



SCMP ID (P)
SCMP ID (EC)
State Use Only

ADVERSE EVENT REPORTING FORM

INSTRUCTIONS
<p>About This Form</p> <p>The purpose of this form is for mandatory reporting of adverse events by Maryland Board of Pharmacy permitted sterile compounding facilities as defined in COMAR 10.34.19.18B(1). This form can be used to report a single adverse patient outcome event as defined in COMAR 10.34.19.03B(1)(a) and/or a single adverse environmental contamination event as defined in COMAR 10.34.19.03B(1)(b). Text fields have limited space. Additional narrative can be included in attachments (see "Attachments" below).</p>
<p>Patient Outcome Adverse Event Reporting</p> <p>For reporting of adverse patient outcomes related to the sterile compounding process, complete sections A, B, C, E, F, G, and I. Note that for section C, additional suspect products beyond two will need to be described in a separate, attached document.</p>
<p>Environmental Contamination Adverse Event Reporting</p> <p>For reporting of evidence of environmental contamination, including microbial contamination above USP <797> thresholds, complete sections A, D, E, F, G, and I. Environmental monitoring reporting requirements include all action level excursions and detection of organisms of concern. Sterility and endotoxin reporting requirements include all instances in which a test failed (i.e., positive/out-of-specification result or invalid test) AND the affected product(s) were distributed for office use or dispensed to patients. Note that this requirement includes instances in which a passing retest for sterility/endotoxin was performed. For all environmental contamination events, assess any patient impact in section D5.</p>
<p>Attachments</p> <p>For all reports, ensure to include all required attachments as highlighted in the separate form sections. As indicated in the applicable sections, you may attach additional documents for more writing space or for supporting documentation. Please reference the section number (e.g., A6) on each applicable attachment.</p> <p>Note that reports for environmental contamination events must also include the applicable environmental or personnel testing reports, including all raw data.</p>
<p>How to Submit</p> <p><u>Option 1:</u> Send this form and all attachments by email attachment to mdpharmacyboard.compounding@maryland.gov.</p> <p><u>Option 2:</u> Send this form and all attachments by regular or certified mail to the Maryland Board of Pharmacy address as follows:</p> <p style="text-align: center;">Sterile Compounding Monitoring Program Maryland Board of Pharmacy 4201 Patterson Avenue Baltimore, MD 21215-2299</p>

A. EVENT INFORMATION
<p>1. Type of Event (<i>Check all that apply</i>)</p> <p><input type="checkbox"/> Patient Event: <i>See section B5 for qualifying events.</i></p> <p><input type="checkbox"/> Environmental Contamination: <i>See section D1 for qualifying events.</i></p>
<p>2. Date Event Occurred (<i>mm/dd/yyyy</i>): ___ / ___ / _____</p>
<p>3. Event Discovery Date (<i>mm/dd/yyyy</i>): ___ / ___ / _____</p>
<p>4. Event Report Date (<i>mm/dd/yyyy</i>): ___ / ___ / _____</p>
<p>5. Link to Known Related Adverse Event(s) (<i>if applicable</i>)</p> <p style="text-align: center;">Attach Adverse Event Reporting Forms for each event</p> <p>Event 1 Reporting Date (<i>mm/dd/yyyy</i>): ___ / ___ / _____</p> <p>Event 2 Reporting Date (<i>mm/dd/yyyy</i>): ___ / ___ / _____</p> <p>Event 3 Reporting Date (<i>mm/dd/yyyy</i>): ___ / ___ / _____</p>
<p>6. Describe Event or Problem (<i>May include attachments</i>)</p> <p style="text-align: right;"><input type="checkbox"/> Attachments Included</p>
<p>7. Relevant Tests/Laboratory Data, Including Dates (<i>Date format mm/dd/yyyy; may include attachments</i>)</p> <p style="text-align: right;"><input type="checkbox"/> Attachments Included</p>



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B. ADVERSE EVENT – PATIENT (If Applicable)

1. Name		2. Phone #	
3. Age		4. Relevant Allergies/Drug Intolerances	

5. **Outcome Attributed to Adverse Event (Check all that apply)**
 Death Include date (mm/dd/yyyy): ___/___/_____
 Life-threatening
 Disability or Permanent Damage
 Hospitalization – initial or prolonged
 Congenital Anomaly/Birth Defects
 Other Serious (Important Medical Events). Describe in section A6.

C. SUSPECT PRODUCT(S) (If Applicable)

All date formats: mm/dd/yyyy

1. Name and Strength	Lot # or Unique ID	Beyond-use Date
#1		
#2		

2. Drug components/ingredients, if known:
Attach compounding logs (if available)

#1	
#2	

3. Dose	Frequency	Route of Administration
#1		
#2		

4. Manufacturer/compounder	5. USP <797> compounding risk category (if known)							
	<table border="1"> <tr> <td>#1</td> <td><input type="checkbox"/> Low</td> <td><input type="checkbox"/> Medium</td> <td><input type="checkbox"/> High</td> </tr> <tr> <td>#2</td> <td><input type="checkbox"/> Low</td> <td><input type="checkbox"/> Medium</td> <td><input type="checkbox"/> High</td> </tr> </table>	#1	<input type="checkbox"/> Low	<input type="checkbox"/> Medium	<input type="checkbox"/> High	#2	<input type="checkbox"/> Low	<input type="checkbox"/> Medium
#1	<input type="checkbox"/> Low	<input type="checkbox"/> Medium	<input type="checkbox"/> High					
#2	<input type="checkbox"/> Low	<input type="checkbox"/> Medium	<input type="checkbox"/> High					

Items 6 – 10: Hospital or Direct Caregivers Only

6. Therapy Dates (If unknown, give duration) from/to (or best estimate)	7. Event Abated After Use Stopped or Dose Reduced?
#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not apply

8. Diagnosis for Use (Indication)	9. Event Reappeared After Reintroduction?
#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Does not apply

10. **Concomitant Medical Products and Therapy Dates (Exclude treatment of event; date format mm/dd/yyyy; may include attachments)**

Attachments Included

D. ADVERSE EVENT – ENV. CONTAMINATION (If Applicable)

1. **Type of Testing and Event (Check all that apply)**
 Environmental Monitoring – Action Level Excursion
 Viable air sampling Viable surface sampling
 Environmental Monitoring – Organism of Concern
 Viable air sampling Viable surface sampling
 Sterility Test – Product distributed or dispensed to patients
 Positive Result Invalid Test
 Endotoxin Test – Product distributed or dispensed to patients
 Out-of-Spec Result Invalid Test

2. **Organisms of Concern Detected (Check all that apply):**
 Mold Yeast
 Gram-negative bacteria Genus/species of concern
 Coagulase positive *Staphylococcus*
 Other: _____

3. **Action Levels**
 Pharmacy uses USP <797> action levels, -OR-
 Pharmacy uses action levels based on trending data as follows:
Attach justification for action levels based on trending data (if applicable)

ISO Class	Air Sampling	Surface Sampling	Fingertip Sampling
ISO 5	CFU/m ³	CFU/plate	CFU/plate
ISO 7	CFU/m ³	CFU/plate	CFU/plate
ISO 8	CFU/m ³	CFU/plate	CFU/plate

4. **Follow-up Actions Following Discovery (May include attachments)**

Attachments Included

5. **Potential and/or Actual Patient Impact Resulting From Event? (May include attachments)**

Attachments Included

This form is for mandatory reporting of adverse events as per COMAR 10.34.19.18.

Direct all inquiries regarding this form and the Sterile Compounding Monitoring Program to mdpharmacyboard.compounding@maryland.gov or contact the Board main phone line at (410) 764-4755.

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E. RECALL INFORMATION	
1. Has a recall been initiated due to adverse event? <input type="checkbox"/> Yes – Complete the remainder of Section E <input type="checkbox"/> No – Justify below, skip to Section F:	
2. Recall Initiation Date (mm/dd/yyyy): ___ / ___ / ____	
3. Nature of Recall <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <input type="checkbox"/> Requested or mandated by FDA ATTACH TO FORM: - Recall Request from FDA (formal or informal) - Recall Submission to FDA - All Documentation Leading to Recall (e.g., Form FDA 483, Warning Letter, etc.) </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <input type="checkbox"/> Voluntary, reported to FDA ATTACH TO FORM: - Recall Submission to FDA - All Documentation Leading to Recall (e.g., evidence of contamination, potency issue, recall of component, etc.) </div> <div style="border: 1px solid black; padding: 5px;"> <input type="checkbox"/> Internal, not reported to FDA ATTACH TO FORM: - Recall Policy, Procedure, or SOP - All Documentation Leading to Recall (e.g., evidence of contamination, potency issue, recall of API, etc.) </div>	
4. Status of Recall <input type="checkbox"/> Pending Action <input type="checkbox"/> Ongoing <input type="checkbox"/> Completed <input type="checkbox"/> Terminated	5. Product Type (Check all that apply) <input type="checkbox"/> Intravenous <input type="checkbox"/> Ophthalmic <input type="checkbox"/> Chemotherapy <input type="checkbox"/> Hazardous <input type="checkbox"/> Repackaged <input type="checkbox"/> Irrigation <input type="checkbox"/> Aqueous bronchial inhalation <input type="checkbox"/> Bath or soak for live organs/tissues <input type="checkbox"/> Proprietary bag/vial system <input type="checkbox"/> Total Parenteral Nutrition
F. INITIAL REPORTER	
1. Name and Address	2. Phone
	3. Email
4. Health Professional? <input type="checkbox"/> Yes <input type="checkbox"/> No	5. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

G. PHARMACY INFORMATION	
1. Name & Address	2. Business Phone
	3. Business Email
4. Maryland Permit Number(s)	
5. 503B Outsourcing Facility? <input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Maryland Licensed Pharmacist Name: _____ License #: _____ Phone: _____ Email: _____	
7. Pharmacy Establishment (Check all that apply) <input type="checkbox"/> Assisted Living Facility <input type="checkbox"/> Hospital – Oncology <input type="checkbox"/> Chain (> 10 stores) <input type="checkbox"/> Independent <input type="checkbox"/> Clinic <input type="checkbox"/> Internet <input type="checkbox"/> Community (< 10 stores) <input type="checkbox"/> Intravenous Therapy <input type="checkbox"/> Comprehensive/Long Term Care <input type="checkbox"/> Mail Order <input type="checkbox"/> Consultant <input type="checkbox"/> Managed Care <input type="checkbox"/> Correctional Institution <input type="checkbox"/> Non-Sterile Compounding <input type="checkbox"/> Durable Medical Equipment/Device <input type="checkbox"/> Nuclear <input type="checkbox"/> Free Clinic <input type="checkbox"/> Nursing Home <input type="checkbox"/> Home Health <input type="checkbox"/> Pharmacy Service Center <input type="checkbox"/> Hospital – Inpatient <input type="checkbox"/> Research <input type="checkbox"/> Hospital – Outpatient <input type="checkbox"/> Veterinary	
H. REMARKS	
Additional Remarks (May include attachments) <div style="text-align: right;"><input type="checkbox"/> Attachments Included</div>	
I. CONTACT INFO AND SIGNATURE	
1. Name	
2. Position/Title	
3. Phone #	
4. Email	
5. Sign and Date	
<div style="border: 1px solid black; padding: 5px; font-size: 2em; font-family: cursive;">X Signature</div>	<div style="border: 1px solid black; padding: 5px; font-size: 2em; font-family: cursive;">Date</div>

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