Pharmacy Drug Disposal Program

Joint Commission on Health Care
September 18, 2018 Meeting

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Study Mandate

- SB 862 (Senator Vogel) would have required participation in a drug disposal program by pharmacies that:
  - dispense Schedule II and III controlled substances;
  - do not dispense primarily by mail, common carrier, or delivery service; and
  - are not located within a hospital.
- SB 862 was Passed by Indefinitely in Senate Education and Health
- Letter from the Senate Clerk requested that the JCHC study the subject matter contained in SB 862
  - Executive Subcommittee and JCHC members approved study for 2018

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Background – Prevalence and Potential Health Risks of Unused Medicines

- Prevalence of unused prescription medicines
  - Two-thirds of prescriptions are not consumed (2015 study)
  - 62% - 92% of surgery patients report having unused prescribed opioids (2017 review)
  - 54% of unused/expired medicines are stored in home (2006 study)
- Potential health risks of unused medication
  - Diversion/misuse
    - Almost 60% of individuals misusing painkillers received those medicines from a friend, family member, or dealer (2016 national survey data)
    - 65% of a sample of veterans stockpiled opioids, with 34% of those stockpiling for recreational use (2014 study)
  - Re-use of prescribed medicines
    - 17% of patients re-used leftover prescription antibiotics without consulting a physician (2001 study)
  - Accidental exposure to medicines
    - Nationally, approximately 60,000 emergency department visits are made annually for unsupervised ingestion of medicine by children under 6
    - While not disposing of unused medicine is a risk factor, evidence of the role of unused medicines on poisonings is highly limited

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Background – Potential Environmental Risks of Unused Medicines

- Main pathways for aquatic presence of Active Pharmaceutical Ingredients (APIs): excretion (e.g., in urine), removal after washing (e.g., topical medicines), sewering/trash disposal
- Guidance:
  - Environmental Protection Agency (EPA): “Prescription and over-the-counter drugs poured down the sink or flushed down the toilet can pass through the treatment system and enter rivers and lakes…Water treatment plants are generally not equipped to routinely remove medicines.”
- Evidence:
  - Prescription/non-prescription medicines detected in 80% of U.S. streams; non-prescription drugs detected at highest frequency (2002 study)
  - 80% of most prescribed active pharmaceutical ingredients detected in at least one stream sampling location (2015 study)
  - However:
    - Some evidence indicates that toxicity risks to humans and antibiotic resistance are low, while toxicity risks to aquatic life may be of concern

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Background – Federal Disposal Regulations

- Secure and Responsible Drug Disposal Act (2010) amended the Controlled Substances Act, allowing public to deliver unused controlled substances to law enforcement agencies
- DEA rule (2014) authorized retail pharmacies to become authorized collectors by modifying DEA registration*
- Key disposal, collection and destruction requirements:
  - Schedule II-V and non-controlled medicines allowed
  - Collection receptacles must meet certain security requirements
  - Pharmacy personnel cannot inspect collected material or handle pharmaceuticals being disposed
  - Destruction must render pharmaceuticals "non-retrievable"
    - Incineration is the only method that currently meets DEA standard

* Other authorized collectors include: manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy

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Background – Common Disposal Methods for Medicines

Method	Meets DEA standard	Recommendation:	
		FDA	EPA
Disposal bin (secure receptacle maintained by authorized collector)	✓	***	***
Mail-back (use of approved envelope)	✓	***	***
Landfill (co-mingling in household trash)		**	**
Sewering (flushing down toilet/drain)		*	*
Medicine destruction products (by disintegration)			

*** 1st choice; ** 2nd choice; * 3rd choice/limited applicability

Illustrative disposal bins:

Illustrative mail back envelope:

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Background – Limited Use of and Access to Recommended Disposal Methods

- Use:
  - < 10% individuals consider or use FDA-recommended disposal methods
- Access:
  - Nationally,< 3% eligible entities have registered as DEA-authorized collectors
  - <15% of rural population live within 5 miles of disposal bins and almost 45% of rural population live more than 30 miles away
- Virginia:
  - Currently, approximately 4% of pharmacies are registered as authorized collectors
  - The percentage of Virginia population living within 5 miles of disposal bin (25% - 49%) is below national average (around 50%)

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Medicine Disposal Initiatives in Virginia – Governor's Task Force Recommendations

- In 2015, Governor's Task Force on Prescription Drug and Heroin Abuse made 10 recommendations related to medicine disposal/collection

Recommendations fully or mostly addressed

Recommendation	Action(s) taken
Promulgate regulations regarding pharmacy collection and mail-back programs	Regulation promulgated (VA 18 VAC110-20-211)
Review/update Office of Attorney General's "Take Back Event" guidance for law enforcement document	OAG confirmed document updated (as of 2015)
Determine feasibility of using mobile incinerators for medicine disposal	Determined to not be a viable/sustainable option
Determine preferred methods for disposing of unwanted/needed medicines	Survey of law enforcement agencies conducted

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Medicine Disposal Initiatives in Virginia – Governor's Task Force Recommendations (2)

Recommendations partially addressed/in progress (as of 2015)

Recommendation	Action(s) taken	Recommended action(s) not taken/in progress
Increase disposal opportunities via medicine take-back events held within the community	Letters sent by HHR/Public Safety Secretaries, DOE to stakeholders stressing importance of proper drug disposal	Emails from Secretaries to various audiences to increase awareness of prescription drug abuse; informational resources for state website; development of mechanism for receiving notifications regarding upcoming take-back events
Encourage placement of collection boxes in every locality and subsequently inform Virginians of their locations	DHP website lists pharmacy take-back locations	Purchase/place additional collection boxes
Increase # of law enforcement agencies participating as medicine collection sites/opportunities for take-back events	Additional law enforcement agencies applied for CVS Health grants for collection boxes	Identify funding resources for collection boxes; identify lead coordinator

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Medicine Disposal Initiatives in Virginia – Governor's Task Force Recommendations (2)

Recommendations not addressed (as of 2015)

Recommendation	Recommended action(s) not taken
Increase disposal opportunities via mail-back programs and collection boxes provided by pharmacies	Meet with stakeholders to evaluate feasibility of increasing voluntary participation
Determine ongoing funding sources for medicine disposal	Consider use of grants and/or state appropriation
Encourage distribution of lock boxes with controlled substances when dispensed	Include funding for printing/shipment of brochures in an agency budget

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Current Medicine Disposal Initiatives in Virginia

- Opioid Prevention, Treatment – Recovery (OPT-R) grant (2018-2019)
  - OPT-R prevention activities include safe medicine storage and disposal initiatives, such as: distribution of medicine deactivation packets, prescription medicine lock boxes for consumers, smart pill bottles; organization of medicine take-back events
  - In OPT-R Year 1, approximately 2,324,000 encounters were made or participants reached
- Local Virginia Department of Health (VDH) offices offer medicine destruction pouches free-of-charge to consumers
  - Approximately 110,000 pouches have been distributed to health districts and 100,000 pouches remain in stock at Virginia Department of Health (VDH) headquarters

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Medicine Take-Back Locations and Statistics in Virginia

- Law enforcement agencies
  - Approximately 6 tons were collected in 2016 by law enforcement agencies receiving CVS Health grants to house medicine disposal bins
  - Approximately 11.5 tons were collected in Virginia in 2016 during National Take Back Days
- Pharmacies
  - Pharmacy locations with drug disposal bins do not consistently track tonnage disposed

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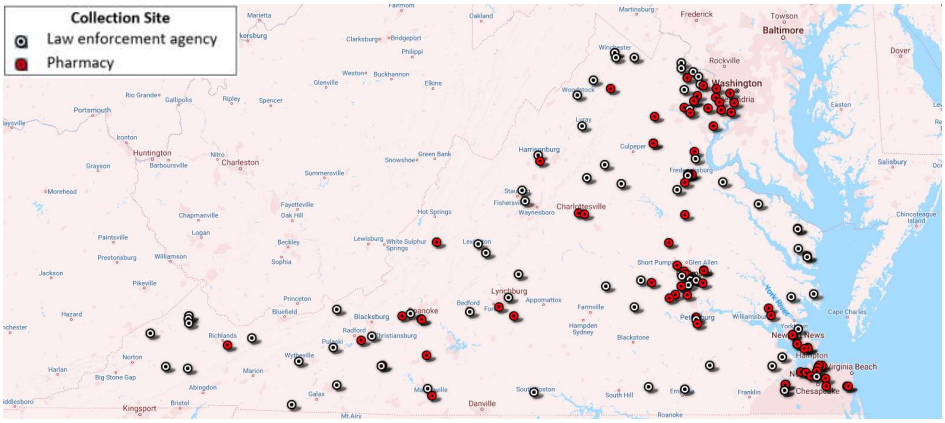
Medicine Take-Back Locations in Virginia



Data sources: CVS Health (2018); Virginia Department of Health Professions (DHP) (2018)

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Medicine Take-Back in Virginia – Pharmacist's Survey

- Survey of Virginia Pharmacists Association (VPhA) membership conducted between July and August, 2018
  - 94 responses (response rate: 12% of VPhA membership)
- Findings
  - 61% of respondents at pharmacies not currently authorized to take-back controlled medicines indicated that SB 862 would have mandated medicine collection / disposal at their pharmacy
  - 60% of all respondents had concerns about requirements listed in SB 862. Among those respondents, concerns related to:

Concern	% expressing concern
Increased costs	60%
Security	33%
Increased workload	29%

  - If there were no costs to pharmacies for medicine collection / disposal, 81% of all respondents would be very likely (44%) or somewhat likely (37%) to voluntarily collect/dispose of prescription medicines

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Medicine Disposal in Virginia – Summary

- Facilitators to increasing appropriate medicine disposal/collection:
  - Several medicine disposal-related recommendations made by Governor's Task Force on Prescription and Heroin Drug Abuse acted upon in whole or in part
  - Over 80 pharmacies (4% of all registered pharmacies in Virginia) are authorized to collect and dispose of controlled/non-controlled medicines
  - Over 70 law enforcement agencies house collection receptacles, collecting 17.5 tons in 2016
  - Pharmacist survey data indicate most respondents would likely voluntarily collect/dispose of medicines if there were no associated costs
- Barriers to increasing appropriate medicine disposal/collection:
  - Most Governor's Task Force recommendations not addressed require additional funding sources
  - Geographic accessibility by Virginians to collection receptacles is below the national average
  - Pharmacist survey data indicate that costs are the most common concern of requiring their participation in medicine collection and disposal

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Medicine Take-Back Models

Program Type	Public funding?	Pharmacy participation required?	Examples
Government-supported / implemented	Yes	No	• CO, NE, NY*
	No	No	• IA, ND
Government-regulated	No	Yes	• Santa Cruz County
	No	No	• WA, MA, NY**, VT • 22 municipalities

* Refers to pilot program (2017)
** Refers to State law (2018)

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Government-Supported/Implemented Programs

- Colorado Household Medication Take-Back Program
  - All DEA-authorized collectors can participate
  - $300k annual budget supported through State funds
  - 18 tons collected annually from 110 collection sites (around 50% pharmacies, 50% law enforcement agencies)
- Iowa
  - Two programs: one limited to non-controlled medicines (EcoReturns) and one that accepts controlled/non-controlled medicines (MedDrop)
  - $175,000 annual budget for both programs supported through reallocation of existing Board of Pharmacy funds
  - 1.5 tons collected in 2017 from 108 pharmacies (through MedDrop program)
- Nebraska MEDS Coalition
  - Coalition of state agencies and community stakeholders
  - Community pharmacies eligible to participate at no cost
  - $600k annual budget supported through State and private sector funds
  - 14 tons collected in 2017 from 330 pharmacies
- North Dakota
  - Any eligible pharmacy can obtain disposal bin, with recurrent costs covered by program
  - Program funded by $200 increase in wholesale manufacturer fees
  - 1.5 tons collected between 2016 and April, 2018

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Government-Supported/Implemented Programs (2)

- New York Pilot Pharmaceutical Take-Back Program (2017)
  - For participating pharmacies, New York purchases disposal bin, provides up to 50 liners, pays for pick-up / transport / destruction for two years
  - Pharmacies required to fully fund continued collection for six months after end of pilot period
  - Funded through $3M in State funds

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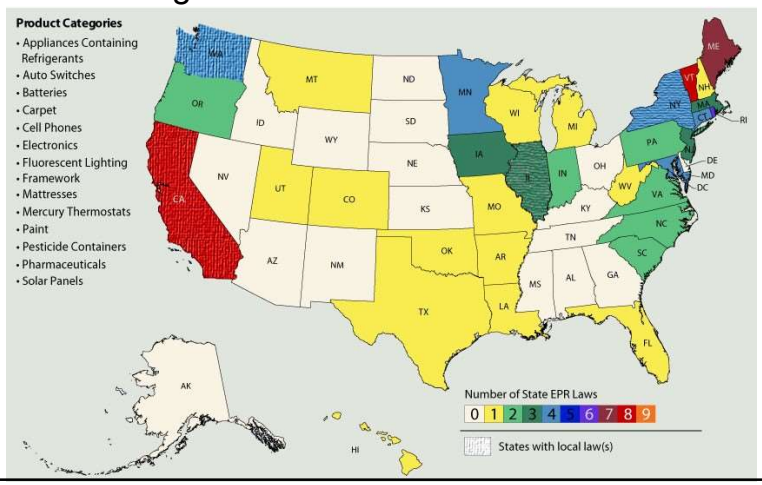
Government-Regulated Programs

- Extended Producer Responsibility (EPR): mandated "product stewardship" system including requirement that manufacturers' responsibility extend to post-consumer product management



Source: Product Stewardship Institute (2018)

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EPR Model – Common Components

- Since 2012, 23 municipalities and 4 States have established EPR programs for medicine take-back
- 2017 analysis of 12 municipal EPR ordinances found:

Included in 100% of programs:

- Program must accept all medicines (prescription/non-prescription)
- Geographic "convenience" standards specified
- Manufacturers responsible for program costs and fees
- Manufacturer point-of-sale and point-of-collection fee prohibited
- Consumer education and outreach required
- Programs can be operated singly or jointly by manufacturers

Included in <100% of programs:

- Mail-back option required (11 of 12 programs)
- Disposal by incineration only (5 of 12 programs)
- Municipality specifies benchmark program (3 of 12 programs)
- Retail pharmacy participation required (1 of 12 programs)

Source: Network for Public Health Law, (2017)

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Washington State EPR model – Unwanted Medication Disposal Act (2018)

- Covered medicines: all controlled/non-controlled medicines (including veterinary)
  - Products not covered include (*inter alia*):
    - Personal care products
    - Medicines/biologicals for which manufacturers provide a pharmaceutical product stewardship or drug take-back program
    - Medicines that are administered in a clinical setting
    - Medical products (e.g., injectors, needles, sharps)
- Primary stakeholders
  - Manufacturers: establish and fund a medicine take-back program
  - Drug wholesalers: provide list of drug manufacturers to the Department of Health (DOH)
  - Program operator: organization that administers medicine take-back program and pays annual DOH administrative fee
    - Usually a 3rd-party vendor funded by manufacturers
  - Department of Health: reviews, approves and monitors implementation of medicine take-back programs

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Washington State EPR model (2)

- Collection/disposal requirements
  - Program must accept any voluntary authorized collector (e.g., pharmacy)
  - If requested, mail-back program must be made available to retail pharmacies that offer to distribute mail-back envelopes
  - Provide “equitable and reasonably convenient access” for state residents: at least one collection site for each city/town and area within 10 mile radius, plus one additional collection site for every fifty-thousand residents
  - Program operator must establish mail-back distribution locations or hold periodic collection events to supplement service in underserved areas
  - Program must be re-authorized every four years
- Program promotion, education, and outreach requirements
  - Minimum elements include: discourage consumers from throwing away or sewering drugs; establish toll-free number for consumer questions; disseminate educational and outreach materials; develop consistent signage, receptacle design, etc.
  - If multiple programs exist, programs must coordinate promotional activities

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Washington State EPR model (3)

- Funding requirements
  - Manufacturers must pay all administrative and programmatic costs
    - Administrative costs paid to DOH via annual fee on program operator
    - Programmatic costs paid to program operator
  - Prohibition on point-of-sale/collection fee to consumers by program operator, manufacturers, authorized collectors
  - Department of Health administrative budget ≤ 10% of each program's annual expenditures
    - Fee study will be performed by Department for first year budget
- Enforcement requirements
  - Department of Health authorized to fine non-compliant wholesalers/manufacturers
- Reporting requirements
  - Program operator must submit report including:
    - List of participating covered manufacturers
    - Weight of medicines collected
    - Description of the education, outreach, and evaluation activities
    - Summary of program goals for collection amounts and public awareness, success in meeting goals and/or efforts to meet goals in following year, annual expenditures

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EPR models in Other States

- Vermont (2016)
  - Funds "statewide unused prescription drug disposal initiatives" through 1% increase in pre-existing fee on manufacturers of medicines paid for by Vermont's Medicaid agency
  - Doesn't specify any particular program model
- Massachusetts (2016)
  - Applies only to opioids and benzodiazepines
  - Generally not as specific as Washington State model (e.g., leaves to administrative regulations to define process for reviewing program applications; required components of annual report limited to program activity "description" and quantification of volume/type of medicines collected)
- New York (2018)
  - Largely similar to Washington State model with minor differences (e.g., program operator program updated every 3 years; differences in geographical convenience standards specifications)

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Estimated Costs of Medicine Take-Back Collection Programs

- Pharmacies in Virginia (self-reported estimates)
  - Low end: $850-$1,200 / year for 3 – 6 collections / year (one pharmacy estimated $1,080 - $1,440 for monthly collection)
  - High end: $12,000 / year for weekly collection
- Statewide programs from other States
  - CO: $1,500 / year / site for 110 sites
  - IA (MedDrop program): $1,100 / year / pharmacy for 108 pharmacies
  - NE: $1,800 / year / pharmacy for 330 pharmacies
  - ND: $500 - $585 / year / pharmacy for 120 pharmacies
- Other programs
  - NY (pilot program): $2,300 / year for 24 collections + one-time $1,250 cost for receptacle
  - MA (pharmacy in large hospital): $10,000 / year for weekly collection
  - MA (Smaller pharmacy campus): $1,200 / year for 6 collections / year

Estimated annual costs of Virginia statewide program if all DEA-authorized collectors participate: $3.2M – $5.4M
(calculation based on: ($1,500 - $2,500 / year / pharmacy) x (1,822 registered pharmacies + 340 law enforcement agencies) = $3.2M – $5.4M / year

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Estimated Costs of Medicine Take-Back Collection Programs (2)

- As a percentage of manufacturer retail sales
  - $0.01 for every $10 in sales (Alemada County estimates)
  - $0.01 to $0.02 per prescription in WI (2012 study)
- In relation to weight collected
  - $3.40 per pound collected (British Columbia, 2011)
  - $5.30 per pound collected (Santa Barbara Sheriff's Department)

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Summary

- Evidence suggests high prevalence of unused medicines, with potential health and environmental risks (e.g., medicine diversion, non-prescribed re-use, accidental exposure; presence of pharmaceutical ingredients in water)
- While disposal bins and mail-back envelopes are authorized by DEA /considered 1st-choice by FDA and EPA, evidence suggests that few use those disposal methods and access to collection sites is low
- Several recommendations of Virginia's Governor's Task Force on Prescription Drug and Heroin Abuse relate to increasing awareness of importance of proper drug disposal among the public and obtaining funding to increase participation of potential collection sites
- A variety of government-involved models exist to increase use of preferred medicine disposal methods, including those funded and/or implemented by governments and those funded by pharmaceutical manufacturers and regulated by State or local authorities (i.e., Extended Producer Responsibility)
- EPR models in the U.S. generally require manufacturers to fully support programmatic and administrative costs, collect prescription and non-prescription medicines, conduct consumer outreach/education, and meet geographic coverage criteria; one mandates pharmacy participation
- Available data suggest that programmatic costs associated with a statewide program may be reasonably expected to be, on average, $1,500 - $2,500 / collection site / year

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Policy Options

Policy Options

Policy Focus	Policy Option(s)
--	Option 1: Take No Action
Public awareness of DEA-compliant / FDA- and EPA-recommended medicine disposal methods	Option 2: Introduce legislation to amend § 54.1-3319 of the Code of Virginia to add counseling on medicine disposal to the list of topics on which pharmacists may counsel persons who present a new prescription for filling (Code currently only lists storage as a topic)
Statewide medicine disposal program ***OR***	Option 3: Re-introduce SB 862 to amend section §54.1-3411.2 of the code of Virginia requiring retail pharmacies to collect and dispose of: • Option 3a: Schedule II-IV medicines; ***OR*** • Option 3b: All prescription/non-prescription medicines
	Option 4a: Introduce legislation and budget amendment to amend Title 54.1 of the code of Virginia to establish an Extended Producer Responsibility law, modeled after Washington State's Unwanted Medication Disposal Act*; ***OR*** Option 4b: Option 4a + 1-year enactment clause**

* DHP estimates resource requirements of $500,000 and 4 new FTEs; fiscal impact to be covered by fee assessed on program operator

** 1-year enactment clause would allow for: implementation of competing DHP priorities (e.g., pharmaceutical processor selection); data from WA State implementation to inform VA legislation

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Public Comment

Written public comments on the proposed options may be submitted to JCHC by close of business on October 15, 2018.

Comments may be submitted via:

- ❖E-mail: jchcpubliccomments@jchc.virginia.gov
- ❖Fax: 804-786-5538
- ❖Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia 23218

Comments will be provided to Commission members and summarized before they vote on the policy options during the JCHC's November 7th decision matrix meeting.

(All public comments are subject to FOIA release of records)

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Appendix

Secure and Responsible Drug Disposal Act (2010)

- Key milestones
  - 2010 – Act amended Controlled Substances Act, allowing public to deliver unused controlled substances to law enforcement agencies
  - 2014: DEA rule (Title 24, Part 1317) expands list of “ultimate users” to include: manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, retail pharmacies
- Key pharmaceutical disposal and collection requirements
  - Schedule II-V drugs and non-controlled medications allowed
  - Pharmacies can’t inspect collected material or handle the drugs being disposed
  - Destruction must render pharmaceuticals “non-retrievable”

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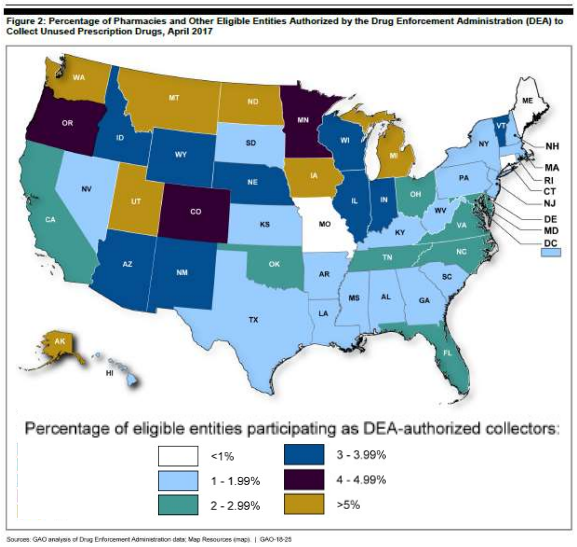
National availability of Pharmacy-Based Drug Disposal Receptacles

- Uptake of pharmacy DEA registration modification



Source: GAO (2017)

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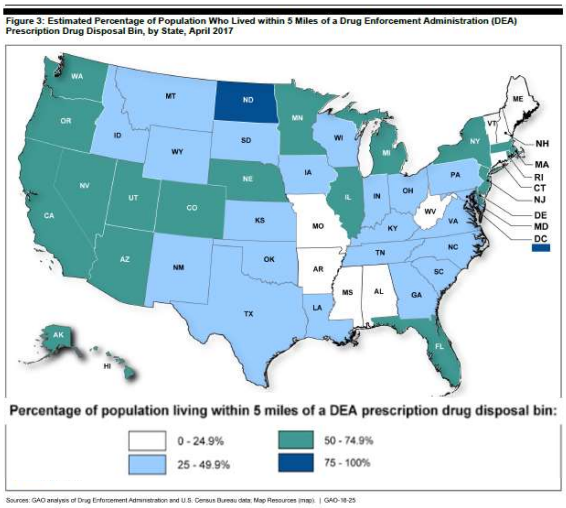
National availability of Pharmacy-Based Drug Disposal Receptacles

- Geographical access to disposal bins



Source: GAO (2017)

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Extended Producer Responsibility Model – Legal Considerations

- 1st municipal-level medicine disposal EPR law passed in U.S. (Alameda County Safe Drug Disposal Ordinance) challenged in Court by manufacturers
- In a lawsuit brought by PhARMA (2012), 9th Circuit upheld ordinance in its entirety
- On May 26, 2018, the Supreme Court denied PhARMA's petition for Writ of Certiorari, thereby upholding the 9th Circuit's decision

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Virginia Prescribing Regulations Limiting Quantities of Medicines in Circulation

- Management of acute pain
  - Initiate opioid treatment with short-acting opioids. Quantity limits*:
    - Acute: 7 days
    - Emergency department discharge: 7 days
    - Post-surgical: 14 days
- Management of chronic pain
  - Discuss with patient their responsibility during treatment, including secure storage and proper disposal
  - Review the course of treatment every 3 months
- Addiction treatment
  - Reduce chances of buprenorphine diversion by (*inter alia*): appropriate frequency of office visits; pill counts

*May prescribe longer and/or exceed the manufacturer's directions for use if extenuating circumstances are clearly documented in the medical record

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Virginia Dispensing Regulations Limiting Quantities of Medicines in Circulation

- 18VAC110-20-310: Partial dispensing of a prescription for Schedule II medicines permissible if:
  - Total quantity dispensed in all partial fillings does not exceed the total quantity prescribed
  - Remaining portions are filled within 30 days of original prescription
- 18VAC110-20-320: Partial dispensing of a prescription for Schedule III-V medicines permissible if:
  - Total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed
  - Dispensing occurs within six months of the original fill

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