussed. This correspondence from the FDA seemed to provide states a newly franchised right to make local determinations concerning this issue. This is the first time that such latitude has been formally offered. Given the date of the letter, and date of the report release, it is unlikely that the new FDA position was fully explored and expanded.

The Oklahoma study was limited to anti-ulcer and anti-arthritic medications of Medicaid patients in 12 Oklahoma nursing homes. Savings on a statewide basis were projected from this sample. It is unclear as to what proportion of all medications were represented by the anti-ulcer and anti-arthritic medications. The statewide savings projected was $253,000. This brief will not argue methodology of findings of that study. However, assuming the lowest of waste estimates and the lowest possible drug use figures ... it is arithmetically impossible that the two categories of drugs could comprise more that a fraction all stocked prescription meds in 2000. Additionally, pharmacology advances continually redefine the mix and costs of popular medications; and changing therapies also influence this mix.

It is suggested that the focus of that study was to recoup savings or rebates for the Medicaid program only in the two categories of medications proscribed. Given those restrictions, one may understand how theoretical recycling process may be thought to offer more cost than benefit.

However, providing the recycled drugs to a single outlet, in a specific area, may produce a different cost-benefit ratio. It is these circumstances that neither the Texas nor Oklahoma studies significantly address. And it is these features that make this Tulsa County Medical Society proposal both unique and feasible.

Analysis & Summary

This brief acknowledges the expertise and diligence of previous considerations given by Boards of Pharmacy and other regulatory agencies. That said, we believe this proposal has several unique features that deserve serious consideration.

This proposal differs from the study objectives in Texas and Oklahoma in two ways.

(1) it is proposed that ALL medications be directed to single identified pharmacies (such as county operated pharmacies) for distribution to medically indigent patients only; and

(2) we believe that simplified regulations may be crafted to allow counties and nursing home groups to either voluntarily participate in recycling to indigent pharmacies ... or continue to destroy the drugs ... whichever is most locally appropriate.

Value of Benefits
There are theoretical savings in every county in Oklahoma. However, these savings may not be "worth it" in low population density areas .. or areas where there are no collegial civic relationships or leadership.

On the other hand, the value to populous areas like Tulsa and Oklahoma counties will likely be significant, particularly if the savings are directed to a single redistribution pharmacy. It would be best if each county could determine the value locally, rather than having a statewide study group determine the value, or lack thereof.

Who Should Benefit?
Some believe that if "recycling" is allowed, it is the right of each patient or insurer to benefit from the recycling. This defeats the economy of scale, civic value, and logistical simplicity of this proposal.

It is likely that a major objection may arise for the principal payor for nursing home care, the Oklahoma Medicaid program. It is suggested that the Medicaid program will benefit much less than will county indigent pharmacies, and that the Oklahoma Health Care Authority excercise leadership in this area by encouraging voluntary and directed recycling to our most needy citizens.

Table 3

Estimated Range
Potential Savings in Oklahoma

Source for 25,021 Occupied NH Beds
Oklahoma State Department of Health, May 2000

	Prescription Drugs Per Patient Per Year		
Waste	**$800**	**$1,300**	**$1,800**
4%	$800,672	1,301,092	1,801,512
7%	1,401,176	2,276,911	3,152,646
10%	2,001,680	3,252,730	4,503,780
15%	3,002,520	4,879,095	6,755,670

Tulsa MSA

Tulsa, Creek, Osage, Rogers and Wagoner Counties

Waste	**$800**	**$1,300**	**$1,800**
4%	123,456	200,616	277,776
7%	216,048	351,078	486,108
10%	308,640	501,540	694,440
15%	462,960	752,310	1,041,660

Oklahoma City MSA

Oklahoma, Cleveland, Canadian,
McClain, Potttawatomie and Logan Counties

Waste	**$800**	**$1,300**	**$1,800**
4%	189,216	307,476	425,736
7%	331,128	538,083	745,038
10%	473,040	768,690	1,064,340
15%	709,560	1,153,035	1,596,510

Notes:

Waste Percentages: The Texas State Medicaid Report provides several estimates of the percentage of prescription drugs destroyed. They are 4% (1991 Texas study); 6.7% (Massachussetts study in 1992); up to 10% (American Medical Directors Association). In addition, an informed Oklahoma pharmacy manager strongly believes that the waste may be up to 15%. The table above uses all four estimates.

Annual Drug Usage: HCFA Office of Strategic Planning reported that the average annual cost of prescription medicine for ALL Medicare beneficiaries in 1995 was $600. It is not unreasonable to assume that cost would be up to $800 in 2000. An informed Oklahoma pharmacy manager has reported that his organization will provide $1,800 of medications per nursing home patient in 2000. It is not unreasonable to assume that the annual cost for nursing home residents will be between $1,300 - $1,800. Therefore these values are used in the above tables.

Savings: The estimated savings are calculated by multiplying the annual drug usage times percent wasted times nursing home census.

Findings

The estimated range of potential "savings" is determined by the 7-15% waste estimate, and the $1,300 - 1,800 annual use estimate. Given these assumptions, is likely that the statewide savings will range from $2.3 million up to $7 million; savings in the Tulsa MSA will range from $350 thousand to over $1 million; and savings in the Oklahoma City MSA will range from over $500 thousand to almost $1.6 million.

Policy Development Timeline

• 1961: the Oklahoma legislature enacted 59-353-24 that made it an unlawful act to reuse prescription drugs under any circumstances. (Exhibit 1, Resource Supplement)

• 1980: the federal Food and Drug Administration enacted a policy guideline stating a similar position. (see Exhibit 2, Resource Supplement)

• 1993: the Oklahoma legislature amended 59-353-24 to include "except as provided by the State Board of Pharmacy." (Exhibit 1, Resource Supplement)

• 1997: the American Medical Association passes a policy statement endorsing the responsible recycling of prescription drugs from nursing homes. (Exhibit 3, Resource Supplement)

• 1998: the State Board of Pharmacy denies having any authority to issue rules for reuse of prescription drugs. The Board cited state law, State Health Department rules, and FDA guidelines. (Exhibit 4, Resource Supplement)

• 2000 (Feb): the FDA states that "the agency would not object if sealed, tamper-evident, within-date medications are returned to the dispensing pharmacy by nursing homes or other LTCFs if the AMA requirements are met ..." (Exhibit 5, Resource Supplement)

• 2000 (May): the Oklahoma legislature did not act upon legislation proposed to create a Special Task Force to resolve this issue. Instead, the Senate President Pro Tem created an Interim Study Committee. (Exhibit 6-7-8, Resource Supplement)

• 2000 (Aug): The FDA writes that it "has concluded that individual States, which have direct responsibility for regulating pharmacies, nursing homes, and LTCFs, are in a better position to make a determination on a case by case basis for the protection of their citizens." (Exhibit 10, Resource Supplement)

Per the recent FDA letter, (Exhibit 10, Resource Supplement) it seems clear that the Oklahoma Board of Pharmacy has both the legal authority, and federal encouragement, to proscribe the policies for the responsible recycling of unused prescription drugs.

Perhaps it is best to enact a clear and defined law that supersedes all existing law, regulations, policies and rules. Many states have gingerly regulated some re-use. No state has yet addressed this issue comprehensively. Many have expressed interest in Oklahoma's leadership. Oklahoma could be, and should be, the first to recognize the net social value of this measure.

Table 4

Estimated Nursing Home Prescription Drug Potential Savings Per County

Source for NH Occupied Beds: Oklahoma State Department of Health, May 2000.
Expense is estimated to be a range of $1,300 (lower) - $1,800 (upper) per patient per year. See discussion at Table 3.
Savings is estimated to be a range of 7-15% of expense. See discussion at Table 3.

County	Patients	Lower	Upper
Adair	132	$12,012	$35,736
Alfalfa	77	7,007	20,799
Atoka	120	10,920	32,444
Beaver	45	4,095	12,220
Beckham	172	15,652	46,353
Blaine	182	16,562	49,149
Bryan	337	30,667	90,938
Caddo	245	22,295	66,176
Canadian	474	43,134	128,032
Carter	520	47,320	140,383
Cherokee	286	26,026	77,176
Choctaw	162	14,742	43,696
Cimarron	32	2,912	8,771
Cleveland	884	80,444	238,776
Coal	64	5,824	17,228
Comanche	498	45,318	134,382
Cotton	72	6,552	19,553
Craig	172	15,652	46,431
Creek	530	48,230	143,074
Custer	248	22,568	66,951
Delaware	390	35,490	105,195
Dewey	120	10,920	32,348
Ellis	52	4,732	13,970
Garfield	876	79,716	236,651
Garvin	489	44,499	132,030
Grady	356	32,396	96,007
Grant	89	8,099	23,934
Greer	59	5,369	16,000
Harmon	92	8,372	24,796
Harper	44	4,004	11,854
Haskell	103	9,373	27,871
Hughes	250	22,750	67,387
Jackson	247	22,477	66,734
Jefferson	147	13,377	39,707
Johnston	104	9,464	27,975
Kay	346	31,486	93,411
Kingfisher	166	15,106	44,933
Kiowa	179	16,289	48,382
Latimer	90	8,190	24,387
LeFlore	417	37,947	112,546
Lincoln	210	19,110	56,752
Logan	384	34,944	103,750
Love	67	6,097	18,029
Major	119	10,829	32,104
Marshall	145	13,195	39,028
Mayes	249	22,659	67,125
McClain	135	12,285	36,433
McCurtain	353	32,123	95,266
McIntosh	224	$20,384	$60,436
Murray	168	15,288	45,290
Muskogee	747	67,977	201,751
Noble	249	22,659	67,160
Nowata	152	13,832	41,005
Okfuskee	147	13,377	39,760
Oklahoma	3,548	322,868	957,908
OKC MSA	5,913	538,083	1,596,449
Okmulgee	423	38,493	114,236
Osage	184	16,744	49,741
Ottawa	240	21,840	64,765
Pawnee	75	6,825	20,259
Payne	434	39,494	117,075
Pittsburg	502	45,682	135,557
Pontotoc	416	37,856	112,250
Pottawatomie	487	44,317	131,551
Pushmataha	142	12,922	38,427
Roger Mills	26	2,366	7,037
Rogers	377	34,307	101,764
Seminole	328	29,848	88,612
Sequoyah	333	30,303	90,006
Stephens	471	42,861	127,240
Texas	66	6,006	17,916
Tillman	131	11,921	35,361
Tulsa	2,625	238,875	708,846
Tulsa MSA	3,858	351,078	1,041,747
Wagoner	142	12,922	38,323
Washington	355	32,305	95,920
Washita	185	16,835	49,854
Woods	159	14,469	42,869
Woodward	155	14,105	41,972
State	**25,021**	**2,276,911**	**6,755,766**

County	Patients	Lower	Upper
OKC MSA	5,913	$538,083	$1,596,449
Tulsa MSA	3,858	351,078	1,041,747
Northeast	4,940	449,540	1,333,765
Southeast	4,412	401,492	1,191,371
Northwest	2,457	223,587	663,477
Southwest	3,441	313,131	928,957
Totals	**25,021**	**$2,276,911**	**$6,755,766**