Presentation by Long Term Care Industry to the Office of Information & Regulatory Affairs Concerning DEA Drug Disposal Rule

OIRA Offices
Washington, D.C.
April 3, 2014

Agenda

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- The Proposed DEA Drug Disposal Rule in LTCFs
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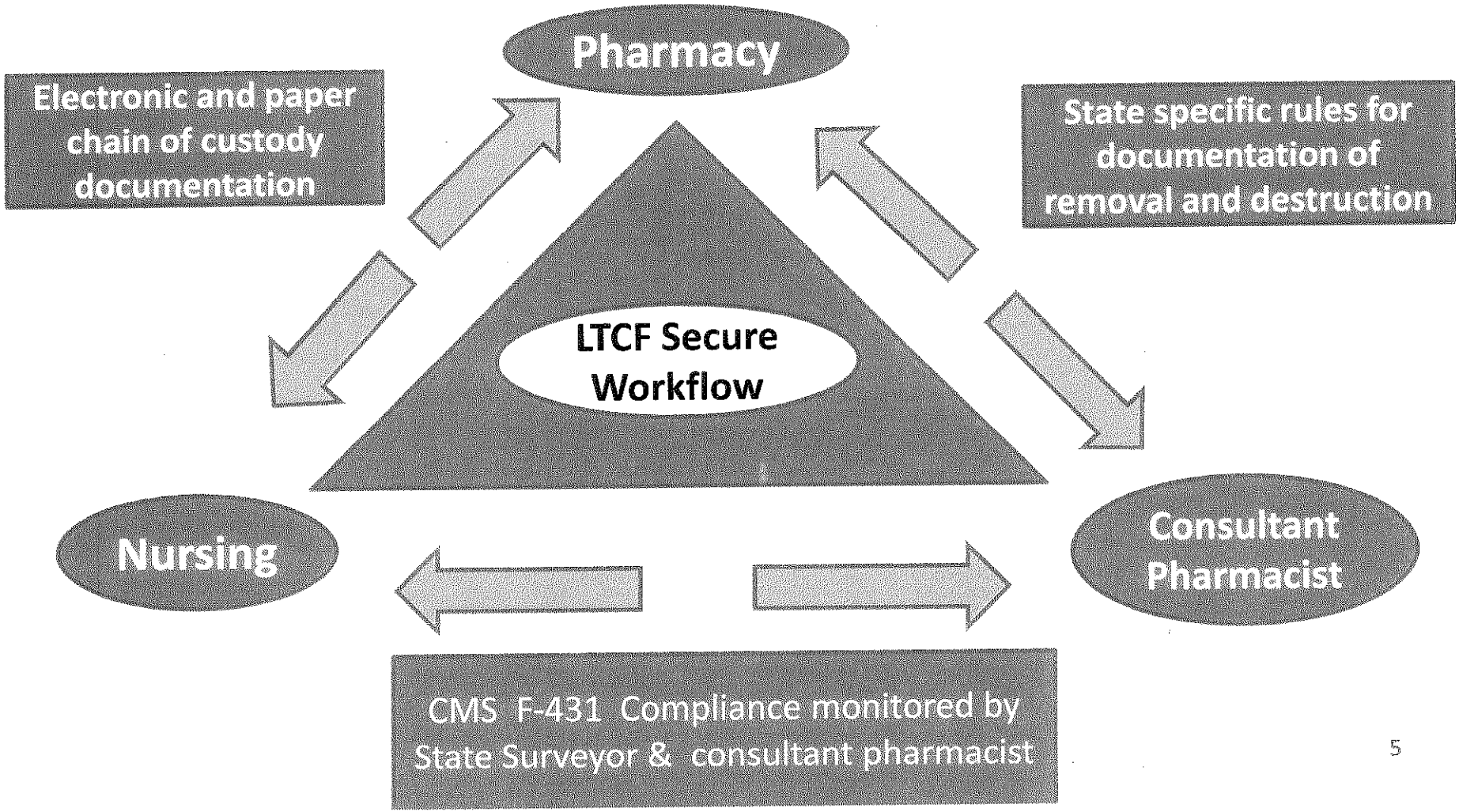
Introductions

- The stakeholders here today include trade groups & business experts in long term care facilities in the U.S.:
  - (a) American Health Care Association (nursing homes)
  - (b) LeadingAge (nursing homes)
  - (c) Genesis (largest post-acute care provider)
  - (d) Omnicare (largest U.S. long term care pharmacy)
  - (e) Millennium Pharmacy (long term care pharmacy)
  - (f) Partners Pharmacy (long term care pharmacy)
  - (g) National Community Pharmacists Association (independent community pharmacies)

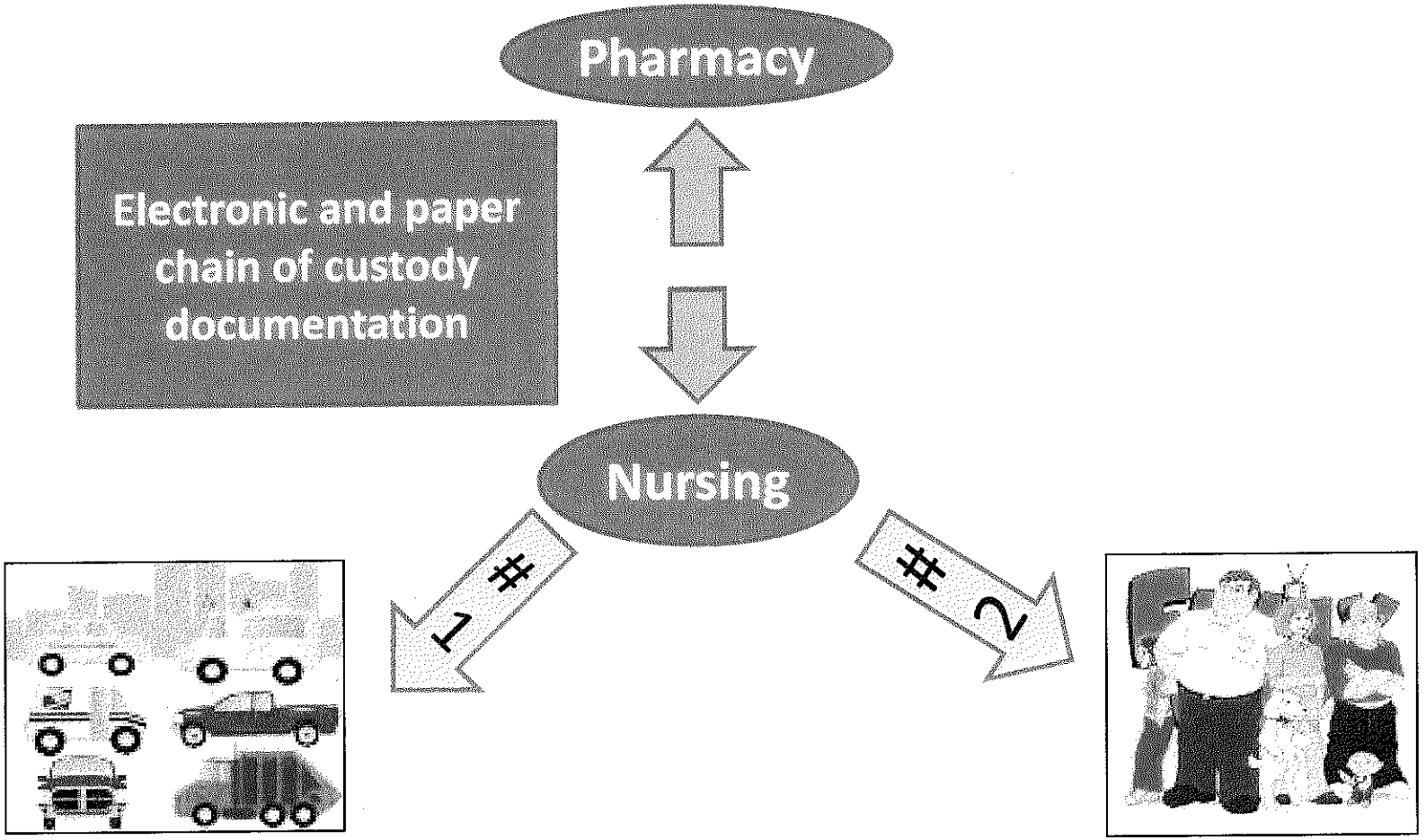
Long Term Care Industry

- The LTC industry serves America's senior citizens & disabled individuals in facilities nationwide.
- There are over 30,000 LTCF facilities across the U.S.
- Very few have on-site pharmacy or pharmacist.
- Most served by specialized "closed door" pharmacies or LTC pharmacies – there are over 2,000 nationwide.
- Medications are specially packaged & typically delivered by independent contractor courier.
- Unlike traditional pharmacies, LTC pharmacies do not have front of house sales.

LTC Industry: The Current Practice for Controlled Drug Management & Destruction



DEA-316 Disposal of Controlled Substances



The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- The proposed rule articulates three methods for "ultimate users" of Rx drugs to dispose of them:
- (1) Take-Back events; (2) Mail-Back Programs; and (3) Collection Receptacles.
- The proposed rule articulates three more specific methods for disposal in LTCFs:
- (1) Self-Disposal by Patient through legal methods; (2) Disposal through Legal Representatives (Family); (3) Disposal via a Collection Receptacle installed and managed at the LTCF only by a retail pharmacy.

The Problems with the Proposed Rule in Long Term Care Facilities

- The disposal methods for LTCFs do not comply with the Secure & Responsible Drug Disposal Act:
  - "In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program. " 21 U.S.C. s. 822(g)(2).
  - Sponsoring Senators wrote DEA to express concerns over LTCFs provisions and compliance with Act requirements.

The Problems with the Proposed Rule in Long Term Care Facilities

- The three proposed LTCF methods are not easily implemented, do not decrease risk of drug diversion risk and their costs outweigh their benefits:
- (1) Self-Disposal – chronically ill & often mentally incompetent seniors cannot self-dispose of drugs;
- (2) Disposal through Legal Representatives (Family) – will lead to more drugs in home medicine cabinets;
- (3) Disposal through a Collection Receptacle - by Only Retail Pharmacies – too costly because new business for pharmacies & LTCF options eliminated.

The True Cost of the Proposed Rule

- The cost of the proposed rule as written is not minimal per DEA because it is not "voluntary" and it does not reflect current business realities in LTCFs.
- The true cost of the proposed rule is between $100M and $300M in the first year across the industry and it is a "significant regulatory action."
- The true cost of proposed rule - it will functionally require LTCFs to install collection receptacles.
- Pharmacies not in the drug collection & disposal business will have to make major capital expenditures without major impact on diversion.

The Proposed Solutions

- The three proposed solutions include:
- (1) LTCF Onsite Disposal – continue to allow LTCFs to do onsite disposal & destruction of drugs;
- (2) Reverse Distributors – allow these DEA registrants currently in business of picking up drugs at LTCFs for destruction to install & empty collection receptacles;
- (3) National Mail-Back Program – create a true national mail-back program through DEA & allow LTCFs to coordinate mailing to central contractor facilities for destruction of unused drugs.

The Proposed Rule

- The proposed rule does not comply with the Secure & Responsible Drug Disposal Act.
- The proposed rule does not create easy to implement options & imposes high costs which outweigh benefits & increase risk.
- The proposed rule is a "significant regulatory action" with costs between $100M & $300M.
- OIRA should ask DEA to consider changing the rule considering actual implementation cost.

Conclusions

- The Long Term Care Facility industry strongly supports the efforts of Congress and DEA to reduce drug diversion & protect Americans.
- The Long Term Care Facility industry supports the effort to create new drug disposal options.
- The Long Term Care Facility industry wants to work with the White House, DOJ and DEA to change the proposed rule to make it easy to implement, cost effective & successful.

ADDENDUM

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

SECURE AND RESPONSIBLE DRUG DISPOSAL ACT OF 2010

Public Law 111–273
111th Congress

An Act

Oct. 12, 2010
[S. 3397]

To amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Secure and Responsible Drug Disposal Act of 2010.
21 USC 801 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Secure and Responsible Drug Disposal Act of 2010".

21 USC 822 note.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The nonmedical use of prescription drugs is a growing problem in the United States, particularly among teenagers.

(2) According to the Department of Justice's 2009 National Prescription Drug Threat Assessment—

(A) the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years;

(B) unintentional overdose deaths involving prescription opioids, for example, increased 114 percent from 2001 to 2005, and the number of treatment admissions for prescription opioids increased 74 percent from 2002 to 2006; and

(C) violent crime and property crime associated with abuse and diversion of CPDs has increased in all regions of the United States over the past 5 years.

(3) According to the Office of National Drug Control Policy's 2008 Report "Prescription for Danger", prescription drug abuse is especially on the rise for teens—

(A) one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds;

(B) teens abuse prescription drugs more than any illicit drug except marijuana—more than cocaine, heroin, and methamphetamine combined; and

(C) responsible adults are in a unique position to reduce teen access to prescription drugs because the drugs often are found in the home.

(4)(A) Many State and local law enforcement agencies have established drug disposal programs (often called "take-back" programs) to facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers.

(B) However, take-back programs often cannot dispose of the most dangerous pharmaceutical drugs—controlled substance medications—because Federal law does not permit take-back programs to accept controlled substances unless they get specific permission from the Drug Enforcement Administration and arrange for full-time law enforcement officers to receive the controlled substances directly from the member of the public who seeks to dispose of them.

(C) Individuals seeking to reduce the amount of unwanted controlled substances in their household consequently have few disposal options beyond discarding or flushing the substances, which may not be appropriate means of disposing of the substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water.

(D) Long-term care facilities face a distinct set of obstacles to the safe disposal of controlled substances due to the increased volume of controlled substances they handle.

(5) This Act gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

(6) The goal of this Act is to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner. This will also serve to reduce instances of diversion and introduction of some potentially harmful substances into the environment.

SEC. 3. DELIVERY OF CONTROLLED SUBSTANCES BY ULTIMATE USERS FOR DISPOSAL.

(a) REGULATORY AUTHORITY.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

"(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

"(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

"(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances. Regulations.

"(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

"(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users

who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

"(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.".

(b) CONFORMING AMENDMENT.—Section 308(b) of the Controlled Substances Act (21 U.S.C. 828(b)) is amended—

(1) by striking the period at the end of paragraph (2) and inserting "; or"; and

(2) by adding at the end the following:

"(3) the delivery of such a substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with section 302(g).".

28 USC 994.

SEC. 4. DIRECTIVE TO THE UNITED STATES SENTENCING COMMISSION.

Pursuant to its authority under section 994 of title 28, United States Code, the United States Sentencing Commission shall review and, if appropriate, amend the Federal sentencing guidelines and policy statements to ensure that the guidelines and policy statements provide an appropriate penalty increase of up to 2 offense levels above the sentence otherwise applicable in Part D of the Guidelines Manual if a person is convicted of a drug offense resulting from the authorization of that person to receive scheduled substances from an ultimate user or long-term care facility as set forth in the amendments made by section 3.

Approved October 12, 2010.

LEGISLATIVE HISTORY—S. 3397:

CONGRESSIONAL RECORD, Vol. 156 (2010):

Aug. 3, considered and passed Senate.

Sept. 29, considered and passed House, amended. Senate concurred in House amendment.

○

The Secure & Responsible Drug Disposal Act of 2010

- The public policy goal is reducing drug diversion by creating new drug disposal methods for "ultimate users."
- The law requires and empowers DOJ/DEA to create these new drug disposal methods and that they be "voluntary."
- The law requires DOJ/DEA to take into account the "public health and safety, as well as the ease and cost of program implementation."
- DOJ/DEA must balance these goals in this rulemaking.
- This proposed rule does not strike the right balance.

The Secure & Responsible Drug Disposal Act of 2010

- The authors of the legislation in the Senate and other Senators – Klobuchar, Cornyn and Grassley wrote to DEA on July 25, 2013 raising the concerns of this group that:
- The proposed rule is not "voluntary;"
- The proposed rule prohibits current disposal options;
- Highlighting that Congress instructed that DEA consider cost and ease of implementation in order to ensure that it truly reduces diversion;
- DOJ/DEA did not publicly respond to substance of Senate comments, but cited APA law and DOJ policy.

United States Senate

WASHINGTON, DC 20510

July 25, 2013

The Honorable Eric Holder
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Michelle M. Leonhart
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Attorney General Holder and Administrator Leonhart:

As the Drug Enforcement Administration (DEA) prepares the final rule to implement the Secure and Responsible Drug Disposal Act of 2010 (Public law 111-273), we urge you to carefully consider the concerns raised by the National Community Pharmacists Association, the Long Term Care Pharmacy Alliance, the American Health Care Association, Leading Age, and other stakeholders in the long term care industry.

The Secure and Responsible Drug Disposal Act of 2010 authorizes the transfer of controlled substances for purposes of safe disposal. It also directs the Attorney General to write regulations for such disposal and to prevent diversion. The law prohibits "a requirement for any entity to establish or operate a delivery or disposal program," thus ensuring the voluntary nature of the program. It also specifically requires the Attorney General to take into account "the public health and safety, as well as the ease and cost of program implementation".

Various stakeholder groups are concerned that the proposed rule is not truly voluntary and that the ease and cost of implementation is too burdensome. Specifically, they are concerned that the proposed rule appears to prohibit all current drug disposal methods used at long term care facilities (LTCFs). While the placement of collection receptacles at LTCFs is technically voluntary under the proposed rule, there is no viable alternative option for disposal of controlled substances if current disposal options are prohibited. LTCFs do not view returning controlled substances to residents or their family as a viable option because it increases the potential for diversion, something that contradicts one of the major reasons why Congress passed the Act.

In addition to directing any new disposal mechanisms be voluntary, the law directs the Attorney General to take into account the cost and burdens of any new disposal programs. The success of any drug disposal rule will be linked to the cost and ease of implementation. To that end, the DEA should make every effort to ensure that the burdens imposed by the rule are not so great as to discourage its use. The DEA should carefully consider the concerns raised by stakeholders related to the added costs of personnel, transportation, and liability required by the proposed rule. We also urge the DEA to meet with stakeholders who have raised concerns before it finalizes

edits to the proposed rule. And finally, we request that you update us on this matter by the end of August.

If you should require further assistance or have any questions concerning our request please contact our staff Caroline Holland at 202-224-3244 or David Bleich and Erika Long at 202-224-3744. We thank you for your prompt attention to our request.

Sincerely,

Amy Klobuchar
U.S. Senator

Charles E. Grassley
U.S. Senator

John Cornyn
U.S. Senator

The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- The proposed DEA Drug Disposal Rule provides for three options in the LTCF context:
- Option # 1: Self-Disposal by LTCF resident - a senior citizen or "ultimate user" at an LTCF can choose to dispose of their own unused drugs through a

  (1) Take-Back event;

  (2) Mail-Back Program; or

  (3) Collection Receptacle at the facility.

The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- Option # 1- Self-Disposal for a LTCF resident is impractical because:

  (1) Seniors are often mentally incompetent;

  (2) Seniors are often chronically ill;

  (3) Seniors are often not mobile;

  (4) Seniors often don't understand their own drugs or when they need to be disposed of;

  (5) Self-disposal by LTCF seniors increases the risk of prescription drug theft or diversion.

The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- Option # 2: Legal Representative Removal - a legal representative or "any person lawfully entitled to dispose of a decedent's property" can take the unused prescription drugs from a deceased relative's LTCF room and walk out of the LTCF or nursing facility with the unused drugs.
- The legal representative is then supposed to dispose of the drugs through lawful means such as through a DEA authorized collector or designated law enforcement official.

The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- Option # 2:

  (1) Increases the diversion risk because it puts the drugs into the hands of someone who can steal them, sell them or put them in a home medicine cabinet;

  (2) Has no record keeping requirement for a family member who takes the unused drugs out of the nursing home so neither DEA nor the home can track them.

The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- Option # 3: Collection Receptacle – LTCF staff can put unused drugs in a "collection receptacle" installed by a DEA registered retail pharmacy authorized to be a "collector."
- The collection receptacle can only be emptied by two authorized full time employees of the installing retail pharmacy who must be present at the LTCF to "remove or supervise" removal of the inner liner from the collection receptacle.

The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- Option # 3 conflicts with the Act's language on cost because:

  (1) It requires retail pharmacies to install and empty the collection receptacles, which is not their business, but does not permit DEA registered "reverse distributors" to empty receptacles alone, even though it is their business;

  (2) Retail pharmacies do not have 2 full time employees to send to LTCFs to install & empty collection receptacles;

  (3) Retail pharmacies must hire hundreds of new employees and buy hundreds of new trucks and equipment to comply with this proposed rule because they are not in the drug retrieval & destruction business.

The Proposed DEA Drug Disposal Rule in Long Term Care Facilities

- DEA is eliminating current options for LTCF drug disposal and destruction at the facility.
- A LTCF is not permitted to deliver or transfer the controlled substances off-site.
- If no collection receptacle, LTCFs are not otherwise permitted to dispose of a controlled substance on behalf of an ultimate user.

The True Cost of the Rule

- The true cost of the rule is between $100 million and $300 million in the first year based on an analysis performed by Omnicare.
- The basic assumptions in the analysis include that:

  (1) Pharmacies will have to hire 2 new employees to install & empty collection receptacles;

  (2) Pharmacies will have to buy new trucks for every pharmacy facility to collect drugs and pay all related costs of maintaining them;

The True Cost of the Rule

- The basic assumptions in the analysis include that:

  (3) Pharmacies or LTCFs will have to purchase thousands of new collection receptacles to install at their LTCF customers across the U.S.

  (4) Pharmacies or LTCFs will have to contract with reverse distributors for the destruction of drugs.

DEA Proposed Rule on Disposal of Controlled Substances

Industry-Wide Cost Estimate

The long-term care (LTC) provisions in the DEA proposed rule on drug disposal could potentially cost between **$100 and $300 million in the first year** based on estimates prepared by the LTC pharmacy industry (using October 2013 data). A detailed cost analysis is below. Please see next page for an explanation of key assumptions made as part of the cost analysis.

Cost Item	High Estimate Cost Calculation 27,000 facilities with receptacles, and 2,000 pharmacies providing disposal service	"High" Cost Estimate	Low Estimate Cost Calculation: 15,000 facilities with receptacles, and 500 pharmacies providing disposal service	"Low" Cost Estimate
Outer Locked Container	$500 per container** 27,000 SNF and ALF facilities	$13.5 million	$500 per outer container. 15,000 SNF facilities (only)	$7.5 million
Sealable Inner Liner	$109 per liner** 12 liners a year ($1,308) for a facility's year supply 27,000 SNF and ALF facilities	$35.3 million	$109 per liner 12 liners a month ($1,308), for a facility's year supply 15,000 SNF facilities (only)	$19.6 million
Vehicle Acquisition	$28,000 for large vehicle 2,000 pharmacies offering disposal service	$56 million	$28,000 for large vehicle 500 pharmacies offering disposal service	$14 million
Vehicle Fuel & Maintenance	$1,069 cost per vehicle Yearly cost of $12,828 2,000 vehicles (one per serving pharmacy)	$25.7 million	$1,069 cost per vehicle Yearly cost of $12,828 500 vehicles (one per serving pharmacy	$6.4 million
Insurance Costs	$1800 (physical damage) + $1200 (liability) per vehicle = $3,000 per vehicle per year $3,000 x 2,000 vehicles	$6 million	$1800 (physical damage) + $1200 (liability) per vehicle = $3,000 per vehicle per yr $3,000 x 500 vehicles	$1.5 million
Dedicated Labor (2 FTEs)	$30,000 annual salary per employee, plus benefits (15% of wages), so $69,000 (2 FTEs) per pharmacy 2,000 pharmacies	$138 million	30,000 annual salary per employee, plus benefits (15% of wages), so $69,000 (2 FTEs) per pharmacy 500 pharmacies	$34.5 million
Disposal/ Destruction Services	$108 per liner per month $1,296 a year per facility 27,000 SNF and ALF facilities	$35 million	$108 per liner per month $1,296 a year per facility 15,000 SNF facilities (only)	$19.4 million
TOTAL First Year Costs		**$309.5 million**		**$102.9 million**
TOTAL Annual Cost (after first year)		$240 million		$81.4 million

**Product not currently available, per DEA specifications. Estimate based on potential prototype developed by leading medical waste company.

DEA Proposed Rule on Disposal of Controlled Substances

Industry-Wide Cost Estimate

** Key Assumptions **

"High" Cost Estimate – the following are assumptions considered as part of this analysis:

- Number of long-term care facilities with receptacles (27,000): According to CDC data, there were 15,702 nursing homes in the U.S. in 2012. According to National Center for Health Statistics data, there were 31,100 residential care facilities in 2010, of which 35% (about 11,000) had 26 or more beds. Therefore, 15,700 SNF beds plus 11,000 ALF beds (in larger facilities).
    - Under the proposed rule, a 'LTC facility' that would be to subject to the drug disposal requirements is "a nursing home, retirement care, mental care, or other facility or institution which provider extended health care to residents."
    - The DEA has interpreted an LTCF to include assisted living facilities under other regulations, such as those related to faxed controlled substance prescription requirements.

- Number of LTC pharmacies that could potentially offer disposal services (2,000 LTCPs): According to SDI Health, there are over 2,700 long-term care pharmacies in the U.S. The "high" estimate assumes 2,000 LTCPs will offer the drug disposal service.

"Low" Cost Estimate – the following are assumptions considered as part of this analysis:

- Number of long-term care facilities with receptacles (15,000). This figure reflects CDC data (mentioned above) on number of nursing homes in the U.S. This cost estimate assumes no other type of facility would have to meet the drug disposal requirements.

- Number of long-term care pharmacies that could potentially offer disposal services (500 LTCPs): According to SDI Health, there are over 2,700 long-term care pharmacies in the U.S. The "high" estimate assumes 500 LTCPs will offer the drug disposal service.

The following are assumptions included in BOTH the "High" and "Low" Cost Estimates:

- Cost of outer locked container ($500 each): This estimate reflects a new prototype outer container that meets DEA requirements.

- Cost of inner liners ($109 each). This estimate provided by a leading medical waste company. The inner liner meets the requirements established under the rule – tear-resistant, tamper-resistant, contents are not visible, etc.

- Disposal and Destruction Services ($108 per liner). This figure is based on a leading drug waste company's estimated cost for the pickup (at the pharmacy) and destruction costs. While reverse distributors are allowed under the rule to haul away and destroy the contents of the inner liner, subject to the pharmacy employees' oversight of the pick up at the facility. Yet this cost – whether it's paid for by the pharmacy or the reverse distributor – is a direct cost resulting from the proposed rule.

- Insurance costs ($3,000 per vehicle per year): This reflects annual costs for both physical damage coverage and liability coverage.

- Vehicle acquisition costs and fuel and maintenance costs ($28,000 vehicle and $1,069 monthly cost). These figures are based on the estimated cost of a Ford Econoline truck, and the gas and maintenance costs.

- Dedicated Labor (Two Full-Time Employees) @ $69,000 total annual cost: The proposed rule requires two pharmacy employees to handle and/or oversee the removal of the inner liners. Each employee's annual salary is estimated to be $30,000, plus benefits as full-time (at 15% of wages).

- Frequency of inner liner removals (monthly): Both estimates assume once-a-month removal of an inner liner at a facility.

- Size of inner liner (18-gallon): Both estimates reflect an 18-gallon inner liner.

The True Cost of the Rule

- One time costs: $21.5 – 69.5 million
  - Container + collection vehicles
- Repeating disposal costs: $39 – 70.3 million
  - Liners + disposal
- Collection costs: $42.4 – 169.7 million
  - Labor + fuel/maintenance/insurance
- Total: $102.9 – 309.5 million

Conclusion

- The Long Term Care Industry is asking that DEA make changes to the proposed rule.
- The Long Term Care Industry is asking that OIRA ask DEA to do a true cost impact based on the fact that the proposed rule as written is mandatory for LTCFs.
- The Long Term Care Industry is willing to work with DEA to make the rule comply with the Act and be easy to implement, cost effective & reduce diversion.