TUESDAY, JUNE 10:
DISPOSAL OF CONTROLLED SUBSTANCES
Management of Unused Patient Dispensed Medications

Merging the Sharps TakeAway with the Sharps MedSafe Program

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In the U.S.

- Approximately 4 billion prescriptions are filled in the United States annually.
- 35% of the dispensed medication goes unused.
- Over 250 million pounds disposed of improperly.
Unused Patient Medication

• Flushing unused patient medications down the toilet or sink can contaminate ground and drinking water
• Waste water treatment plants ill-equipped
• Improper disposal into the trash may lead to accidental ingestion and leaching from landfills
• Unintended ingestion by children or pets can also occur
• Prescription drug abuse is on the rise
The IPA Current Program

TAKEAWAY™
ENVIRONMENTAL RETURN SYSTEM

medsafe
In 2005 Iowa State Legislature passed House File 724 - Prescription Drug Donation Repository Program

• Authorizes medical facilities and pharmacies to re-dispense prescription drugs and supplies that would otherwise be destroyed.
February, 2007, FDA worked with the White House Office of National Drug Control Policy (ONDCP) to develop the first consumer guidance for proper disposal of prescription drugs:

– Follow any specific disposal instructions
– Do not flush prescription drugs unless instructed you to do so
– Kitty litter and trash
– Take advantage of community drug take-back programs
– Scratch out identifying information
– Do not share drugs
– When in doubt about proper disposal, talk to your pharmacist.
How did the TakeAway™ Environmental Return System program come into being?

- Senate File 467 signed into law
- Pharmacy-based pharmaceutical collection and disposal pilot program.
- A $165,000 grant from the Iowa Department of Natural Resources was awarded to the Iowa Board of Pharmacy
- Implemented and administered by Iowa Pharmacy Association and Sharps Environmental Services, Inc.
TakeAway Environmental Return Systems™
TakeAway® Capabilities

• Unique operational agreement with USPS for envelopes
• Boxes shipped through UPS
• Tracked, validated and measurable results
• Process
  – Handled by licensed law enforcement officials
  – Securely stored (packaging is never opened)
  – Weight and date stamped
  – Witnessed and assured destruction
• No controls allowed
# IOWA Pharmacy Association Activity Summary

Reporting Period As Of Sunday, March 23, 2014

## 20 Gallon TakeAway Environmental Return

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systems Shipped</td>
<td>3,998</td>
</tr>
<tr>
<td>Returns</td>
<td>2,972</td>
</tr>
<tr>
<td>Compliance (Systems Returned / Systems Shipped)</td>
<td>74.34 pct</td>
</tr>
<tr>
<td>Total Return Weight</td>
<td>92,607.50 Lbs</td>
</tr>
<tr>
<td>Average Return Weight</td>
<td>31.16 Lbs</td>
</tr>
<tr>
<td>Total Return Tare Weight</td>
<td>79,530.70 Lbs</td>
</tr>
<tr>
<td>Average Return Tare Weight</td>
<td>26.76 Lbs</td>
</tr>
<tr>
<td>Estimated Scripts Count</td>
<td>231,362 Scripts</td>
</tr>
<tr>
<td>Average Scripts Per Return</td>
<td>78 Scripts</td>
</tr>
</tbody>
</table>
Secure & Responsible Drug Disposal Act of 2010

- Controlled substances are 5 to 10% of medications collected, but are the larger problem
- Currently, long term care facilities (LTCF) can only dispose of controlled substances through Reverse Distributors or by destroying onsite
- Retail pharmacies cannot take back controlled substances from ultimate users
- Act allows for
  - Take-back events (must include law enforcement)
  - Mail-back programs (certain situations)
  - Collection receptacles (certain locations)
2012 Proposed Change to 21 CFR Part 1300

• 21 CFR part 1300 regulations
  • Can deliver unused portions of controlled substances to another entity for destruction without DEA registration if
    • The person receiving controlled substance is “authorized”
    • The drug is disposed of in accordance with regulations issued by the Attorney General.
    • Finalized rule requirements from the DOJ/DEA expected June, 2014
MedSafe and TakeAway Envelopes

The Sharps Compliance Solutions

MedSafe Onsite Collection Receptacle

Mailback Envelope
MedSafe
Pharmacy Collection Receptacle

Collection Receptacle

Inner Liner
Collection Receptacle

• Replaces the TakeAway boxes
• 14-gauge powder-coated steel construction
• Two locks secure main door
• One-way medicine drop with lock
• Removable, shipback Inner Liner
• Ships fully assembled with an Inner Liner, two padlocks and keys for the 3 locks
• Low maintenance
• Secures to floor or wall
• Signage for ultimate user instructions
• Collection instructions on inside of door
• Currently undergoing security testing to UL 291
Inner Liner

• Cost-effective pre-paid return via common carrier
• Traceable with unique barcode
• Includes all components to package for return
• Modeled after popular 20-Gallon TakeAway Environmental Return System
  – Footprint similar (slightly larger)
• Meets pending DEA regulations for both non-controlled and controlled drug collection and removal for destruction
The Process

• MedSafe receptacle is placed visible to pharmacy counter
• Signage and marketing materials instruct ultimate users what to place into receptacle
• Customer places controls and non-controls into receptacle...not taken by pharmacist
• Shipped UPS or picked up when full
• Never opened or sorted
TakeAway Envelopes and the New DEA Regulations

• Mailback envelopes will still be utilized
• A few adjustments will be made to current envelope
• Provided to ultimate users at the pharmacy counter to be taken home, filled and mailed
SharpsTracer® Tracking Capabilities

- Same as TakeAway
- Secure, proprietary online data warehouse, unique for each client.
  - Outbound inventory
  - Returned inventory
  - Date of return
  - Condition of return
  - Weight of return
  - Current status of return (stored)
  - Date of destruction
  - Effectiveness check
  - Number of scripts returned
  - 7/24 access
  - Availability of customized reporting
MedSafe - Marketing Materials

- 4-page full color brochure
- 4-page pdf brochure (email)
- PI Sheet
- Promotional slick
• Sharps: www.sharpsinc.com; 800-772-5657
THANKS FOR ATTENDING!

JOIN US TUESDAY, JULY 8:
MEDICAL CANNABIS ACROSS THE UNITED STATES

Questions? Contact Laura Miller at lmiller@iarx.org or 515-270-0713