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v1.6 4/2026	State Use Only

BOARD OF PHARMACY

ADVERSE EVENT REPORTING FORM

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INSTRUCTIONS

About This Form

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).

Patient Outcome Adverse Event Reporting

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.

Environmental Contamination Adverse Event Reporting

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.

Attachments

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.

Note that reports for environmental contamination events must also **include the applicable environmental or personnel testing reports, including all raw data.**

How to Submit

Option 1:
Send this form and all attachments by email attachment to mdpharmacyboard.compounding@maryland.gov.

Option 2:
Send this form and all attachments by regular or certified mail to the Maryland Board of Pharmacy address as follows:

Sterile Compounding Monitoring Program
Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215-2299

A. EVENT INFORMATION

1. **Type of Event** *(Check all that apply)*
☐ Patient Event: *See section B5 for qualifying events.*
☐ Environmental Contamination: *See section D1 for qualifying events.*

2. **Date Event Occurred** *(mm/dd/yyyy)*: __ __ / __ __ / __ __ __ __

3. **Event Discovery Date** *(mm/dd/yyyy)*: __ __ / __ __ / __ __ __ __

4. **Event Report Date** *(mm/dd/yyyy)*: __ __ / __ __ / __ __ __ __

5. **Link to Known Related Adverse Event(s)** *(if applicable)*

Attach Adverse Event Reporting Forms for each event

Event 1 Reporting Date *(mm/dd/yyyy)*: __ __ / __ __ / __ __ __ __

Event 2 Reporting Date *(mm/dd/yyyy)*: __ __ / __ __ / __ __ __ __

Event 3 Reporting Date *(mm/dd/yyyy)*: __ __ / __ __ / __ __ __ __

6. **Describe Event or Problem** *(May include attachments)*

☐ Attachments Included

7. **Relevant Tests/Laboratory Data, Including Dates** *(Date format mm/dd/yyyy; may include attachments)*

☐ Attachments Included

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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**

#1 _____

#2 _____

5. **USP <797> compounding risk category** *(if known)*

#1	☐ Low	☐ Medium	☐ High
#2	☐ Low	☐ Medium	☐ High

Items 6 – 10: Hospital or Direct Caregivers Only

6. **Therapy Dates** *(If unknown, give duration) from/to (or best estimate)*

#1 _____

#2 _____

7. **Event Abated After Use Stopped or Dose Reduced?**

#1	☐ Yes	☐ No	☐ Does not apply
#2	☐ Yes	☐ No	☐ Does not apply

8. **Diagnosis for Use** *(Indication)*

#1 _____

#2 _____

9. **Event Reappeared After Reintroduction?**

#1	☐ Yes	☐ No	☐ Does not apply
#2	☐ Yes	☐ No	☐ 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

☐ **Organisms 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

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Maryland
DEPARTMENT OF HEALTH
Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary

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E. RECALL INFORMATION

1. **Has a recall been initiated due to adverse event?**
☐ Yes – Complete the remainder of Section E
☐ No – Justify below, skip to Section F:

2. **Recall Initiation Date** *(mm/dd/yyyy):* __ __ / __ __ / __ __ __ __

3. **Nature of Recall**

☐ 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.)

☐ 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.)

☐ 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.)

4. **Status of Recall**
☐ Pending Action
☐ Ongoing
☐ Completed
☐ Terminated

5. **Product Type** *(Check all that apply)*
☐ Intravenous
☐ Chemotherapy
☐ Repackaged
☐ Ophthalmic
☐ Hazardous
☐ Irrigation
☐ Aqueous bronchial inhalation
☐ Bath or soak for live organs/tissues
☐ Proprietary bag/vial system
☐ Total Parenteral Nutrition

F. INITIAL REPORTER

1. **Name and Address**

2. **Phone**

3. **Email**

4. **Health Professional?** ☐ Yes ☐ No

5. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unknown

G. PHARMACY INFORMATION

1. **Name & Address**

2. **Business Phone**

3. **Business Email**

4. **Maryland Permit Number(s)**

5. **503B Outsourcing Facility?** ☐ Yes ☐ No

6. **Maryland Licensed Pharmacist**

Name: License #:

Phone: Email:

7. **Pharmacy Establishment** *(Check all that apply)*

☐ Assisted Living Facility
☐ Chain (> 10 stores)
☐ Clinic
☐ Community (< 10 stores)
☐ Comprehensive/Long Term Care
☐ Consultant
☐ Correctional Institution
☐ Durable Medical Equipment/Device
☐ Free Clinic
☐ Home Health
☐ Hospital – Inpatient
☐ Hospital – Outpatient
☐ Hospital – Oncology
☐ Independent
☐ Internet
☐ Intravenous Therapy
☐ Mail Order
☐ Managed Care
☐ Non-Sterile Compounding
☐ Nuclear
☐ Nursing Home
☐ Pharmacy Service Center
☐ Research
☐ Veterinary

H. REMARKS

Additional Remarks *(May include attachments)*

☐ Attachments Included

I. CONTACT INFO AND SIGNATURE

1. **Name**

2. **Position/Title**

3. **Phone #**

4. **Email**

5. **Sign and Date**

Date if signed by hand:

X Signature | Date

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