

### Support:

- Safeguards to ensure that drugs made in compounding pharmacies are uncontaminated, and at consistent, appropriate dosage levels
- Appropriate regulations and standards requiring licensure and inspection of compounding pharmacies
- Ethical patient marketing and pricing
- Physician authority to [prepare and administer medications in the office-setting](#) when literature supports safety and efficacy
- Medication preparation in the office-based clinical setting is the practice of medicine and should not be regulated by state pharmacy boards.

### Oppose:

- Regulation and standards which restrict physician access to non-sterile compounded pharmaceuticals by prohibiting the purchase of these materials in bulk for use by physicians in a clinical setting
- Prescription of controlled compounded pharmaceuticals by non-physicians
- Regulations and standards that restrict physicians from utilizing their clinical judgment in administering prepared medications.

**Compounded injectable drugs (defined as drugs that are mixed, diluted, reconstituted and prepared in an office setting) must be made in an environment that has appropriate safeguards against the spread of disease and that the components of compounded drugs are the appropriate strength and makeup to avoid placing patients in harm's way.** When taking proper precautions, physicians are able to safely prepare and store certain drugs in office-settings.<sup>1</sup> For example, dermatologic surgeons frequently and safely use lidocaine mixed with bicarbonate to buffer lidocaine, making injections less painful prior to surgery for the patient.

**Providing uncontaminated drugs at consistent, appropriate dosage levels must be of paramount concern.** A 2011 study published in the scientific journal *Dermatologic Surgery* found that five out of six samples of compounding pharmacy-made polidocanol – a drug used for the treatment of varicose veins – did not contain the claimed concentrations of the active ingredient, and all six contained impurities.<sup>2</sup> Such discrepancies put patients at risk of inappropriate dosage and infection. According to a 2004 study published in the same journal, another drug used to treat varicose veins – sodium tetradecyl sulfate manufactured in three different compounding pharmacies –not only contained varying concentrations but also was diluted with an industrial detergent not manufactured for use in humans.<sup>3</sup>

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<sup>1</sup>American Society of Dermatologic Surgery Association. (2015). *Position on storage and reuse of reconstituted injectable botulinum toxin type A*. Rolling Meadows, IL: ASDSA

<sup>2</sup>Weiss, R., et al. Absence of Concentration Congruity in Six Compounded Polidocanol Samples Obtained for Leg Sclerotherapy. *Dermatol Surg* 2011;37:812–815

<sup>3</sup>Goldman, M. Sodium Tetradecyl Sulfate for Sclerotherapy Treatment of Veins: Is Compounding Pharmacy Solution Safe? *Dermatol Surg* 2004;30:1454–1456

**Compounded pharmacies should be licensed and regularly inspected to make certain appropriate sterility safeguards are in place.** According to an April 2013 U.S. Food and Drug Administration (FDA) inspection report of 29 compounding pharmacies, “Select FDA observations during the inspections include: incomplete and/or inadequate drug product batch failure investigations, inappropriate and/or inadequate clothing for sterile processing, lack of appropriate air filtration systems, insufficient microbiological testing, and other practices that create risk of contamination.”<sup>4</sup>

**Any topical or injectable medication made in a compounded pharmacy should be ordered by a physician and administered according to the physician’s instructions.**<sup>5</sup>

**Physician access to bulk purchase of drugs made in compounding pharmacies should be preserved for physician use in a clinical setting.** Regulations and standards which prohibit physicians from purchasing drugs made in compounding pharmacies in bulk for the purpose of in-office use delay patient treatment and increase the cost of healthcare overall. These products made for purchase by physicians for in-office use should be clearly marked “for office use” and should not be re-sold to patients for use outside of the office.

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<sup>4</sup>2013, April 11. U.S. Food and Drug Administration. Summary: 2013 FDA Pharmacy Inspection Assignment. Retrieved April 25, 2013 from: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm>

<sup>5</sup>North Carolina Medical Board v Ira David Uretsky, MD. Retrieved April 18, 2013 from

<https://glsuite.ncmedboard.org/DataTier/Documents/Repository/0/0/3/9/94ceb2f9-42a0-49b6-8444-7242067a09f5.pdf>

Related AMA Policy:

### **D-120.931 Compounding**

Our American Medical Association will: (1) conduct a 50-state analysis of state law requirements governing in-office preparation of medications in physicians' offices, including which states have adopted USP Chapter 797 and how compounding is defined by state law; (2) advocate that the preparation of medications by a physician for administration to patients treated in the physician's office is the practice of medicine; and (3) will work with medical specialty societies to preserve a physician's ability to prepare medications in physicians' offices, and to be able to do so without being subject to unreasonable and burdensome equipment and process requirements by engaging with state policymakers (including but not limited to state legislatures, state medical boards, and state pharmacy boards) as well as accreditors. (BOT Action in response to referred for decision Res. 517, A-19)

### **D-120.949 Ensuring the Safe and Appropriate Use of Compounded Medications**

Our AMA will: (1) monitor ongoing federal and state evaluations and investigations of the practices of compounding pharmacies; (2) encourage the development of regulations that ensure safe compounding practices that meet patient and physician needs; (3) report back on efforts to establish the necessary and appropriate regulatory oversight of compounding pharmacy practices; (4) provide a 50-state analysis of state law requirements governing in-office preparation of medications in physicians' offices, including which states have adopted USP Chapter 797 and how compounding is defined by state law; and (5) work with medical specialty societies to preserve a physician's ability to prepare medications in physicians' offices, and to be able to do so without being subject to unreasonable and burdensome equipment and process requirements by engaging with state policymakers (including but not limited to state legislatures, state medical boards, and state pharmacy boards) as well as accreditors. (Sub. Res. 923, I-12 Reaffirmed: Res. 204, A-16 Reaffirmed in lieu of: Res. 817, I-16 Appended: Res. 517, A-19)

### **H-115.994 Prescription Product Labeling**

1. The official labeling should not be regarded as the sole standard of acceptable or accepted medical practice nor as a substitute for clinical judgment or experience nor as a limitation on usage of the drug in medical practice. The official labeling statements approved by the FDA establish the parameters governing advertising or promotion of the drug product.

2. Our AMA will advocate that the FDA work to establish a process whereby the official drug labeling can be updated in a more expeditious fashion when new evidence becomes available affecting the clinical use of prescription medications and that evidence-based standards or peer-reviewed medical literature can add to legacy information contained in official drug labeling statements to guide drug administration and usage.

(Sub. Res. 30, A-78; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Modified: CSAPH Rep. 1, A-10; Modified: Res. 505, A-15)

### **H-120.929 Protect Individualized Compounding in Physicians' Offices as Practice of Medicine**

Our AMA will advocate that the US Food and Drug Administration remove physician offices and ambulatory surgery centers from its definition of a compounding facility.  
(Res. 219, I-16)

### **H-120.930 USP Compounding Rules**

1. Our AMA will engage in efforts to convince United States Pharmacopeia (USP) to retain the current special rules for procedures in the medical office that could include but not be limited to allergen extract compounding in the medical office setting and, if necessary, engage with the U.S. Food and Drug Administration (FDA) and work with the U.S. Congress to ensure that small volume physician office-based compounding is preserved.
2. Our AMA will undertake to form a coalition with affected physician specialty organizations such as allergy, dermatology, immunology, otolaryngology, oncology, ophthalmology, neurology, and rheumatology to jointly engage with USP, FDA and the U.S. Congress on the issue of physician office-based compounding preparations and the proposed changes to USP Chapter 797.
3. Our AMA reaffirms that the regulation of compounding in the physician office for the physician's patients be under the purview of state medical boards and not state pharmacy boards.
4. Our AMA supports the current 2008 USP Chapter 797 sterile compounding rules as they apply to allergen extracts, including specifically requirements related to the beyond use dates of compounded allergen extract stock.
5. Our AMA will continue its compounding working group consisting of national specialty organizations, state medical societies, relevant agencies, and other appropriate stakeholders to advocate for appropriate application of standards and to monitor policy impacting physicians.  
(Res. 204, A-16 Reaffirmation: A-17 Reaffirmation: A-18 Appended: Res. 501, A-19)

### **H-120.934 Appropriate Use of Compounded Medications in Medical Offices**

Our American Medical Association supports regulatory changes to improve access to (1) the compounding and repackaging of manufactured FDA-approved drugs and substances usually prepared in the office-based setting and (2) purchasing from compounding pharmacies of FDA-approved drugs, repackaged or compounded for the purpose of in-office use.  
(Res. 207, A-15)

### **H-120.945 Pharmacy Compounding**

Our AMA: (1) recognizes that traditional compounding pharmacies must be subject to state board of pharmacy oversight and comply with current United States Pharmacopeia and National Formulary (USP-NF) compounding monographs, when available, and recommends that they be required to conform with USP-NF General Chapters on pharmaceutical compounding to ensure the uniformity, quality, and safety of compounded medications; (2) encourages all state boards of pharmacy to reference sterile compounding quality standards, including but not limited to those contained in United States Pharmacopeia Chapter <797>, as the standard for sterile compounding in their state, and to satisfy other relevant standards that have been promulgated by the state in its laws and regulations governing pharmacy practice; (3) supports the view that facilities (other than pharmacies within a health system that serve only other entities within that health system) that compound sterile drug products without receiving a prescription order prior to beginning compounding and introduce such compounded drugs into interstate commerce be recognized as compounding manufacturers subject to FDA oversight and regulation; (4) supports the view that allowances must be made for the conduct of compounding practices that can realistically supply compounded products to meet anticipated clinical needs, including urgent and emergency care scenarios, in a safe manner; and (5) in the absence of new federal legislation affecting the oversight of compounding pharmacies, continues to encourage state boards of pharmacy and the National Association of Boards of Pharmacy to work with the United States Food and Drug Administration to identify and take appropriate enforcement action against entities that are illegally manufacturing medications under the guise of pharmacy compounding.

(BOT Action in response to referred for decision Res. 521, A-06; Revised: CSAPH Rep. 9, A-13)

### **H-330.884 Access to In-Office Administered Drugs**

1. Our American Medical Association will advocate that physician access to in-office administered drugs, including drugs dispensed by pharmacies, be preserved.

2. Our AMA will work with the Center for Medicare & Medicaid Services, The Joint Commission, America's Health Insurance Plans, Federation of State Medical Boards, National Association of Boards of Pharmacy, and other involved stakeholders to improve and support patient access to in-office administered drugs.

3. Our AMA will advocate for coverage for in-office administered drugs and related delivery services for patients who are physically unable to self-administer the drug.

(Res. 702, A-15)