### Butte-Silver Bow Health Dept. Opioid Abatement Project

2025 Montana Opioid Abatement Trust Grants

#### Butte-Silver Bow Health Department

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#### **Application Form**

#### Region Selection

To collaborate with someone else on this request, click the blue "Collaborate" button in the top-right corner.

#### Project Name\*

Butte-Silver Bow Health Dept. Opioid Abatement Project

You may only select one Abatement Region, if you are applying for funding from more than one region you will need to fill out and submit a separate application for each region.

#### Select Multi County Abatement Region OR Metro Region\*

Select the Multi-County Abatement Region <u>OR</u> the Metro Region you are requesting grant funds from. Click HERE for a detailed map of Multi-County Regions and Metro Regions.

Silver Bow County Metro Region

#### **Application Overview**

#### About the Organization/Program\*

Give a brief description of the Organization/Program/Project. Include the mission statement and the services provided.

At the health department, our overall focus is prevention, preparedness, and promotion. The objective of this project is to reduce the harmful impacts of OUD on both the individual and the community by providing education and resources, preventing people at risk from developing OUD, promoting equity, and reducing stigma. Our goal is to expand program awareness, availability, capacity, and effectiveness through a media campaign, promotional materials, drug-disposal, and supplies not covered by existing funding sources. Our services include:

- a syringe services/harm reduction program (SSP),
- HIV case management,
- HIV, HCV, and syphilis testing,
- · Naloxone education and distribution, and
- youth prevention education.

Our SSP began in 2020 and is open 1-4 pm on Wednesdays and by appointment. We would like to be able to expand capacity by providing another walk-in time, but we need to be able to meet the additional cost for supplies, including syringes.

The anonymous program provides:

- sterile syringes,
- a sharps container to return used ones,
- rapid HIV/HCV/Syphilis testing and linkage to medical care,
- harm reduction supplies including Naloxone, Fentanyl test strips, and condoms, and
- warm hand-off to treatment services.

Participants complete a form upon each SSP visit which allows us to track several useful measures such as demographics, overdose not involving EMS, sharing behaviors, and housing status. These data are recorded and analyzed weekly, quarterly, and annually, and are used to drive evidence-based decision making for the program.

Prevention is a vital component to reducing the OUD risk group long-term. BSB-HD has a Health Educator who teaches Butte students about health issues, including vaping and substance use. They use national evidence-based programs such as "Natural High" and "Prime For Life" that educate and engage students, parents, teachers, and vulnerable populations on the harmful realities of substance use.

#### What category does the program fit into\*

Check the category/categories the program fits into. You may select more than one option.

Click **HERE** for a list of approved opioid remediation uses

Prevention

#### **Exhibit E List of Opioid Remediation Uses**

Schedule A - select all that apply

A. NALOXENE/OTHER FDA-APPROVED DRUG TO REVERSE OPIOID OVERDOSES G. PREVENTION PROGRAMS

H. EXPANDING SYRINGE SERVICE PROGRAMS

#### **Exhibit E List of Opioid Remediation Uses**

Schedule B - select all that apply

C. CONNECTIONS TO CARE

H. PREVENT OVERDOSE DEATHS & OTHER HARMS (HARMS REDUCTION)

#### How does the program meet the Opioid Remediation Guidelines\*

In detail, describe how the program fits into the approved Opioid Remediation Guidelines selected in the above question.

Please be specific

- A.A1 Expand training for first responders, schools, community support groups, and families
- A.A2 Increase distribution to individuals who are uninsured or whose insurance does not cover the needed service
- A.G1 Funding for media campaigns to prevent opioid use
- A.G2 Funding for evidence-based prevention programs in schools
- A.H1 Provide comprehensive syringe services programs (access to sterile syringes and linkage to care and treatment of infectious diseases
- B.C12 Support prevention programs focused on young people

• B.H1-9 – Increased availability and distribution of naloxone, providing free naloxone to anyone, training and education, improving data tracking overdose/naloxone revivals, public education relating to emergency responses to overdoses and Good Samaritan laws, and syringe service programs to reduce SUD-related harms

#### New Program or Existing\*

Is the funding intended for a new program or to expand an existing program?

A proposed supplement or expansion to a program.

#### Fiscal Information

#### Requested Amount\*

\$33,590.25

#### **Program Budget\***

How will the funds be allocated? Attach a detailed line item budget breakdown for the program. If the funds are intended for a multi-year program please specify the amount budgeted for each year.

Opioid Grant Application Budget Final.xlsx

#### Source of Funding\*

Does the program currently receive funding from another source? If yes, please explain in detail. (i.e. amount, funding source, etc.)

Grant funding is intended for the creation or expansion of opioid prevention, treatment, and recovery projects. The money is **NOT** meant to replace or supplant existing funding.

- DPHHS STD/HIV Section: Hepatitis-C Prevention Activities Within Harm Reduction Programs; 5/1/23-3/31/25; \$37,500 Provides most harm reduction supplies such as Naloxone and rapid tests.
- National Institute of Health (NIH): Community Partnerships to Advance Science for Society (ComPASS); 8/1/23-7/30/25; \$127,852 Covers salary of SSP Coordinator, misc. expansion costs
- BSB: General Fund; Annual; \$4,000 Part of county budget allocated to SSP syringes
- Butte Cares MOU; \$249 Prime For Life training, class, and workbook (excluding Juvenile)

#### Do you have a Fiscal Agent\*

Yes

#### Fiscal Agent Contact Info

#### Fiscal Agent Name\*

Diane Regan

#### Fiscal Agent Email Address\*

dregan@bsb.mt.gov

#### Program Abstract

#### Program Description\*

Describe the objectives of this project. Provide a detailed overview of the program, including its purpose, priorities & objectives, and intended results.

The BSB Health Dept. has a multi-faceted approach to addressing OUD and harm reduction, as listed above. Our SSP provides Naloxone training for groups every 3rd Thursday of the month and upon request. We also provide free Naloxone to our SSP participants and anyone who requests it. To expand the reach of these services, we would like to invest in promotion and marketing, as well as covering the additional cost of supplies needed for the expanded capacity. A 6-month digital campaign could help us reach more people, informing them about Naloxone training, drug disposal, and perhaps educational messages such as what to do if encountering a used syringe.

The costs of running SSP are mostly covered by the NIH ComPASS grant, but we are not able to pay for syringes with a federal grant. We have used General Fund to cover this cost, which allows us \$4,000 per fiscal year. Our need is already stretching this budget. If we are to grow, we need to be able to afford the additional supplies. If we can pay for syringes with money intended for uses addressing OUD, we can redirect the \$4000 in taxpayer dollars elsewhere. Please see Appendix A for data on the effectiveness of SSP.

We would like to be able to offer an option for drug disposal. Deterra is a drug deactivation and disposal product. We would like be able to offer it for free to anyone who wants to dispose of drugs or medications.

The carbon-based contents deactivate and neutralize prescription and illicit drugs. The plant-based packaging and the inks used have a lower impact on the environment than incineration or mail-back programs. They prevent the substances from getting into our air, soil, and water by flushing or throwing in the garbage without deactivation. Studies show that when people are given these pouches, they are more likely to use them than drop-boxes, mail-back, or disposal without deactivation such as flushing or throwing away. See Appendix B for more information from Deterra, specifically slide 15 for environmental impact.

Our Health Educator provides tobacco and drug prevention for our community's youth. Currently, she is using two evidence-based programs, "Natural High" and "Prime For Life". Preventing people from entering the risk group is vital for long-term success of addressing the opioid crisis. We are asking for help with the cost of printing the workbooks needed for these classes as well as the cost of the "Juvenile Prime For Life" program training. The Prime curriculum is developed by Prevention Research Institute (PRI). The current MOU does not cover the Juvenile training, but this will allow our HE to start the program in the 4th grade. Studies show that starting prevention programs earlier shows improved success.

#### Program Reach:

- From April through December 2024, our SSP saw 236 individuals for a total of 1127 visits.
- Naloxone training was provided to 154 individuals
- · All Butte students from 4th-12th grade

#### Specific Goals\*

What are the specific goals of the program? List several goals the program hopes to accomplish and how the program intends to meet these goals.

- Increase the number of individuals given Naloxone training from 154 in 2024 to 200 in 2025 (~30%)
- Reduce number of kids in drug court classes by 10% by 2026
- $\bullet$  Reduce self-reported needle sharing among SSP participants among return visits from 27% to 20% for 2025
- $\bullet$  Keep ratio of number of syringes returned by SSP participants to the number distributed greater than or equal to 1 in 2025
- Increase the average number of SSP visits per week from 30.5 to between 35 and 40 (15-31%) in 2025
- Increase the average amount of rapid HIV/HCV/Syphilis tests per week from 1.5 to 3.0 (100%) in 2025

#### Evaluation Method\*

Describe how you plan to evaluate the effectiveness of the program and what the method for evaluation will be.

We already keep track of the data we would need to evaluate this program, which is regularly summarized. We plan to measure success by aiming for the Specific Goals listed above. These are measures that we feel we have some degree of influence over. We tried to set goals that are both reasonable and challenging. Each year, we can evaluate not only the project's productivity, but also the goals themselves, adjusting to suit the needs of the community.

#### Data Source\*

What information are you going to collect or use to demonstrate you have accomplished your goals?

- Primary data provided by SSP intake form
- SSP and Family Planning testing data
- ODMAP

#### Awareness\*

How do you plan to create awareness of this program? Briefly describe what action the program plans to take to create awareness in the community.

- Digital Concepts Media Campaign; 6 ads to run for 6 months,  $\sim$ 28,000-30,000 ads per month across multiple platforms
- Print materials such as flyers and brochures
- Social media to promote training dates
- Information and resources available and kept up to date on BSB-HD website

#### **Additional Documents**

#### Tax Exempt Organization\*

By clicking this box you are confirming the applying organization is a tax exempt organization.

Yes

#### Tax Exempt Determination Letter\*

Please upload a copy of the Organization 501(C)(3) Tax Exempt Determination Letter.

W9\_BSBHD\_11-25-24.pdf

Use this section to upload or explain any additional information regarding the program/organization. ie. a detailed budget projection, program/organization history, etc.

#### Upload #1

Applicatioin\_Opioid Grant\_Appendix A.pdf

#### Upload #2

Application\_Opioid Grant\_Appendix B.pdf

#### Upload #3

**Additional Information** 

#### File Attachment Summary

#### Applicant File Uploads

- Opioid Grant Application Budget Final.xlsx
- W9\_BSBHD\_11-25-24.pdf
- Applicatioin\_Opioid Grant\_Appendix A.pdf
- Application\_Opioid Grant\_Appendix B.pdf

Budget OPIOID Abatement	Price	Quantity	Units	Total	
Operation Supplies					
Syringes	\$76.92	65	65000	\$4,999.80	
Deterra pouches - Medium size	\$856.00	10	2000	\$8,560.00	
Deterra consumer trifolds	\$6.25	10	500	\$62.50	
Naloxone Nasale Spray-Type	440.00	_	25	400.00	
Training Kit 5/pk	\$19.80	5	25	\$99.00	
Printing /Duplicating					
Printing Materials (Work Books fo	r				
Prime for Life)	\$6.62	500		\$3,308.95	
Printing Materials Naloxone					
Trainings - Brochures	\$1.00	1000		\$1,000.00	
Printing Materials Naloxone Trainings - Flyers	\$1.00	500		\$500.00	
Hallings - Flyers	\$1.00	300		\$300.00	
Publicity & Dues					
Digital Concepts Media Campaign					
(6 months)	\$15,000.00			\$15,000.00	
Training					
Juvenile Prime for Life -Evidence					
Based program	\$60.00			\$60.00	
Total				\$33,590.25	

Form W-9
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

#### Request for Taxpayer Identification Number and Certification

Go to www.irs.gov/FormW9 for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Befor	e yo	bu begin. For guidance related to the purpose of Form w-9, see Purpose of Form, below.									
	1	Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner entity's name on line 2.)	's na	me d	on line	e 1, and	l enter t	ne bus	iness/dis	regarded	
	BUTTE-SILVER BOW CONSOLIDATED GOVERNMENTS										
		Business name/disregarded entity name, if different from above.									
3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only one of the following seven boxes.    Individual/sole proprietor								not indivi on page	duals;		
only one of the following seven boxes.  Individual/sole proprietor							Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)				
Pr Specific I	3b	If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax class and you are providing this form to a partnership, trust, or estate in which you have an ownership interest this box if you have any foreign partners, owners, or beneficiaries. See instructions	ssifica est, cl	tion heck	· 	(A			ınts maii nited Sta		
ee	5	Address (number, street, and apt. or suite no.). See instructions.	quest	er's	name	and a	dress (d	ptiona	ıl)		
0)	15	5 W. Granite St.									
	6	City, state, and ZIP code									
	Bu	tte, MT 59701									
	7	List account number(s) here (optional)									
Par	t I	Taxpayer Identification Number (TIN)									
Enter	you	r TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid	ļ	Soc	cial s	ecurity	numbe	<u>r</u>			
		ithholding. For individuals, this is generally your social security number (SSN). However, for a				_		-			
reside	ent a	ilien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other is your employer identification number (EIN). If you do not have a number, see How to get a	L	ana a							
TIN, la				or E	ploye	r idon	ificatio	a num	har		
Motor	14 +1	ne account is in more than one name, see the instructions for line 1. See also What Name and	Ļ	EIII	pioye	riden	T	Tium		#	
		To Give the Requester for guidelines on whose number to enter.		8	1	- 0	3	6 8	6 9	8	
Par	t II	Certification									
		nalties of perjury, I certify that:									
1. The	nu	mber shown on this form is my correct taxpayer identification number (or I am waiting for a nu	ımbe	r to	be is	ssued	to me);	and			
Ser	vice	ot subject to backup withholding because (a) I am exempt from backup withholding, or (b) I ha e (IRS) that I am subject to backup withholding as a result of a failure to report all interest or di ger subject to backup withholding; and	ve no vider	ot b nds	een i	notifie c) the	d by the RS has	e Inter notif	nal Rev	enue hat I am	
3. I ar	n a	U.S. citizen or other U.S. person (defined below); and									
4. The	e FA	TCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is	corr	ect.							
becau acqui	se y	ion instructions. You must cross out item 2 above if you have been notified by the IRS that you a you have failed to report all interest and dividends on your tax return. For real estate transactions, n or abandonment of secured property, cancellation of debt, contributions to an individual retirem n interest and dividends, you are not required to sign the certification, but you must provide your or	item ent a	2 d arran	oes r ngem	ot app ent (IF	oly. For A), and	mortg , gene	age inte rally, pa	rest paid, yments	
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#### **General Instructions**

Section references are to the Internal Revenue Code unless otherwise noted.

**Future developments.** For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to <a href="https://www.irs.gov/FormW9">www.irs.gov/FormW9</a>.

#### What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

#### Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

#### Appendix A:

#### A1: SSP Impacts the Risk of Fatal Overdose

BSB-HD opened its SSP in 2020. The first four years have not been easy. Despite the initial opening being hindered by the pandemic, and then having to close from Nov. 2023 to April 2024, the program has survived. More than that, it has contributed to a measurable positive impact on the community.

Figure 1 looks at the percentage of reported overdoses that were fatal in Butte and the rest of Montana. We do not have good estimates for total overdoses before 2021, only the number of deaths due to overdose. Thanks to ODMAP we have a good idea of activity in the years since. Using that data, we can see that in the few years since opening an SSP, alongside policy changes that allowed Naloxone and fentanyl test strips distribution, the community's risk of fatal overdose has dramatically decreased.

In 2021, the percentage of all overdoses that were fatal in Butte was between 2 and 3 times greater than the rest of Montana<sup>1</sup>. That percentage has steadily declined so that in 2024, no deaths were attributed to overdose<sup>2</sup>.

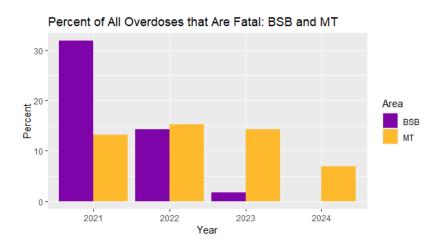


Figure 1: Percent of Overdoses that are Fatal

#### A2: SSP Reduces the Risk of Spreading of Bloodborne Diseases

<sup>&</sup>lt;sup>1</sup> The Montana values are calculated with Silver Bow values subtracted for the sake of comparison.

<sup>&</sup>lt;sup>2</sup> This figure is subject to change as it is possible that some deaths may be under review. As of Jan. 13, 2025, there are no deaths reported for Silver Bow in 2024 in ODMAP.

Table 1 shows that overall, about 32% of SSP participants reported sharing supplies on their intake forms. However, if we separate first time visits and return visits we see about 51% for first time and 27% for returning. This indicates that people in SSP are about half as likely to share, reducing the risk of spreading bloodborne diseases.

There is not enough data to say anything conclusively about causation, but we hope that over time our data will provide more evidence. We believe with education and earning participants' trust, we can move the needle further.

Table 1: SSP Participants Who Report Sharing

00 Q	Strata	Percent "Yes"
rrtec	Overall	32%
epo	First Visit	51%
S S	Return Visit	27%

From April through December 2024, about a quarter (~24%) of participants received rapid testing for HIV, HCV, and/or syphilis. Those who had positive results were referred to either our inhouse provider or another provider for confirmatory testing and treatment. This program provides access to testing, care, and treatment to people who wouldn't otherwise have it, nor would they seek it. Table 2 shows the positivity rate of these tests given through SSP.

Table 2: Rapid Tests Done Through SSP

TEST	# Given	Positivity Rate
HIV	55	0%
HCV	57	26.3%
Syphilis	59	8.5%

#### A3: SSP Participants Return Their Used Syringes and Collect from Others

Participants are encouraged to return all their used syringes on their next visit, and in general, they do their best. They also collect syringes from non-participant users. They understand that the program is an exchange, and they need to do their part to keep it running. Some participants have expressed concern about being stopped by law enforcement while attempting to return used syringes to SSP. This is a barrier which has yet to be resolved.

Nevertheless, in the 9 months of operation in 2024, we documented 39,028 returned and 39,170 distributed. This is an In/Out ratio of 0.996. We believe that with encouragement, we can keep the In/Out ratio greater than or equal to 1 for 2025.

# DETERRA® DRUG DEACTIVATION & DISPOSAL SYSTEM – TECHNICAL FAQ's

VERDE® TECHNOLOGIES, INC.



## WHAT IS THE MECHANISM OF ACTION OF DETERRA?

Deterra works by adsorbing (deactivating) medications by activated carbon. Activated carbon contains numerous pores that bind medications via London Forces (a type of Van der Waals force). Once adsorbed by activated carbon, medications are no longer available for abuse or extraction by potential abusers or environmental conditions.

## WHAT IS THE END SUBSTANCE AFTER DETERRA IS USED AS DIRECTED?

The end substance will be activated carbon granules containing adsorbed medications. Since the adsorbed medications cannot be removed from the carbon, they are chemically and biologically inert and inactive.

## WHAT VALIDATION DATA TO YOU HAVE TO SUPPORT THE MECHANISM OF ACTION?

Deterra has been rigorously tested by a third party (College of Pharmacy Science, Mercer University), under a government contract with the National Institute on Drug Abuse (NIDA), a division of the National Institutes of Health (NIH). Mercer examined 20 psychoactive medications of different dosage forms and strengths including pills, capsules, liquids, transdermal patches, and sublingual films. They demonstrated an average deactivation (conversion to an unusable, non-hazardous state) of 89% in 8 hours. This increased to 96% by day 2 and greater than 99% by day 14. Mercer then examined the ability to extract the carbon-bound drugs using water and 30% ethanol. They found negligible levels of extractable drugs. The NIDA report is linked here.

Mercer University has published five peer-reviewed articles and seven posters detailing testing of the Deterra System. These publications are linked below:

#### Peer Reviewed Articles:

- Activated Carbon-Based System for the Disposal of Psychoactive Medications
- Development of Disposal Systems for Deactivation of Unused/Residual/Expired Medications
- Evaluation of an activated carbon disposal system for safe disposal of model prescription sedative medications
- Evaluation of an activated carbon-based deactivation system for the disposal of highly abused opioid medications
- Development and validation of an HPLC-UV method for analysis of methylphenidate hydrochloride and loxapine succinate in an activated carbon disposal system

#### WHAT VALIDATION DATA TO YOU HAVE TO SUPPORT THE MECHANISM OF ACTION (CONTINUED)? Poster Presentations:

- Evaluation of an Activated Carbon Based Drug Disposal System for Deactivation of Psychoactive Medications.
- Deactivation of Psychoactive Drugs Using an Activated Carbon Based Drug Disposal System
- Activated Carbon Based Disposal of Fentanyl Transdermal Patches.
- Development and Validation of a Reverse Phase-HPLC method for Methylphenidate and its disposal using activated charcoal based system.
- Activated Carbon Based Disposal of Model Psychoactive Medications.
- Comparison of Adsorbents for Development of Disposal kits for Solid Oral Dosage Forms
- Development of a disposal system for deactivation of transdermal patches of fentanyl

#### Conclusions include:

- Thus, this deactivation system can be successfully used for the disposal of psychoactive medications.
- Hence, the Deterra activated carbon disposal system provides a simple and convenient way to dispose of these medications in normal trash, without causing any environmental or safety risks.
- Drug substances did not get released from activated carbon when washed out with large volumes of water or 30% ethanol indicating minimal environmental effect. Therefore, this unique system provides a simple, safe and an efficient drug disposal system which can be used in households and healthcare settings to deactivate unused or expired medications.

# WHICH PRODUCTS (DRUG SUBSTANCES, FORMULATIONS AND STRENGTH) HAVE BEEN USED TO VALIDATE YOUR MECHANISMS OF ACTION?

Medication	Form	Strength
Alprazolam	Tablets	2 mg
Buprenorphine	Sublingual film	8 mg
Dextroamphetami	Tablets	10 mg
ne		
Diazepam	Tablets	10 mg
Fentanyl	Transdermal patch	25 mcg/hr
Fluoxetine	Capsule	20 mg
Hydromorphone	Tablet	4 mg
Ketamine	Liquid	500 mg/10 ml
Lorazepam	Tablet	2 mg
Loxapine	Capsule	10 mg
Meperidine	Tablet	50 mg
Methadone	Tablet	10 mg
Methylphenidate	Tablet	20 mg
Morphine	Liquid	300 mg/20 ml
Oxycodone	Tablet	10 mg
Oxycontin	Tablet	10 mg
Quetiapine	Tablet	100 mg
Temazepam	Capsule	30 mg
Tramadol	Capsule	50 mg
Zolpidem	Tablet	5 mg

Third party testing by the College of Pharmacy Science, Mercer University, examined 20 psychoactive medications of different dosage forms and strengths including pills, capsules, liquids, transdermal patches, and sublingual films. These dosage forms cover the vast majority of psychoactive medications. Mercer study medications are listed in the table.

# HOW LONG DOES IT TAKE FOR YOUR PRODUCTS TO START WORKING? DOES IT VARY DEPENDING ON THE SUBSTANCE OR CHARACTERISTICS? WHAT VALIDATION DATA SUPPORTS THIS?

Deactivation begins immediately. Deterra has been rigorously tested by a third party (College of Pharmacy Science, Mercer University), under a government contract with the National Institute on Drug Abuse (NIDA), a division of the National Institutes of Health (NIH). Mercer examined 20 psychoactive medications of different dosage forms and strengths including pills, capsules, liquids, transdermal patches, and sublingual films. They demonstrated an average deactivation (conversion to an unusable, non-hazardous state) of 89% in 8 hours. This increased to 96% by day 2 and greater than 99% by day 14. The NIDA report is attached.

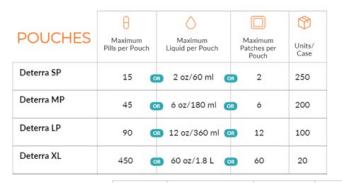
Factors that influence deactivation rate include pill/tablet dissolution rate, drug solubility and agitation.

Full Report Here

# WHAT ARE THE MAXIMUM CAPACITIES OF YOUR PRODUCT AND HOW DID YOU DETERMINE THIS?

Recommended capacity according to label instructions:

#### **DETERRA PRODUCT MIX**



	θ	$\Diamond$		
CONTAINERS	Maximum Pills per Container	Maximum Liquid per Container	Maximum Patches per Container	Units/ Case
Deterra Liquids Only (1.0 gallon)	N/A OR	3 L/100 oz 🧿	B N/A	4
Deterra Multi-Purpose (1.0 gallon)	1,000	1 L/34 oz	100	4
Deterra Multi-Purpose (2.5 gallon)	2,500 🗪	2.5 L/84 oz	250	2

The maximum capacity and the recommended capacity on the label are often times very different, leaning towards a very conservative approach.

Internal studies at Verde have determined that the activated carbon contained in Deterra has the capacity to deactivate pure Active Pharmaceutical Ingredients (API) at a 4:1 carbon:API ratio by weight.

Internal studies at Verde have determined that the activated carbon contained in Deterra has the capacity to deactivate the following tablets at a 2:1 carbon:tablet ratio by weight: diazepam (4 mg tablets), hydromorphone (4 mg tablets), quetiapine (100 mg tablets) and tramadol (50 mg tablets). How does it differ depending on the formulation and/or drug substance and strengths? As an example, this carbon:tablet ratio means that a MP Pouch has the "maximum" capacity to deactivate 135 diazepam, 225 hydromorphone, 110 quetiapine and 98 tramadol tablets. When you compare to the recommended capacity on the label instructions at 45 pills, you can see how Verde has taken an extremely conservative approach to label guidelines.

# WHAT PERCENTAGE OF DRUG SUBSTANCE CAN BE EXTRACTED AFTER USE OF YOUR PRODUCTS?

Mercer demonstrated negligible levels of drug when Deterra was exposed to additional volumes of water or 30% ethanol. <u>Data to NIDA report linked here.</u>

In addition to testing performed by Mercer University, Verde performed studies to examine the potential for leaching under simulated landfill (acidic) conditions:

Verde examined the ability of Deterra carbon to retain adsorbed drug under simulated landfill conditions by using the acidic extraction solution designated in the Environmental Protection Agency's "Toxicity Characteristic Leaching Procedure" (TCLP). In this investigation, three model test drugs (acetaminophen, ibuprofen, and naproxen) were evaluated for leachability from Deterra activated carbon. The percentage of drug leached from activated carbon was 0.00, 0.00 and 0.21% for acetaminophen, ibuprofen and naproxen, respectively. TCLP report is linked here.

California has produced a procedure, Waste Extraction Testing (WET), for determining the potential for solid wastes to leach hazardous materials in landfill conditions. While Deterra does not contain hazardous materials, Verde examined the potential for tramadol and zolpidem to be extracted from Deterra activated carbon using a modified WET procedure. The percentage of drug leached from activated carbon was less than 0.01% for both medications. WET report in linked here.

# AFFIRM WHETHER DETERRA RENDERS CONTROLLED SUBSTANCES NON-RETRIEVABLE UNDER DEA STANDARD 21 CFR 1300.05 (B)

The DEA does not certify any products just as it does not specify disposal methods, as long as the disposal method meets the requirements. The following from the DEA standard Disposal Q&A might be helpful. Although Deterra has been shown to meet these standards, at home disposal is exempt from these requirements and residents are not registrants. Although the DEA does not certify disposal methods or products, the DEA Educational Foundation and CADCA (Community Anti-Drug Coalitions of America) both <u>endorse Deterra</u> as the recommended option for safe at home drug deactivation and disposal.

Question (Chemical Digester Disposal): Some pharmaceutical disposal products on the market, like a chemical digester, say they meet DEA's "non-retrievable" standard. May I use it to destroy my controlled substance inventory?

Answer: To comply with the DEA regulations when disposing of a controlled substance, registrants must use a method which renders the substance "non-retrievable" (21 CFR 1317.90(a)) and otherwise complies with relevant law and regulations. The term "non-retrievable" is defined in a results oriented manner as DEA requires the substance to be permanently rendered to an unusable state. 21 CFR 1300.05. The performance standard is that the method irreversibly renders the substance such that it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. Thus, regardless of whether the product claims to render controlled substances non-retrievable, to comply with the DEA regulations, a registrant that disposes of a controlled substance must use a product or method that actually does render the controlled substance non-retrievable within the meaning of the DEA regulations. Much like DEA does not evaluate, review, or approve the specific processes or methods utilized to produce, synthesize or propagate a controlled substance, DEA will not evaluate, review, or approve the processes or methods utilized to render a controlled substance "non-retrievable," as long as the desired result is achieved. EO-DEA178, October 5, 2020

Question: What alternatives to incineration do I have to destroy controlled substances in my inventory?

Answer: A registrant can transfer expired or unwanted controlled substances to a reverse distributor for final destruction; the reverse distributor will typically use incineration or a method that renders the controlled substance non-retrievable. A registrant also has the option of destroying controlled substances on-site at their registered location provided the destruction method meets the <u>non-retrievable standard</u>. Registrants who destroy their controlled substance inventory must document the destruction on a <u>DEA Form 41</u> (see <u>21 CFR 1304.21</u>(e). EO-DEA200, October 5, 2020

# WHAT PERCENTAGE OF DRUG SUBSTANCE CAN BE EXTRACTED AFTER USE OF YOUR PRODUCTS?

Mercer demonstrated negligible levels of drug when Deterra was exposed to additional volumes of water or 30% ethanol. <u>Data to NIDA report linked here.</u>

In addition to testing performed by Mercer University, Verde performed studies to examine the potential for leaching under simulated landfill (acidic) conditions:

Verde examined the ability of Deterra carbon to retain adsorbed drug under simulated landfill conditions by using the acidic extraction solution designated in the Environmental Protection Agency's "Toxicity Characteristic Leaching Procedure" (TCLP). In this investigation, three model test drugs (acetaminophen, ibuprofen, and naproxen) were evaluated for leachability from Deterra activated carbon. The percentage of drug leached from activated carbon was 0.00, 0.00 and 0.21% for acetaminophen, ibuprofen and naproxen, respectively. TCLP report is linked here.

California has produced a procedure, Wet Extraction Testing (WET), for determining the potential for solid wastes to leach hazardous materials in landfill conditions. While Deterra does not contain hazardous materials, Verde examined the potential for tramadol and zolpidem to be extracted from Deterra activated carbon using a modified WET procedure. The percentage of drug leached from activated carbon was less than 0.01% for both medications. WET report is linked here.

# DESCRIBE CONDITIONS END USERS OR PEOPLE SEEKING TO MISUSE OPIOIDS MIGHT USE TO OVERCOME DETERRA TO EXTRACT DRUG SUBSTANCES?

Abusers may attempt to extract using typical household solvents. These include alcohol and acidic juices. The studies and results listed in a, above, demonstrate that these solvents will not allow extraction of opioids from the activated carbon contained in Deterra.

### WHAT HUMAN FACTORS DATA DO YOU HAVE TO SUPPORT THE USER INTERFACE OF YOUR PRODUCTS?

There are several independent studies involving Deterra that all support the conclusion that when given a Deterra pouch, consumers are more likely to use vs other methods such as flushing, garbage without deactivation, bringing to a take back location/kiosk or mail back.

Third party independent analysis includes the following published studies:

- A March 2019 <u>JAMA Surgery Research Letter</u> on a University of Michigan clinical trial indicates that Deterra use is correlated with an 8-times greater likelihood of proper disposal of unused and unwanted drugs as compared to usual care. Results assume proper disposal excludes flushing, sinking, or mixing with an unpalatable substance such as kitty litter and coffee grounds.
- A June 2019 Randomized Clinical Trial published in <u>JAMA Pediatrics</u> indicates Deterra is correlated with a 43-times greater likelihood of proper disposal of unused and unwanted drugs as compared to usual care. Results assume proper disposal excludes flushing, sinking, or mixing with an unpalatable substance such as kitty litter and coffee grounds.
- A November 2020 abstract approved for presentation at the pandemic-canceled annual meeting of <u>The American Society of Regional Anesthesia and Pain Medicine</u> concluded that prior to intervention 52% of surgery patients did not dispose of their narcotics and after the education and disposal bags were given, this rate increased to 93.5%

Research conducted under the <u>National Institute on Drug Abuse (NIDA)</u> (pages 4-21) contract found good results for adoption and usability, including the following:

- 96% of consumers report using Deterra within four weeks of receipt; nearly half report product use within 24 hours.
- 95% of consumers report using Deterra with no difficulty.

## WHAT OTHER DATA DO YOU HAVE TO SUPPORT USEABILITY?

There are several independent studies involving Deterra that all support the conclusion that when given a Deterra pouch, consumers are more likely to use vs other methods such as flushing, garbage without deactivation, bringing to a take back location/kiosk or mail back.

Survey data collected from consumers (388 respondents) who requested and received a Deterra LP as part of the <u>Safe Project's</u> Gone for Good campaign add the following findings:

- 74% of consumers planned to use Deterra within one week, with 47% planning to use immediately/the day received. 98% of respondents planned to use Deterra within one month of receiving.
- Unlike take back events, which have shown to return a low percentage of controlled substances, when given Deterra, 30% of respondents used it to destroy dangerous medications such as opioids and benzodiazepines.
- 95% of respondents found Deterra very ease or easy to use, while less than 1% found it difficult or very difficult to use.
- 56% of respondents reported that prior to being provided Deterra, they would have either kept their medication or disposed of them by flushing or putting in the trash.

# HOW HAVE YOU CONSIDERED THE ENVIRONMENTAL IMPACT DURING THE LIFECYCLE OF DETERRA?

A large portion of the product's pouch plastic is manufactured from a sustainable crop, sugarcane, and has earned the Braskem "I'm Green" certification as well a USDA Certified Bio-Based Product. The only other product component is organic carbon in a water soluble pod.

A complete lifecycle analysis of the environmental impact of the manufacture of the pouch has been completed by Accredo, the manufacturer of the pouch. This analysis shows a *NEGATIVE* GWP (Global Warming Potential), meaning it is a positive contributor to global warming. Contrasted with incineration or mail back + incineration, which produces a larger GWP, the production of a Deterra pouch has a positive effect on the environment in terms of Global Warming Potential.

Further, Accredo's sustainability metrics include the following:

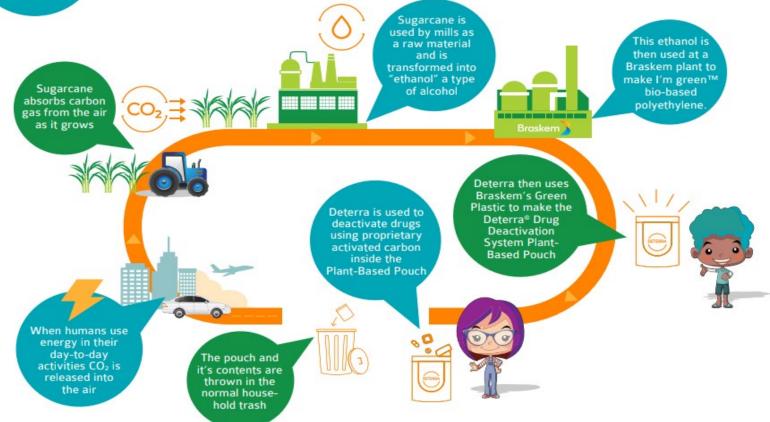
- LEED silver certification
- Powered on 100% wind based energy
- Expanded color gamut process printing allows for:
  - o 35% reduction in ink consumption
  - o 95% reduction in ink waste
  - o 80% reduction in solvent use, emissions, and hazardous waste

Lastly, studies show that consumers are less likely to flush and throw away medications when given Deterra, so by simply providing this tool, the consumer can avoid polluting the ecosystem with the unused medications.



#### DETERRA'S PLANT-BASED POUCH HAS A SMALLER CARBON FOOTPRINT

The packaging is USDA Certified, 50% or more bio-based, and has received the I'm green™ plastic certification from Braskem. According to Braskem's calculations every case of Deterra® produced can prevent up to 5 lbs of CO₂ from contributing to Global Warming Potential.



### LINKS TO ALL INDEPENDENT RESEARCH PROVING EFFECTIVENESS

#### NIDA THIRD PARTY RESEARCH

#### PEER REVIEWED ARTICLES

Contract N43DA-13-4420 (Phase 1)

Contract N44DA-14-4420 (Phase 2)

**NIDA Final Report** 

Activated Carbon-Based System for the Disposal of Psychoactive Medications

<u>Development of Disposal Systems for Deactivation of</u> Unused/Residual/Expired Medications

Evaluation of an activated carbon disposal system for safe disposal of model prescription sedative medications

Evaluation of an activated carbon-based deactivation system for the disposal of highly abused opioid medications

<u>Development and validation of an HPLC-UV method for analysis of methylphenidate hydrochloride and loxapine succinate in an activated carbon disposal system</u>

#### POSTER PRESENTATIONS

Evaluation of an Activated Carbon Based Drug Disposal System for Deactivation of Psychoactive Medications.

<u>Deactivation of Psychoactive Drugs Using an</u>
Activated Carbon Based Drug Disposal System

<u>Activated Carbon Based Disposal of Fentanyl</u> Transdermal Patches.

Development and Validation of a Reverse Phase-HPLC method for Methylphenidate and its disposal using activated charcoal based system.

Activated Carbon Based Disposal of Model Psychoactive Medications.

<u>Comparison of Adsorbents for Development of Disposal kits for Solid Oral Dosage Forms</u>

<u>Development of a disposal system for deactivation of transdermal patches of fentanyl</u>

## LINKS TO INDEPENDENT RESEARCH PROVING BEHAVIOR CHANGE

- A March 2019 <u>JAMA Surgery Research Letter</u> on a University of Michigan clinical trial indicates that Deterra use is correlated with an 8-times greater likelihood of proper disposal of unused and unwanted drugs as compared to usual care. Results assume proper disposal excludes flushing, sinking, or mixing with an unpalatable substance such as kitty litter and coffee grounds.
- A June 2019 Randomized Clinical Trial published in <u>JAMA Pediatrics</u> indicates Deterra is correlated with a 43-times greater likelihood of proper disposal of unused and unwanted drugs as compared to usual care. Results assume proper disposal excludes flushing, sinking, or mixing with an unpalatable substance such as kitty litter and coffee grounds.
- A November 2020 abstract approved for presentation at the pandemic-canceled annual meeting of <u>The American Society of Regional Anesthesia and Pain Medicine</u> concluded that prior to intervention 52% of surgery patients did not dispose of their narcotics and after the education and disposal bags were given, the disposal rate increased to 93.5%
- A January 2022 prospective cohort study published in <u>Obstet Gynecol. 2022 Jan 1: 139(1): 91-96</u> concluded that "despite a restrictive opioid prescribing algorithm, 41% of gynecological patients had leftover opioid pills". The study concluded that when patients were provided an opioid disposal bag and postoperative education, these leftover pills were safety discarded 73% of the time, which was contrasted with other studies reporting disposal rates at <40%.