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# Drug Dispensing: What do I need to document

Management of Controlled Substances and Dangerous Drugs Webinar

April 10, 2024



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Research Compliance  
and Regulatory Affairs

Research Administration



# In this presentation

- Dispensing documentation
- General documentation requirements
- Updates to Dispensing Forms
- Different dispensing documentation forms
  - Use Forms (Stock Bottles)
  - Dilutions (Working Bottles)
  - Meloxicam
  - Isoflurane
- Questions?



# Regulations for Dispensing Dangerous Drugs and Controlled Substances

GBP rule 480-7-.04 requires the Researcher establish and maintain records of all transactions regarding receipt, distribution or other disposition of dangerous drugs or controlled substances.

21 CF 1304.22(c) requires that each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with § 1304.26.

# Dispensing Documentation

## What forms do I need to use?

Emory forms are not required however, the information contained in them is required by the regulations. If you choose to use your own forms make sure they contain all the specified regulations. We have forms on our website to help you!

<https://rcra.emory.edu/oric/controlled-substances/forms.html>







- If you made a mistake, ~~strikethrough it~~ and add the date and your initials. Add the correct information next to it.
    - Do not use liquid eraser or scratch out the information!
  - Make sure you document any discrepancies (Form 5 or E), and always keep the receiving and destructions forms
  - Your documentation is telling a story!
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## General Documentation Requirements

# Updates to Dispensing Forms

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Emory forms have been updated to remove the disposition/destructions from the dispensing forms. This was done to prevent counting errors for drug accountability checks.

All dispositions/destructions should occur on Form 4 or I (example on the next slide).

Additionally, all forms were updated to use continuously so long as the drug name and concentration remain the same. The unique bottle ID and expiration date of that bottle is now captured on each line.

## Sample Form 4: Schedule I – II Controlled Substance Destruction Log

Box 1: Registrant Information		
Registrant's Name: <i>John Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room #123, Atlanta, GA, 30325</i>

Required to track DEA #'s  
To and From

Box 2: Reverse Distributor DEA Registrant Information		
Registrant's Name: <i>Reverse Distribution LLC</i>	DEA #: <i>DR4758590</i>	Registered Address: <i>45738 Destruction Way, Atlanta, GA, 30325</i>

Box 3: Schedule I – II Destruction Log						
Date of Destruction	DEA 222 Order Form #	Name of Controlled Substance	Concentration/Strength	Total Volume/Quantity to be destroyed	Drug Form	Unique Bottle ID
<i>02/11/23</i>	<i>21234345354</i>	<i>Psilocybin</i>	<i>100</i>	<i>0.5g</i>	<i>powder</i>	<i>PSB002</i>
<i>02/11/23</i>	<i>21234345354</i>	<i>Fatal Plus</i>	<i>390mg/ml</i>	<i>20ml</i>	<i>liquid</i>	<i>FP0010</i>
<i>02/11/23</i>	<i>21234345354</i>	<i>MDMA HCL</i>	<i>100</i>	<i>2g</i>	<i>powder</i>	<i>MDMA003</i>
<i>02/11/23</i>	<i>21234345354</i>	<i>Morphine Sulfate ER</i>	<i>20mg</i>	<i>2</i>	<i>capsules</i>	<i>MS0013</i>
<i>02/11/23</i>	<i>21234345354</i>	<i>Fentanyl Base</i>	<i>100</i>	<i>1g</i>	<i>powder</i>	<i>FB0001</i>
<i>02/11/23</i>	<i>21234345354</i>	<i>Oxycodone HCL</i>	<i>100</i>	<i>0.75g</i>	<i>Powder</i>	<i>Oxy1001</i>
<i>02/11/23</i>	<i>21234345354</i>	<i>Dexamethylphenidate HCL</i>	<i>5mg</i>	<i>5</i>	<i>tablets</i>	<i>DMeth001</i>





## Controlled Substances

[Form 7: Controlled Substance Current Use Log \(DOCX\)](#) UPDATED 1/30/24

[Form 11: Controlled Substance Dilution Use Log \(DOCX\)](#)- UPDATED 1/30/24

## Dangerous Drugs

[Form C: Dangerous Drugs Use \(DOCX\)](#)-UPDATED 1/30/24

[Form D: Isoflurane Current Use Log \(DOCX\)](#)UPDATED 3/13/2024

[Form F: Dangerous Drug Dilution log](#)-UPDATED 1/30/24

[Form G: Meloxicam\\* \(Stock Bottle\) Use Log](#)- UPDATED 3/13/2024

[Form H: Meloxicam\\* Dilution Use Log](#)- UPDATED 3/13/2024

## Prescription Controlled Substances

[Form 13: Use and Disposition Log Prescription](#)

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# Forms



Note: This form is to be used to track the usage of all Schedule I – V controlled substance stock bottles. Select the drug schedule above.

Box 1: Registrant Information		
Registrant's Name: <i>Joe Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room 123, Atlanta, GA, 30325</i>

Box 2: Stock Bottle Information	
Name of Substance: <i>Fatal Plus</i>	Concentration/Strength: <i>390mg/ml</i>

Note: Record the total quantity of the substance to the nearest metric unit weight or the total number of units. The log balance must always match the physical balance of Controlled Substances. Any log discrepancies, or other circumstances that indicate significant loss or theft of controlled substance must be promptly reported using Form 5.

Box 3: Controlled Substance Use Log					Drug Name/Concentration/Strength: <i>Fatal Plus 390mg/ml</i>		
Date	Unique Bottle ID	Expiration Date of Unique Bottle ID	Starting Volume/Quantity	Amount Used	Balance Remaining	Printed Name of Person who Dispensed/Administered Drug	Reason for Use (optional)
<i>02/11/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>250 ml</i>	<i>10ml</i>	<i>240ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>02/15/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>240ml</i>	<i>20ml</i>	<i>220ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>02/19/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>220ml</i>	<i>10ml</i>	<i>210ml</i>	<i>Joe Smith</i>	<i>Dilution FPSA002</i>
<i>02/28/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>210ml</i>	<i>30ml</i>	<i>180ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/05/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>180ml</i>	<i>50ml</i>	<i>130ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>-----New Bottle Started (per PI/protocol change)-----</i>							
<i>03/10/23</i>	<i>FP002</i>	<i>06/30/26</i>	<i>250ml</i>	<i>40ml</i>	<i>210ml</i>	<i>JoAnn Taylor</i>	<i>Dr. Claus</i>
<i>03/11/23</i>	<i>FP002</i>	<i>06/30/26</i>	<i>210ml</i>	<i>10ml</i>	<i>200ml</i>	<i>JoAnn Taylor</i>	<i>Protocol 12345677</i>
<i>-----Return to Bottle FP001 -----</i>							
<i>03/15/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>130ml</i>	<i>30ml</i>	<i>100ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/17/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>100ml</i>	<i>30ml</i>	<i>70ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/18/23</i>	<i>FP001</i>	<i>06/30/26</i>	<i>70ml</i>	<i>50ml</i>	<i>20ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>

## Sample Form 11: Controlled Substance Formulation/Dilution Use

Note: This form may only be used if the drug name, concentration, and total volume, created remains the same. A new form must be used if the concentration changes.

Box 1: Registrant Information				
Registrant's Name: <i>John Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room #4567, Atlanta, GA, 30325</i>		
Box 2: Calculating Concentrations from Stock Bottles				
(2a)	(2b)	(2c)	(2d)	(2e)
C/S Drug #1 name: <i>ketamine</i>	Concentration (C): <i>100mg/ml</i>	Volume Added (V): <i>2ml</i>	<b>10ml</b>	Conversion Factor (CF)* (CF=C x V/TV): <i>100mg x 2ml/10ml= 20</i>
Drug #2 Name: <i>xylazine</i>	Concentration (C): <i>100mg/ml</i>	Volume Added (V): <i>3ml</i>		Conversion Factor (CF)* (CF=C x V/TV): <i>100mg x 3ml/10ml= 30</i>
Drug #3 Name(if applicable): <i>bacteriostatic saline</i>	Concentration (C): <i>n/a = 1</i>	Volume Added (V): <i>5ml</i>		Conversion Factor (CF)* (CF=C x V/TV): <i>1 x 5ml/10ml= 0.5</i>
Drug #4 Name(if applicable): <i>N/A</i>	Concentration (C): <i>N/A</i>	Volume Added (V): <i>N/A</i>		Conversion Factor (CF)* (CF=C x V/TV): <i>N/A</i>

Box 3: Working Bottle Information and Label	Working Bottle Unique ID*: <i>varied</i>
Drug Name (Box 2): <i>Ketamine/Xylazine/Saline</i>	Working Bottle Expiration Date*: <i>varied</i>
Concentration (Box 2): <i>20mg/30mg/0.5ml per ml</i>	Working Bottle 1st Puncture Date: <i>varied</i>
Total Volume Created : <i>10ml</i>	Date Mixed and Initials of person Mixing: <i>varied</i>
Fill in this side of Box 3. This info must be on the working bottle	This side of Box 3 varies per bottle but must be on the working bottle

Box 4: Drug Usage for Working Bottle				Drug Name and Concentration: <i>Ketamine/Xylazine/Saline 20mg/30mg/0.5ml per ml</i>			
Date	Unique Bottle ID	Unique Bottle ID Expiration Date	Starting Volume (ml)	Volume removed (ml)	Total Volume Remaining (TVR) (ml)	Initials of person dispensing/ administering	Reason for Use (optional)
<i>01/01/24</i>	<i>KXS010124</i>	<i>03/01/24</i>	<i>10ml</i>	<i>1ml</i>	<i>9ml</i>	<i>DB</i>	<i>Protocol #12456</i>
<i>01/05/24</i>	<i>KXS010124</i>	<i>03/01/24</i>	<i>9ml</i>	<i>5ml</i>	<i>4ml</i>	<i>DB</i>	<i>Protocol #12456</i>
<i>01/06/24</i>	<i>KXS010124</i>	<i>03/01/24</i>	<i>4ml</i>	<i>3ml</i>	<i>1ml</i>	<i>JS</i>	<i>Protocol #12456</i>
-----New Bottle created-----							



## Sample Form C – DANGEROUS DRUG USE FORM

Note: This form is to be used to track the usage of all dangerous drug stock bottles.

Box 1: Registrant Information		
Registrant's Name: <i>Joe Smith</i>	GBP #: <i>PHRS1234567</i>	Registered Address: <i>123 Main Street, Room # C5100, Atlanta, GA, 30325</i>

Box 2: Stock Bottle Information	
Name of Substance: <i>Isoflurane</i>	Concentration/Strength: <i>100%</i>

Note: Record the total quantity of the substance to the nearest metric unit weight or the total number of units. The log balance must always match the physical balance of dangerous drug. **Any discrepancies (overfill or underfill), or other circumstances that indicate significant loss or theft of dangerous drug must be promptly reported** using Form E. **DO NOT RECORD DISPOSITION/DESTRUCTION OF DRUG ON THIS FORM. USE FORM I FOR DISPOSITION/DESTRUCTION**

Box 3: Current Dangerous Drug Use Log				Drug Name and Concentration/Strength: <i>Isoflurane 100%</i>			
Date	Unique Bottle ID	Expiration Date	Starting Volume/Quantity	Amount Used	Balance Remaining	Printed Name of Person who used the drug	Notes/Comments (optional)
<i>02/11/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>250 ml</i>	<i>10ml</i>	<i>240ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>02/15/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>240ml</i>	<i>20ml</i>	<i>220ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>02/19/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>220ml</i>	<i>10ml</i>	<i>210ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>02/28/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>210ml</i>	<i>30ml</i>	<i>180ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/05/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>180ml</i>	<i>50ml</i>	<i>130ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/10/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>130ml</i>	<i>40ml</i>	<i>110ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>03/11/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>110ml</i>	<i>50ml</i>	<i>60ml</i>	<i>JoAnn Taylor</i>	<i>Euthanasia</i>
<i>03/15/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>60ml</i>	<i>30ml</i>	<i>30ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
<i>03/17/23</i>	<i>ISO021123</i>	<i>06/30/26</i>	<i>30ml</i>	<i>30ml</i>	<i>0ml</i>	<i>Joe Smith</i>	<i>Euthanasia</i>
-----New Bottle-----							
<i>03/18/23</i>	<i>ISO031823</i>	<i>04/01/23</i>	<i>250ml</i>	<i>150ml</i>	<i>100ml</i>	<i>Joe Smith</i>	<i>Protocol #456</i>
<i>03/30/23</i>	<i>ISO031823</i>	<i>04/01/23</i>	<i>100ml</i>	<i>80ml</i>	<i>20ml</i>	<i>Joe Smith</i>	<i>Protocol #456, remainder sent to EHSO</i>

## Sample Form D: Isoflurane Used in Vaporizer Current Use Log

Box 1: Registrant Information		
Registrant's Name: <i>Joe Smith</i>	GA Board of Pharmacy #: <i>PHRS12345678</i>	Registered Address: <i>123 Main Street, Room 45, Atlanta, GA, 30325</i>
Box 2: Stock Bottle Information		
Name of the Substance (as written on the label): <i>Isoflurane</i>	Strength/Concentration (mg/ml): <i>100%</i>	

To use this form continuously, each bottle must have the same drug name and concentration. DO NOT record disposition/destruction on this form. Use Form I for destructions.

Box 3: Stock Bottle Drug Usage					Drug Name and Strength/Concentration: <i>Isoflurane 100%</i>			
Date	Unique Bottle ID	Expiration Date of Bottle	Starting Mass of Container (g) (A)	Ending Mass of Container (g) (B)	Total Isoflurane Used (g) (C= A-B)	Weight of empty container for each Unique Bottle ID (g)	Initials of person administering drug	Reason for Use (optional – may document species & number of animals dosed)
<i>04/01/23</i>	<i>ISO0001</i>	<i>06/30/24</i>	<i>499g</i>	<i>314g</i>	<i>185g</i>	<i>N/A</i>	<i>JS</i>	<i>euthanasia</i>
<i>05/10/23</i>	<i>ISO0001</i>	<i>06/30/24</i>	<i>314g</i>	<i>274g</i>	<i>40g</i>	<i>N/A</i>	<i>JS</i>	<i>euthanasia</i>
<i>05/20/23</i>	<i>ISO0001</i>	<i>06/30/24</i>	<i>274g</i>	<i>125g</i>	<i>149g</i>	<i>125g</i>	<i>DB</i>	<i>Euthanasia (empty bottle)</i>
----- <i>New Bottle</i> -----								
<i>05/21/23</i>	<i>ISO0002</i>	<i>06/30/24</i>	<i>509g</i>	<i>351g</i>	<i>158g</i>	<i>N/A</i>	<i>DB</i>	<i>euthanasia</i>
<i>05/26/23</i>	<i>ISO0002</i>	<i>06/30/24</i>	<i>351g</i>	<i>277g</i>	<i>74g</i>	<i>N/A</i>	<i>JS</i>	<i>euthanasia</i>
<i>05/28/23</i>	<i>ISO0002</i>	<i>06/30/24</i>	<i>277g</i>	<i>125g</i>	<i>152g</i>	<i>125g</i>	<i>JS</i>	<i>empty bottle - overfilled 6.7ml - incident report</i>
----- <i>New Bottle</i> -----								
<i>06/01/23</i>	<i>ISO0003</i>	<i>06/30/24</i>	<i>501g</i>	<i>300g</i>	<i>201g</i>	<i>N/A</i>	<i>DB</i>	<i>euthanasia</i>
<i>06/01/23</i>	<i>ISO0003</i>	<i>06/30/24</i>	<i>300g</i>	<i>245g</i>	<i>55g</i>	<i>N/A</i>	<i>JS</i>	<i>euthanasia</i>
<i>06/01/23</i>	<i>ISO0003</i>	<i>06/30/24</i>	<i>245g</i>	<i>127g</i>	<i>118g</i>	<i>127g</i>	<i>JS</i>	<i>Euthanasia (empty bottle)</i>
----- <i>New Bottle</i> -----								



## Sample Form G: Meloxicam\* (Stock Bottle) Use and Disposition Log

(see working instructions on how to complete this form)

*The purpose of this log is to help track the use of the drug and the number of punctures in the stock bottle.*

Box 1: Registrant Information		
Registrant's Name: <i>Joe Smith</i>	GA Board of Pharmacy #: <i>PHRS12345678</i>	Registered Address: <i>123 Main Street, Room 45, Atlanta, GA, 30325</i>
Box 2: Stock Bottle Information		
Name of the Substance (as written on the label): <i>Meloxidyl</i>		Concentration (mg/ml): <i>1.5mg/ml</i>

*This form may be used continuously if the drug name and concentration remain the same. Each Stock bottle must each have a unique identification. DO NOT record destructions on this form, use Form I.*

Box 3: Stock Bottle Drug Usage					Drug Name and Concentration: <i>Meloxidyl 1.5mg/ml</i>					
Stock bottle puncture #	Date	Unique Bottle ID No:	Manufacturer Expiration Date:	1st Puncture Date:	180 days after 1 <sup>st</sup> Puncture date:	Initial volume (ml)	Volume removed (ml)	Total volume remaining (ml)	Initials of person administering	Optional: Reason for Use (species & number of animals dosed)
1	<i>04/01/23</i>	<i>ME011515-1</i>	<i>05/30/24</i>	<i>04/01/23</i>	<i>09/28/23</i>	<i>10ml</i>	<i>1ml</i>	<i>9ml</i>	<i>db</i>	<i>dilutions</i>
2	<i>05/10/23</i>	<i>ME011515-1</i>	<i>05/30/24</i>	<i>04/01/23</i>	<i>09/28/23</i>	<i>9ml</i>	<i>2ml</i>	<i>7ml</i>	<i>md</i>	<i>dilutions</i>
3	<i>05/20/23</i>	<i>ME011515-1</i>	<i>05/30/24</i>	<i>04/01/23</i>	<i>09/28/23</i>	<i>7ml</i>	<i>1ml</i>	<i>6ml</i>	<i>db</i>	<i>dilutions</i>
4	<i>05/21/23</i>	<i>ME011515-1</i>	<i>05/30/24</i>	<i>04/01/23</i>	<i>09/28/23</i>	<i>6ml</i>	<i>1ml</i>	<i>5ml</i>	<i>md</i>	<i>dilutions</i>
5	<i>05/21/23</i>	<i>ME011515-1</i>	<i>05/30/24</i>	<i>04/01/23</i>	<i>09/28/23</i>	<i>5ml</i>	<i>1ml</i>	<i>4ml</i>	<i>md</i>	<i>dilutions</i>
6	<i>05/21/23</i>	<i>ME011515-1</i>	<i>05/30/24</i>	<i>04/01/23</i>	<i>09/28/23</i>	<i>4ml</i>	<i>2ml</i>	<i>2ml</i>	<i>md</i>	<i>Dilutions - 2ml sent to destruction</i>
<i>-----New Bottle-----</i>										
1	<i>06/12/23</i>	<i>ME011515-2</i>	<i>05/30/24</i>	<i>06/12/23</i>	<i>12/09/23</i>	<i>10ml</i>	<i>2ml</i>	<i>8ml</i>	<i>db</i>	<i>n/a</i>
2	<i>06/12/23</i>	<i>ME011515-2</i>	<i>05/30/24</i>	<i>06/12/23</i>	<i>12/09/23</i>	<i>8ml</i>	<i>5ml</i>	<i>3ml</i>	<i>db</i>	<i>dilution</i>
3	<i>06/15/23</i>	<i>ME011515-2</i>	<i>05/30/24</i>	<i>06/12/23</i>	<i>12/09/23</i>	<i>3ml</i>	<i>2ml</i>	<i>1ml</i>	<i>mh</i>	<i>dilution</i>
4	<i>06/16/23</i>	<i>ME011515-2</i>	<i>05/30/24</i>	<i>06/12/23</i>	<i>12/09/23</i>	<i>1ml</i>	<i>1ml</i>	<i>0ml</i>	<i>db</i>	<i>dilution</i>



Researchers are required to establish and maintain records of all transactions regarding the receipt, distribution or other disposition of controlled substances and dangerous drugs.

You are not required to use the forms on our website but make sure the forms you use have all the documentation requirements per the regulations.

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## Conclusion



Questions?

