

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501  
(A-19)

Introduced by: Virginia

Subject: USP 800

Referred to: Reference Committee E  
(\_\_\_\_\_, Chair)

Whereas, USP <800> becomes effective December 1, 2019 and describes hazardous drug handling related to the receipt, storage, compounding, dispensing, administration, and disposal of both sterile and nonsterile products and preparations in all locations including physician offices; and

Whereas, USP <800> is mainly applicable to large pharmacies and hospitals which employ pharmacists, pharmacy technicians, etc.; and

Whereas, United States Pharmacopeia (USP) standards such as USP <800> are enforced by local, state and federal regulatory agencies such as The Joint Commission, the US Food and Drug Administration, the Centers for Medicare and Medicaid Services, and some state licensing boards; and

Whereas, The National Institute for Occupational Safety and Health (NIOSH) develops risk assessment levels for antineoplastic and other hazardous drugs in healthcare settings; and

Whereas, There is some debate about the NIOSH categorization of some medications previously given safely in the office setting; and

Whereas, USP expressly defined administration as the mixing or reconstituting of a drug according to manufacturers' recommendations for a single patient for immediate use in USP Chapter 797 update to be published on June 1, 2019 in the USP-NF, a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF); and

Whereas, USP defines compounding as the mixing of two or more FDA-approved drugs or ingredients, with exceptions; and

Whereas, National specialty societies can develop white papers/best practices for the safe and appropriate handling of medications utilized in physician offices and systems for ongoing monitoring of potential complications; and

Whereas, If all of the new USP <800> requirements for preparation of medications in the office setting are implemented December 1, 2019, patient access to proven therapies will decrease, costs will increase, and patient harm may result from not receiving needed treatment in a timely manner; therefore be it

RESOLVED, That our American Medical Association adopt as policy that physicians and other health care providers administering medications (defined as the mixing or reconstituting of a drug according to manufacturers' recommendations for a single patient for immediate use) not be subject to the USP 800 compounding guidance (New HOD Policy); and be it further

1 RESOLVED, That our AMA support development of specialty specific white papers/best  
2 practices and systems for both safe medication administration practices and ongoing monitoring  
3 of potential complications from the administration of medications deemed suitable for  
4 exemptions from the National Institute for Occupational Safety and Health, United States  
5 Pharmacopeia, and other regulatory bodies when used in an office setting under the direction of  
6 a licensed physician (New HOD Policy); and be it further  
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8 RESOLVED, That our AMA continue its working group, consisting of national specialty  
9 organizations, state medical societies and other stakeholders to advocate for such exemptions.  
10 (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.

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