



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

December 16, 2014

The Honorable Martin O'Malley
Governor
100 State Circle
Annapolis, MD 21401-1991

The Honorable Joan Carter Conway
Chair, Senate Education, Health,
and Environmental Affairs Committee
Miller Senate Office Building, 2 West Wing
Annapolis, MD 21401-1991

The Honorable Peter A. Hammen
Chair, House Health and Government
Operations Committee
House Office Building, Room 241
Annapolis, MD 21401-1991

**RE: Senate Bill 1108 (Chapter 580 of the Acts of 2014) – Sterile Compounding Permits –
Definition of “Compounding,” Study and Recommendations**

Dear Governor O'Malley and Chairmen Conway and Hammen:

The Safety Standards workgroup was established by Senate Bill 1108, Chapter 580 of the Acts of 2014 (Section 2), to study appropriate national safety standards for mixing, reconstituting, and other similar acts routinely performed by, or under the supervision of, an oncologist, a rheumatologist, or a hematologist who administers chemotherapy (anti-neoplastic agents), biologic therapy, supportive care medication, rheumatology therapy, or any other therapy in the treatment of cancer, a rheumatology condition, or a blood condition. Pursuant to this legislation, the Department of Health and Mental Hygiene (Department) submits the workgroup's recommendations, as well as the Department's recommendations for the appropriate oversight of outpatient offices engaged in use of these therapeutics.

Please note this report has been updated with additional feedback since first submitted with a date of December 5, 2014. The changes are limited to Section VI. Home Infusion on page 9. The changes clarify that there is more than one independent accrediting body for home infusion companies.

Workgroup Recommendations

The workgroup was composed of stakeholders from the Board of Physicians, Board of Pharmacy, Maryland Society for Health-System Pharmacy, Maryland Chapter of Oncology Nursing Society, Maryland Occupational Safety and Health, Maryland Rheumatology Society, Rheumatologists, Maryland State Medical Society (MedChi), Oncologists, Nurse Oncologists, and Maryland DC Society for Clinical Oncology. The workgroup met over the summer and fall of 2014 and reviewed relevant national safety standards in three areas:

1. **Infection Control.** Patients with cancer or rheumatologic disorders are often immunocompromised by the nature of their disease and the effects of drug treatments. This puts them at risk for developing serious infections that may lead to significant morbidity and even mortality. Infection control standards are necessary to reduce this increased risk of infection.
2. **Accurate Dosing and Administration.** Anti-neoplastic agents and biologic agents used in rheumatologic disorders have a narrow therapeutic window. Accurate dosing and administration is critical.
3. **Hazardous Drugs.** Most anti-neoplastic agents are considered hazardous drugs per the National Institute of Occupational Safety and Health (NIOSH). According to the Centers for Disease Control and Prevention, studies have associated workplace exposures to hazardous drugs with negative health effects. There is a need to have occupational safety standards in place to protect staff and patients from unintentional exposures to hazardous drugs.

The workgroup developed recommendations on the appropriate safety standards for outpatient oncology/hematology practices and rheumatology infusion centers when mixing/reconstituting chemotherapy, biologic therapy, supportive care medication, rheumatology therapy, or any other therapy in the treatment of cancer, a rheumatology condition, or a blood condition in the three identified areas.

Department's Recommendations

Based upon the workgroup's proposed safety standards, the following recommendations represent the appropriate oversight of mixing/reconstituting chemotherapy, biologic therapy, supportive care medication, rheumatology therapy, or any other therapy in the treatment of cancer, a rheumatology condition, or a blood condition in an outpatient setting:

1. Maryland Occupational Safety and Health (MOSH) has proposed regulations on occupational exposure to hazardous drugs, and once they are completed, these should be

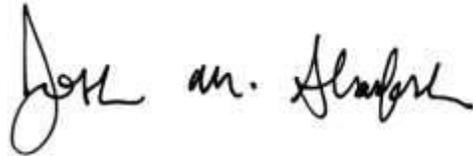
the standards used to govern hazardous drug use in Maryland. MOSH should continue to work on the proposed regulation and finalize by the close of 2015; and

2. The Maryland DC Society for Clinical Oncology and the Maryland Rheumatology Society have committed to formalizing guidance to all outpatient practices on the need to be in compliance with the safety standards incorporated in the workgroup's recommendations. In addition, the Board of Physicians should use these recommendations as a reference when evaluating questions of standards of practice and quality.

The Department would like to thank all the members for participating in the workgroup, especially Dr. Mona Gahunia, who chaired the workgroup, and Sara Cherico. These recommendations will promote the safety of all Marylanders.

If you have any questions or need additional information on this subject, please do not hesitate to contact Ms. Allison Taylor, Director of Governmental Affairs at (410) 767-6480.

Sincerely,

A handwritten signature in black ink that reads "Josh M. Sharfstein". The signature is written in a cursive, flowing style.

Joshua M. Sharfstein, M.D.
Secretary

Enclosure

cc: Mona Gahunia, D.O.
Allison Taylor, M.P.P., J.D.
Sara Cherico, M.P.H.
Sarah Albert, MSAR# 10225

Safety Standards Work Group Recommendations

Chapter 580 of the Acts of 2014 (SB 1108) requires the Secretary of Health and Mental Hygiene to convene a stakeholder workgroup to study and recommend appropriate national safety standards for mixing, reconstituting, and other similar acts routinely performed by, or under the supervision of, an oncologist, a rheumatologist, or a hematologist who administers chemotherapy, biologic therapy, supportive care medication, rheumatology therapy, or any other therapy in the treatment of cancer, a rheumatology condition, or a blood condition.

The Safety Standards Workgroup met five times over the summer and fall of 2014. Workgroup members represent the following stakeholders: Board of Physicians, Board of Pharmacy, Maryland Society for Health-System Pharmacy, Maryland Chapter of Oncology Nursing Society, Maryland Occupational Safety and Health, Rheumatologists, Med-Chi, Oncologists, Nurse Oncologists, and Maryland DC Society for Clinical Oncology. Given the importance of this topic, the American Society of Clinical Oncology convened a committee in November 2014 to establish national evidenced based chemotherapy safety standards to ensure safe chemotherapy preparation and administration for patients and staff.

Safe drug storage, preparation, and administration standards are needed due to the:

- Immunocompromised state of patients with higher risk of infection; need for infection control standards;
- Narrow therapeutic index of drugs; accurate dosing and administration is critical; and
- Hazardous nature of the drugs; need to address occupational safety risks.

Based on its work, the workgroup developed recommendations in three specific areas: infection control, accurate dosing and administration, and hazardous drugs.

I. Infection Control Standards for Outpatient Oncology Practices

The workgroup recommends the Basic Infection Control and Prevention Plan for Outpatient Oncology Settings¹, developed by the Centers for Disease Control and Prevention (CDC), as the appropriate national safety standard for outpatient oncology practices, with the following modifications:

1. Exclude Section IV: Standard Precautions, Subsection E: Medical Storage and Handling; see Hazardous Drugs recommendations below for recommendations regarding the safe storage and handling of medication.

¹ Centers for Disease Control and Prevention. *Basic Infection Control and Prevention Plan for Outpatient Oncology Settings*. December 2011. Available at: http://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/index.html?s_cid=govD_PreventInfections_004.

2. Clarify that only sterile gloves should be worn when changing catheter site dressing, as outlined in Section VI: Central Venous Catheters, Subsection A: General Maintenance and Access Procedures, 4. Changing Catheter Site Dressing.

II. Infection Control Standards for Outpatient Rheumatology Infusion Centers

The workgroup recommends the Basic Infection Control and Prevention Plan for Outpatient Oncology Settings², developed by the CDC, as the appropriate national safety standard for outpatient rheumatology infusion centers.

III. Accurate Dosing and Administration of Oncology Drugs

The workgroup recommends the 2013 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy³ as the appropriate national safety standard with the following modifications:

1. Modify line 21 B to read, “Drug dose – both practitioners should independently double check the math (BSA calculation, kg, or area under the curve) to ensure the correct dose was ordered.”
2. Encourage a computerized physician order entry (CPOE) system to offer clinical decision support.

IV. Accurate Dosing and Administration of Rheumatologic Drugs

Currently, there are no national standards for the accurate dosing and administration of rheumatologic drugs. However, several professional societies, including the Rheumatology Nurse Society, are working toward their development. Once national standards are established, a new workgroup would need to be convened to review and vote upon their adoption.

V. Hazardous Drugs

Hazardous drugs in this section refer to those drugs on the National Institute for Occupational Safety and Health (NIOSH) hazardous drug list⁴ which require mixing or reconstituting prior to patient administration in an oncology or rheumatology office.

These recommendations are not a substitute for federal Occupational Safety and Health Administration and Environmental Protection Agency requirements.

² Ibid.

³ Neuss et al. (2013) “2013 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy,” *Journal of Oncology Practice*. Volume 2 Supplemental. Available at: http://www.instituteforquality.org/sites/instituteforquality.org/files/asco_ons_safety_standards_2013_0.pdf.

⁴ The most current list from 2014 can be found online at: <http://www.cdc.gov/niosh/docs/2014-138/>.

1. Develop a hazardous drug plan that incorporates recommendations 2-10, listed below.

2. Training on Hazardous Drugs

- a. Prepare and implement a written hazard communication program, as detailed in the Hazardous Communication Standards (29 CFR 1910.1200), including ensuring that all containers are labeled, employees are provided access to material safety data sheets (MSDSs), and an effective training program is conducted for all employees handling hazardous drugs at the time of their initial job assignment and on an annual basis.

3. Personal Protective Equipment

Develop written policies and procedures to address and provide proper personal protective equipment (PPE) for all staff handling hazardous drugs. Refer to Appendix A for a sample plan.

The policies and procedures should be based on guidelines such as the Oncology Nursing Society (ONS) Safe Handling of Hazardous Drugs,⁵ the 2004 NIOSH Alert,⁶ the American Society of Health-System Pharmacists (ASHP) Guidelines on Handling Hazardous Drugs,⁷ and/or other nationally accepted standards that include the following key elements:

- a. Powder-free, high-quality gloves made of latex, nitrile, polyurethane, neoprene, or other materials that meet the American Society for Testing and Materials (ASTM) standard for chemotherapy gloves.
- b. Disposable gowns of material tested to be protective against hazardous drugs with a solid front (back closure) and knit or elastic cuffs.
- c. Eye and face protection such as plastic face shields, safety glasses with side shields, and eye goggles.
- d. Shoe and hair coverings as appropriate.
- e. Gloves that are chemically resistant to the decontamination or cleaning agent used.

⁵ Polovich (ed) (2012) *Safe Handling of Hazardous Drugs, 2nd Edition*. Pittsburg,PA: Oncology Nursing Society Publications Department. Available at: <https://www.ons.org/products/safe-handling-hazardous-drugs-second-edition>.

⁶ NIOSH. *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings*. September 2004. Available at: <http://www.cdc.gov/niosh/docs/2004-165/>.

⁷ ASHP. *ASHP Guidelines on Handling Hazardous Drugs*. American Journal of Health-System Pharmacists. 2006; 63: 1172–93. Available at: http://www.ashp.org/s_ashp/docs/files/bp07/prep_gdl_hazdrugs.pdf.

- f. Respiratory protection when drug aerosols during admixture are present.

4. Storage of Hazardous Drugs

- a. Segregate hazardous drugs from other drugs.
- b. All transport of hazardous drug packages under the control of the practice— not including transport from the manufacturer/ground transportation company —must be done in a manner to reduce environmental contamination in the event of accidental dropping. For example, store and transport hazardous drugs in closed containers that minimize the risk of breakage.
- c. Make sure the storage area has sufficient general exhaust ventilation to dilute and remove any airborne contaminants.

5. Hazardous Drug Preparation

- a. Limit access to areas where drugs are prepared to protect persons not involved in drug preparation.
- b. Use a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs (see following section entitled Ventilated Cabinets).
- c. When drug preparation is complete, seal the final product in a plastic bag or other sealable container for transport to the patient.
- d. Wash hands with soap and water immediately after removing gloves.
- e. Have responsible personnel prime the IV tubing and syringes inside the ventilated cabinet, or prime them in-line with non-drug solutions—never in the patient’s room.

6. Hazardous Drug Administration

- a. Develop written policies and procedures to address the proper administration of hazardous drugs for all staff handling hazardous drugs. Refer to Appendix B and C for sample plans.
- b. The policies and procedures should be based on guidelines such as the ONS Safe Handling of Hazardous Drugs, the 2004 NIOSH Alert, the ASHP Guidelines on Handling Hazardous Drugs, and/or other nationally accepted standards.

7. Ventilated Cabinets

- a. Use a ventilated cabinet appropriate for the sterile preparation of chemotherapy and other hazardous medications, such as a class II biological safety cabinet.

- b. Properly install and routinely clean any ventilated cabinets.
- c. Properly maintain any ventilated cabinets, and document such maintenance.

8. Cleaning, Decontamination, Housekeeping, and Waste Disposal

- a. Establish procedures for cleaning and decontamination of areas and equipment where hazardous drugs and excreta are present.
- b. Require that contaminated equipment be cleaned in a well-ventilated area.
- c. Require that work surfaces are cleaned before and after each continuous activity and at the end of the work shift.
- d. Follow any laws and regulations promulgated by the Maryland Department of the Environment regarding the Hazardous Waste Program.

9. Spill Control

- a. Establish written policies and procedures to manage hazardous drug spills. Assure that the written policies and procedures address the protective equipment required for various spill sizes, the possible spreading of material, restricted access to hazardous drug spills, and signs to be posted.
- b. Manage hazardous drug spills according to the established, written policies and procedures in the workplace.
- c. Locate spill kits or clean-up materials near all potential spill sources.
- d. Dispose of all spill cleanup materials in a hazardous chemical waste container, in accordance with EPA/RCRA regulations regarding hazardous waste—not in a chemotherapy waste or biohazard container.

10. Medical Surveillance

- a. For acute exposure, such as after a spill on the skin or mucous membrane, the worker should have a post-exposure evaluation.

Additionally, the workgroup reviewed and discussed recommendations for medical surveillance programs contained in national safety standards recommendations. The workgroup agreed that there needs to be further investigation and study of medical surveillance programs, especially related to how to operationalize a program in a community setting.

VI. Home Infusion

The workgroup discussed situations where there is continuous infusion of a chemotherapy agent over the course of several days. In these situations, treatment is generally initiated at the clinic/oncology practice and continued at home. Based upon the best information available to the workgroup, home infusion companies are often used to provide this service. Home infusion companies are regulated by the Maryland Board of Pharmacy and can be accredited by an independent accrediting body such as the Community Health Accreditation Program, Inc. (CHAP) or the Joint Commission (TJC). CHAP and TJC have developed standards for pharmacies that make chemotherapy agents and other sterile preparation. The standards also address the infusion nursing aspect of the delivery of the agents by home health workers. In addition, some outpatient oncology offices that provide these continuous infusions follow USP 797 standards when mixing/reconstituting these medicines.

In light of this information, the workgroup did not offer any recommendations regarding home infusions.

VII. Hazardous Drug Statement for Rheumatologists

There have been several guidelines written primarily dealing with the safe use of hazardous drugs in the outpatient infusion setting. While most drugs principally infused by rheumatologists do not fulfill the group's definition of hazardous drugs, any infusion center that administers drugs that do meet the workgroup's definition would be expected to follow the guidelines developed by the workgroup.

Appendix A. Sample Personal Protective Equipment Policies and Procedures, 2004 NIOSH Alert

Provide all staff with the proper PPE when handling hazardous drugs:

- 1) Wear chemotherapy gloves [ASTM], protective clothing, and eye protection when opening containers to unpack hazardous drugs. Such PPE protects workers and helps prevent contamination from spreading if damaged containers are found. Wear chemotherapy gloves to prevent contamination when transporting the vial or syringe to the work area.
- 2) Wear PPE (including double gloves and protective gowns) while reconstituting and admixing drugs, as outlined below:
 - a. Make sure that gloves are labeled as chemotherapy gloves and make sure such information is available on the box [ASTM in press] or from the manufacturer.
 - b. Consider latex-sensitive workers [NIOSH 1997] and remember that a number of glove materials are suitable for protecting workers from antineoplastic drugs [Connor 1999; Singleton and Connor 1999; Klein et al. 2003].
 - c. Consider using chemotherapy gloves for hazardous drugs that are not chemotherapy drugs or for which no information is available.
 - d. Use double gloving for all activities involving hazardous drugs. Make sure that the outer glove extends over the cuff of the gown [Connor 1999; Brown et al. 2001].
 - e. Inspect gloves for physical defects before use.
 - f. Wash hands with soap and water before donning protective gloves and immediately after removal.
 - g. Change gloves every 30 minutes or when torn, punctured, or contaminated. Discard them immediately in a yellow chemotherapy waste container [ASHP 1990; Brown et al. 2001].
 - h. Use disposable gowns made of polyethylene-coated polypropylene (which is nonlinting and nonabsorbent). These gowns offer better protection than polypropylene gowns against many of the antineoplastic drugs [Connor 1993; Harrison and Kloos 1999]. Make sure gowns have closed fronts, long sleeves, and elastic or knit closed cuffs.
 - i. Dispose of protective gowns after each use.
 - j. Use disposable sleeve covers to protect the wrist area and remove the covers after the task is complete.

- 3) Wear PPE (including double gloves, goggles, and protective gowns) for all activities associated with drug administration—opening the outer bag, assembling the delivery system, delivering the drug to the patient, and disposing of all equipment used to administer drugs.
- 4) At a minimum, wear safety glasses with side shields and protective gloves for cleaning and decontaminating work. Wear face shields if splashing is possible.
 - a. Wear protective double gloves for decontaminating and cleaning work.
 - b. Select them by referring to the material safety data sheet, glove selection guidelines, or information from the glove manufacturer and make sure the gloves are chemically resistant to the decontamination or cleaning agent used.
- 5) Wear two pairs of protective gloves and a disposable gown if you must handle linens, feces, or urine from patients who have received hazardous drugs within the last 48 hours. Wear face shields if splashing is possible.
 - a. Dispose of the gown after each use or whenever it becomes contaminated and remove the outer gloves and the gown by turning them inside out and placing them into the chemotherapy waste container.
 - b. Repeat the procedure for the inner gloves.

Appendix B. Sample Recommendations for Administration of Hazardous Drugs, ONS Safe Handling of Hazardous Drugs

1. Ensure appropriate supplies for administration are available.
2. Have access to a spill kit.
3. Wash hands thoroughly before donning PPE.
4. Wear two pairs of chemotherapy-tested gloves.
5. Wear a face shield if there is a chance of the drug splashing.
6. Wear a NIOSH-approved respirator if hazardous drug aerosols may be present.
7. Inspect the drug delivery bag and its contents prior to handling.
8. Don PPE before reaching into the deliver bag to remove the drug container.
9. Remove gloves and gown in such a way as to prevent transfer of hazardous drug contamination to the skin.
10. Whenever possible, avoid touching equipment with gloves hands after handling hazardous drugs.
11. Do not hang up gowns and reuse them.
12. Wash hands with soap and water (as opposed to alcohol-based hand gels) because friction and rinsing are necessary to assist in removing hazardous drug contamination.
13. Perform all work below eye level.
14. Use a closed-system transfer device when available.

Appendix C. Sample Plan for Safe Handling for Specific Routes of Hazardous Drug Administration, Based upon the ASHP Guidelines on Handling Hazardous Drugs

Intravenous administration

1. The use of gloves, gown, and face shield (as needed for splashing) is required.
2. Gather all necessary equipment and supplies, including PPE.
3. Use needleless systems whenever possible.
4. Use Luer-Lok fittings for all needleless systems, syringes, needles, infusion tubing, and pumps.
5. Needleless systems may result in droplets leaking at connection points; use gauze pads to catch leaks.
6. Designate a workplace for handling hazardous drugs.
7. Have a spill kit and hazardous drug waste container readily available.
8. Procedure for gowning and gloving: Wash hands, don first pair of gloves, don gown and face shield, and then don second pair of gloves. Gloves should extend beyond the elastic or knit cuff of the gown. Double-gloving requires one glove to be worn under the cuff of the gown and the second glove over the cuff.
9. Always work below eye level.
10. Visually examine hazardous drug dose while it is still contained in transport bag.
11. If hazardous drug dose appears intact, remove it from the transport bag.
12. Place a plastic-backed absorbent pad under the administration area to absorb leaks and prevent drug contact with the patient's skin.
13. Place a gauze pad under the connection at injection ports during administration to catch leaks.
14. Use the transport bag as a containment bag for materials contaminated with hazardous drugs, drug containers, and sets.
15. Discard hazardous drug containers with the administration sets attached; do not remove the set.
16. Wash surfaces that come into contact with hazardous drugs with detergent, sodium hypochlorite solution, and neutralizer, if appropriate.
17. Wearing gloves, contain and dispose of materials contaminated with hazardous drugs and remaining PPE as contaminated waste.
18. Hazardous drug waste container must be sufficiently large to hold all discarded material, including PPE.
19. Do not push or force materials contaminated with hazardous drugs into the hazardous drug waste container.
20. Carefully remove, contain, and discard gloves. Wash hands thoroughly after removing gloves.

Intramuscular or subcutaneous administration

1. The use of double gloves is required.
2. Gather all necessary equipment and supplies, including PPE.
3. Use Luer-Lok safety needles or retracting needles or shields.
4. Syringes should have Luer-Lok connections and be less than three-fourths full.
5. Designate a workplace for handling hazardous drugs.
6. Have a spill kit and hazardous drug waste container readily available.
7. Procedure for gloving: Wash hands; don double gloves.
8. Always work below eye level.
9. Visually examine hazardous drug dose while still contained in transport bag.
10. If hazardous drug dose appears intact, remove it from the transport bag.
11. Remove the syringe cap and connect appropriate safety needle.
12. Do not expel air from syringe or prime the safety needle.
13. After administration, discard hazardous drug syringes (with the safety needle attached) directly into a hazardous drug waste container.
14. Wearing gloves, contain and dispose of materials contaminated with hazardous drugs.

15. Do not push or force materials contaminated with hazardous drugs into the hazardous drug waste container.

16. Carefully remove, contain, and discard gloves.

17. Wash hands thoroughly after removing gloves.

Oral administration

1. Double gloves are required, as is a face shield if there is a potential for spraying, aerosolization, or splashing.
2. Workers should be aware that tablets or capsules may be coated with a dust of residual hazardous drug that could be inhaled, absorbed through the skin, ingested, or spread to other locations and that liquid formulations may be aerosolized or spilled.
3. No crushing or compounding of oral hazardous drugs may be done in an unprotected environment.
4. Gather all necessary equipment and supplies, including PPE.
5. Designate a workplace for handling hazardous drugs.
6. Have a spill kit and hazardous drug waste container readily available.
7. Procedure for gloving: Wash hands and don double gloves.
8. Always work below eye level.
9. Visually examine hazardous drug dose while it is still contained in transport bag.

10. If hazardous drug dose appears intact, remove it from the transport bag.

11. Place a plastic-backed absorbent pad on the work area, if necessary, to contain any spills.

12. After administration, wearing double gloves, contain and dispose of materials contaminated with hazardous drugs into the hazardous drug waste container.

13. Do not push or force materials contaminated with hazardous drugs into the hazardous drug waste container.

14. Carefully remove, contain, and discard gloves.

15. Wash hands thoroughly after removing gloves.