



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
239 Causeway Street, Suite 500, Boston, MA 02114

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MARYLOU SUDDERS
Secretary
MONICA BHAREL, MD, MPH
Commissioner

STERILE COMPOUNDING REPORTING FORM

January 1 - June 30 _____(year)
July 1 – December 31 _____(year)

All Massachusetts pharmacies that are licensed by the Massachusetts Board of Registration in Pharmacy (“Board”) and engage in compounding of sterile products are required to complete and submit product, volume, distribution, and compliance data every six months pursuant to 247 CMR 6.15(5). This reporting process is designed to ensure that all pharmacies licensed by the Board that perform **sterile compounding are in compliance with all state and federal laws and regulations, including in particular the United States Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding – Sterile Preparations. The completed form must be submitted to the Board on or before **August 15 for the first half of the year or February 15 for the second half.****

Massachusetts pharmacies that do **not** engage in **sterile compounding, as defined in USP General Chapter 797**, are **NOT** required to submit this form to the Board. Hospital pharmacies engaged in sterile compounding are not required to submit this form at this time.

The **FAILURE** of any Massachusetts pharmacy that performs sterile compounding to provide the requested information to the Board by the deadline may be grounds for discipline under 247 CMR 10.03(q).

Any Massachusetts pharmacy that performs sterile compounding that does NOT provide the requested information to the Board by the required date is NOT authorized to engage in sterile compounding and must IMMEDIATELY CEASE preparing and dispensing all sterile products.

Please **electronically** submit the Sterile Compounding Reporting Form and Table of CSP Prescriptions found at: <http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/mandated-reporting-forms-.html> to sterilecompoundingreportingforms@massmail.state.ma.us

Please Note: Table of CSP Prescriptions must be submitted using Board provided template in **Excel format only** (i.e. not pdf versions).

All questions regarding the Sterile Compounding Reporting Form and /or the Table of CSP Prescriptions should be directed to William Frisch, Director of Pharmacy Compliance at William.Frisch@state.ma.us or Michelle Chan, Quality Assurance Pharmacist at Michelle.Chan@State.MA.US.

Thank you.

Name of Pharmacy: _____

STERILE COMPOUNDING REPORTING FORM

January 1 - June 30 _____(year)

July 1 – December 31 _____(year)

Name of Massachusetts Pharmacy _____

Street Address _____

City/Town _____ Zip Code _____

Tel. No. _____ Fax No. _____

Pharmacy E-mail _____

MA Drug Store Permit Numbers:

Drug Store (DS No.) _____ Exp. Date _____

Controlled Substance (CS No.) _____ Exp. Date _____

List any other registrations below related to the Massachusetts Pharmacy (e.g., manufacturer, wholesale distributor):

DEA Registration No. _____

DCP Registration No. _____

FDA Registration No. _____ (manufacturer/distributor only)

Other: _____

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Answer all of the following questions for the specified reporting period ONLY

A. STERILE COMPOUNDING ACTIVITY:

1. Indicate the total number of prescriptions dispensed by month and by USP General Chapter 797 risk-level category (low, medium, high) for the reporting period listed below:

Low Risk Compounding: single volume transfers of not more than 3 sterile dosage forms and not more than 2 entries into a sterile container (e.g., hydrating solutions, irrigations, antibiotics and oncology medications).

Medium Risk Compounding: the compounding process includes complex aseptic manipulations other than single volume transfer (e.g., TPN, cardioplegia solutions, multiple sterile ingredient admixtures).

High Risk Compounding: non-sterile ingredients, including manufactured products not intended for sterile routes of administration, are incorporated or a non-sterile device is employed before terminal sterilization.

Total Number of Prescriptions / Orders				
	Risk Level			
Month/Volume	# Low	# Medium	# High	Total

2. Does the pharmacy hold a license in any other state than Massachusetts?

☐Yes ☐No

If yes, identify all other state(s) in which the pharmacy holds a license and indicate the status of each non-resident license as: active, expired, on probation, restricted or revoked.

<input type="checkbox"/> Alabama	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Alaska	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Arizona	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Arkansas	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> California	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Colorado	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Connecticut	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Delaware	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> D.C.	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Florida	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Georgia	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked

Name of Pharmacy: _____

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<input type="checkbox"/> Hawaii	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Idaho	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Illinois	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Indiana	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Iowa	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Kansas	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Kentucky	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Louisiana	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Maine	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Maryland	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Michigan	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Minnesota	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Mississippi	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Missouri	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Montana	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Nebraska	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Nevada	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> New Hampshire	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> New Jersey	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> New Mexico	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> New York	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> North Carolina	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> North Dakota	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Ohio	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Oklahoma	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Oregon	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Pennsylvania	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Rhode Island	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> South Carolina	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> South Dakota	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Tennessee	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Texas	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Utah	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Vermont	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Virginia	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Washington	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> West Virginia	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Wisconsin	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Wyoming	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Other _____	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked
<input type="checkbox"/> Other _____	<input type="checkbox"/> Active	<input type="checkbox"/> Expired	<input type="checkbox"/> Probation	<input type="checkbox"/> Restricted	<input type="checkbox"/> Revoked

Name of Pharmacy: _____

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3. Does the pharmacy dispense Compounded Sterile Preparations (CSPs) to any states and/or jurisdictions outside of Massachusetts?

☐Yes ☐No

If yes, identify all state(s) and jurisdictions outside of Massachusetts which the pharmacy dispenses to.

<input type="checkbox"/> Alabama	<input type="checkbox"/> Illinois	<input type="checkbox"/> Nebraska	<input type="checkbox"/> South Carolina
<input type="checkbox"/> Alaska	<input type="checkbox"/> Indiana	<input type="checkbox"/> Nevada	<input type="checkbox"/> South Dakota
<input type="checkbox"/> Arizona	<input type="checkbox"/> Iowa	<input type="checkbox"/> New Hampshire	<input type="checkbox"/> Tennessee
<input type="checkbox"/> Arkansas	<input type="checkbox"/> Kansas	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Texas
<input type="checkbox"/> California	<input type="checkbox"/> Kentucky	<input type="checkbox"/> New Mexico	<input type="checkbox"/> Utah
<input type="checkbox"/> Colorado	<input type="checkbox"/> Louisiana	<input type="checkbox"/> New York	<input type="checkbox"/> Vermont
<input type="checkbox"/> Connecticut	<input type="checkbox"/> Maine	<input type="checkbox"/> North Carolina	<input type="checkbox"/> Virginia
<input type="checkbox"/> Delaware	<input type="checkbox"/> Maryland	<input type="checkbox"/> North Dakota	<input type="checkbox"/> Washington
<input type="checkbox"/> D.C.	<input type="checkbox"/> Michigan	<input type="checkbox"/> Ohio	<input type="checkbox"/> West Virginia
<input type="checkbox"/> Florida	<input type="checkbox"/> Minnesota	<input type="checkbox"/> Oklahoma	<input type="checkbox"/> Wisconsin
<input type="checkbox"/> Georgia	<input type="checkbox"/> Mississippi	<input type="checkbox"/> Oregon	<input type="checkbox"/> Wyoming
<input type="checkbox"/> Hawaii	<input type="checkbox"/> Missouri	<input type="checkbox"/> Pennsylvania	<input type="checkbox"/> Other: _____
<input type="checkbox"/> Idaho	<input type="checkbox"/> Montana	<input type="checkbox"/> Rhode Island	<input type="checkbox"/> Other: _____

4. Is the pharmacy currently registered, licensed, or permitted as a wholesale distributor in any state?

☐Yes ☐No

If yes, identify all other state(s) which the pharmacy is currently registered, licensed, or permitted as a wholesale distributor.

<input type="checkbox"/> Alabama	<input type="checkbox"/> Illinois	<input type="checkbox"/> Nebraska	<input type="checkbox"/> South Carolina
<input type="checkbox"/> Alaska	<input type="checkbox"/> Indiana	<input type="checkbox"/> Nevada	<input type="checkbox"/> South Dakota
<input type="checkbox"/> Arizona	<input type="checkbox"/> Iowa	<input type="checkbox"/> New Hampshire	<input type="checkbox"/> Tennessee
<input type="checkbox"/> Arkansas	<input type="checkbox"/> Kansas	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Texas
<input type="checkbox"/> California	<input type="checkbox"/> Kentucky	<input type="checkbox"/> New Mexico	<input type="checkbox"/> Utah
<input type="checkbox"/> Colorado	<input type="checkbox"/> Louisiana	<input type="checkbox"/> New York	<input type="checkbox"/> Vermont
<input type="checkbox"/> Connecticut	<input type="checkbox"/> Maine	<input type="checkbox"/> North Carolina	<input type="checkbox"/> Virginia
<input type="checkbox"/> Delaware	<input type="checkbox"/> Maryland	<input type="checkbox"/> North Dakota	<input type="checkbox"/> Washington
<input type="checkbox"/> D.C.	<input type="checkbox"/> Michigan	<input type="checkbox"/> Ohio	<input type="checkbox"/> West Virginia
<input type="checkbox"/> Florida	<input type="checkbox"/> Minnesota	<input type="checkbox"/> Oklahoma	<input type="checkbox"/> Wisconsin
<input type="checkbox"/> Georgia	<input type="checkbox"/> Mississippi	<input type="checkbox"/> Oregon	<input type="checkbox"/> Wyoming
<input type="checkbox"/> Hawaii	<input type="checkbox"/> Missouri	<input type="checkbox"/> Pennsylvania	<input type="checkbox"/> Other: _____
<input type="checkbox"/> Idaho	<input type="checkbox"/> Montana	<input type="checkbox"/> Rhode Island	<input type="checkbox"/> Other: _____

Name of Pharmacy: _____

STERILE COMPOUNDING REPORTING FORM

January 1 - June 30 _____(year)

July 1 – December 31 _____(year)

5. Identify all wholesale distributors, including both contracted entities and manufacturers, that the pharmacy receives products from, including chemicals, medications, syringes, vials, and other related equipment and materials required to produce CSPs:

- | | | |
|--|--|--|
| <input type="checkbox"/> Amerisource Bergen | <input type="checkbox"/> Fagron | <input type="checkbox"/> McKesson |
| <input type="checkbox"/> American Reagent | <input type="checkbox"/> FFF Enterprises | <input type="checkbox"/> Medical Specialties |
| <input type="checkbox"/> Anda | <input type="checkbox"/> Gallipot | <input type="checkbox"/> Medisca |
| <input type="checkbox"/> Apothecare Products | <input type="checkbox"/> Haemonetics | <input type="checkbox"/> Medline |
| <input type="checkbox"/> APP | <input type="checkbox"/> HD Smith | <input type="checkbox"/> MSD |
| <input type="checkbox"/> ASD | <input type="checkbox"/> Healthcare Logistics | <input type="checkbox"/> ODC |
| <input type="checkbox"/> Attentus | <input type="checkbox"/> Healthcare Technologies | <input type="checkbox"/> PCCA |
| <input type="checkbox"/> Baxter | <input type="checkbox"/> Hospira | <input type="checkbox"/> Sagent |
| <input type="checkbox"/> Bbraun | <input type="checkbox"/> Independence Medical | <input type="checkbox"/> Sandor Pharm |
| <input type="checkbox"/> Bellco | <input type="checkbox"/> Integrated Medical | <input type="checkbox"/> Smiths Medical |
| <input type="checkbox"/> Bio Soln | <input type="checkbox"/> IMS | <input type="checkbox"/> Sun Pharmaceuticals |
| <input type="checkbox"/> CAPS- Birmingham | <input type="checkbox"/> JOM | <input type="checkbox"/> Vygon |
| <input type="checkbox"/> CAPS- Chicago | <input type="checkbox"/> Kinray | <input type="checkbox"/> West Ward |
| <input type="checkbox"/> CAPS- Lehigh Valley | <input type="checkbox"/> Letco | <input type="checkbox"/> Wolf Medica |
| <input type="checkbox"/> Cardinal | <input type="checkbox"/> Letzo | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> CSL Behring | <input type="checkbox"/> Liberty Industries | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Cubist | <input type="checkbox"/> Lifeline | |

6. Identify all manufacturers that provide the pharmacy with non-sterile Active Pharmaceutical Ingredients (API):

- | | | |
|-----------------------------------|---|---------------------------------------|
| <input type="checkbox"/> Anda | <input type="checkbox"/> Letco | <input type="checkbox"/> PCCA |
| <input type="checkbox"/> Bellco | <input type="checkbox"/> Mallinckrodt Group | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Fagron | <input type="checkbox"/> McKesson | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Freedom | <input type="checkbox"/> Medisca | |
| <input type="checkbox"/> Gallipot | <input type="checkbox"/> ODC | |

Name of Pharmacy: _____

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B. STAFFING/TRAINING/COMPETENCY EVALUATIONS:

1.

- a) Identify by name, title and license number of all pharmacy personnel engaged in preparing CSPs.
(Attach additional pages if necessary.)

Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____
Name _____	Title _____	License# _____

- b) State the current number of pharmacists involved in any way in the preparation and/or dispensing of CSPs. _____

State the current number of pharmacy technicians involved in any way in the preparation and/or dispensing of CSPs. _____

2. Do all pharmacists and pharmacy technicians involved in the preparation and/or dispensing of CSPs have documented training consistent with USP 797?

☐ Yes ☐ No

3. Do all pharmacists and pharmacy technicians involved in the preparation and/or dispensing of CSPs undergo at least one regularly scheduled competency validation every 12 months?

☐ Yes ☐ No

If yes, specify the frequency of competency validations:

<input type="checkbox"/> Every month	<input type="checkbox"/> Every 5 months	<input type="checkbox"/> Every 9 months
<input type="checkbox"/> Every 2 months	<input type="checkbox"/> Every 6 months	<input type="checkbox"/> Every 10 months
<input type="checkbox"/> Every 3 months	<input type="checkbox"/> Every 7 months	<input type="checkbox"/> Every 11 months
<input type="checkbox"/> Every 4 months	<input type="checkbox"/> Every 8 months	<input type="checkbox"/> Every 12 months

Name of Pharmacy: _____

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C. QUALITY ASSURANCE

Please complete the following table:

Type of Equipment/Resources	How many of each does the pharmacy have?	Have they been ISO certified within the past 6 months?
Laminar air flow hoods		
Biological safety cabinets (BSCs)		
Compounding Aseptic Isolators (CAIs, glove boxes)		
Compounding Aseptic Containment Isolators (CACIs)		
Clean rooms, positive pressure		
Ante Rooms, positive pressure		
Clean rooms, negative pressure		

1.

a) Identify all sterilization processes used by pharmacy:

- ☐ Filter
 ☐ Dry Heat
 ☐ Other: _____

☐ Steam Autoclave

b) Does the pharmacy follow USP <797> standards for sterilization of CSPs?

☐ Yes ☐ No ☐ N/A

c) If used, does the pharmacy properly sterilize non-sterile vials, non-sterile stoppers, or any other non-sterile components in the preparation of CSPs?

☐ Yes ☐ No ☐ N/A

Name of Pharmacy: _____

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- d) Has pharmacy verified that all methods achieve sterility while maintaining appropriate strength, purity, quality, and packaging integrity?

☐Yes ☐No ☐N/A

2. Does the pharmacy store, use, and maintain all supplies and equipment used to prepare CSPs in accordance with manufacturers' specifications?

☐Yes ☐No

3. When was the most recent USP <797> Gap Analysis completed? ____/____/____ (mm/dd/yyyy)

4. Does the Pharmacy have a data driven Quality Assurance/Performance Improvement Program?

☐Yes ☐No

5. Does the pharmacy always use USP <797> Beyond-Use-Dating?

☐Yes ☐No

If the pharmacy does not always use USP <797> Beyond-Use-Dating, answer the following questions:

- a) For what risk level(s) does the pharmacy extend the USP <797> Beyond-Use-Date?

☐ Low ☐ Medium ☐ High

- b) What is the pharmacy's longest Beyond-Use-Date (in days)? _____ and what is this CSP's risk level?

☐ Low ☐ Medium ☐ High

- c) Does the pharmacy use scientific literature in order to establish Beyond-Use-Dating?

☐Yes ☐No

- d) Does the pharmacy independently validate its Beyond-Use-Dating?

☐Yes ☐No

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D. COMPLIANCE/SANCTIONS

1. Does the pharmacy only prepare and dispense CSPs after receipt of a valid prescription for a single patient?

☐ Yes ☐ No

2. Check all risk levels of CSPs the pharmacy prepared during the reporting period.

☐ Low ☐ Medium ☐ High

3. Does the pharmacy maintain a written policy and procedure manual for preparing and dispensing Compounded Sterile Preparations in conformance with USP <797>?

☐ Yes ☐ No

4. Did the pharmacy engage in batch compounding of CSPs during this reporting period?

☐ Yes ☐ No

If yes:

- a) How many units were in the largest batch? (Units= 1 cassette, 1 bag, 1 syringe, etc.) _____

- b) Does the pharmacy perform sterility testing on all batches?

☐ Yes ☐ No

If no, please explain why not. _____

- c) Does the pharmacy perform endotoxin testing on all batches?

☐ Yes ☐ No

If no, please explain why not. _____

5. Has the pharmacy been disciplined, as defined in 247 CMR 6.15, during the reporting period?

☐ Yes ☐ No

If yes:

- a) Did the pharmacy report the disciplinary action(s) to the Massachusetts Board of Registration in Pharmacy?

☐ Yes ☐ No

If no, please explain why not. _____

Identify the agency or agencies that disciplined the pharmacy:

☐ N/A

☐ Medicare

☐ Medicaid

☐ DEA

☐ FDA

☐ Alabama BOP

☐ Alaska BOP

☐ Arizona BOP

☐ Arkansas BOP

☐ California BOP

☐ Colorado BOP

☐ Connecticut BOP

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- | | | |
|---|--|--|
| <input type="checkbox"/> Delaware BORP | <input type="checkbox"/> Minnesota BORP | <input type="checkbox"/> Pennsylvania BORP |
| <input type="checkbox"/> D.C. BORP | <input type="checkbox"/> Mississippi BORP | <input type="checkbox"/> Rhode Island BORP |
| <input type="checkbox"/> Florida BORP | <input type="checkbox"/> Missouri BORP | <input type="checkbox"/> South Carolina BORP |
| <input type="checkbox"/> Georgia BORP | <input type="checkbox"/> Montana BORP | <input type="checkbox"/> South Dakota BORP |
| <input type="checkbox"/> Hawaii BORP | <input type="checkbox"/> Nebraska BORP | <input type="checkbox"/> Tennessee BORP |
| <input type="checkbox"/> Idaho BORP | <input type="checkbox"/> Nevada BORP | <input type="checkbox"/> Texas BORP |
| <input type="checkbox"/> Illinois BORP | <input type="checkbox"/> New Hampshire BORP | <input type="checkbox"/> Utah BORP |
| <input type="checkbox"/> Indiana BORP | <input type="checkbox"/> New Jersey BORP | <input type="checkbox"/> Vermont BORP |
| <input type="checkbox"/> Iowa BORP | <input type="checkbox"/> New Mexico BORP | <input type="checkbox"/> Virginia BORP |
| <input type="checkbox"/> Kansas BORP | <input type="checkbox"/> New York BORP | <input type="checkbox"/> Washington BORP |
| <input type="checkbox"/> Kentucky BORP | <input type="checkbox"/> North Carolina BORP | <input type="checkbox"/> West Virginia BORP |
| <input type="checkbox"/> Louisiana BORP | <input type="checkbox"/> North Dakota BORP | <input type="checkbox"/> Wisconsin BORP |
| <input type="checkbox"/> Maine BORP | <input type="checkbox"/> Ohio BORP | <input type="checkbox"/> Wyoming BORP |
| <input type="checkbox"/> Maryland BORP | <input type="checkbox"/> Oklahoma BORP | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Michigan BORP | <input type="checkbox"/> Oregon BORP | <input type="checkbox"/> Other: _____ |

6. Did the pharmacy experience any adverse change in status of accreditation, as defined in 247 CMR 6.15, including but not limited to withdrawal, discontinuance, termination, revocation, suspension, probation, or warning, during the reporting period?

☐ Yes ☐ No

If yes:

- a) Did the pharmacy report this change in status to the Massachusetts Board of Registration in Pharmacy?

☐ Yes ☐ No

- b) For which accreditation organization(s)?

☐ PCAB ☐ Joint Commission ☐ Other _____

Name of Pharmacy: _____

STERILE COMPOUNDING REPORTING FORM

January 1 - June 30 _____(year)

July 1 – December 31 _____(year)

E. LEGISLATIVE REPORTING REQUIREMENTS

1. Fill out the **Table of CSP Prescriptions for This Reporting Period** in Excel that is provided on the Board's website under Mandated Reporting Forms.
2. What is the number of **in-state** individual sterile compounded prescriptions or orders for end users your pharmacy has dispensed during this reporting period? _____
3. What is the number of **out-of-state** individual sterile compounded prescriptions or orders for end users your pharmacy has dispensed during this reporting period? _____
4. Have the MOR and all pharmacists and technicians on staff completed all required CE credits?
☐Yes ☐No
5. List the name and title of the MOR and all principal managers (include all current managers in the pharmacy; not just sterile compounding).

Name _____ **Title** _____

Name _____ **Title** _____

Name _____ **Title** _____

Name _____ **Title** _____

Name _____ **Title** _____

Name _____ **Title** _____

Name _____ **Title** _____

Name _____ **Title** _____

6. Attach a list of the name and title of every employee at the facility (remember to include all non-licensed and non-pharmacy individuals).
7. Is the pharmacy compliant with all requests for information by the Massachusetts Board of Registration in Pharmacy?

☐Yes ☐No

Name of Pharmacy: _____

STERILE COMPOUNDING REPORTING FORM

January 1 - June 30 _____(year)

July 1 – December 31 _____(year)

Attestation regarding compliance with laws and regulations:

I, _____ (name), the Manager of Record of _____ (name of pharmacy), attest under the pains and penalties of perjury that _____ (name of pharmacy) is in compliance with all laws and regulations pertinent to sterile compounding, including USP General Chapter 797 - Sterile Preparations. _____ (name of pharmacy) only dispenses medication pursuant to a valid prescription as defined in M.G.L. c. 94C, §19 for a single patient, regardless of whether the medication is prepared for a Massachusetts or out-of-state patient.

Print Name of Manager of Record: _____ MA License Number: _____

Signature of Manager of Record: _____ Date: _____

Please direct any questions regarding this form to William Frisch, Director of Pharmacy Compliance at William.Frisch@state.ma.us or Michelle Chan, Quality Assurance Pharmacist at Michelle.Chan@State.MA.US

DO NOT submit this form by means other than E-mail. Mailed paper and faxed copies will not be accepted. Thank you.

Name of Pharmacy: _____