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, 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 support development of specialty specific white papers/best practices and systems for ongoing monitoring of potential complications from the delivery of medications deemed suitable for exemptions from the National Institute for Occupational Safety and Health, United States Pharmacopeia, and other regulatory bodies when used in an office setting under the direction of a licensed physician (New HOD Policy); and be it further

RESOLVED, That our AMA continue its working group, consisting of national specialty organizations, state medical societies and other stakeholders to advocate for such exemptions. (Directive to Take Action)
Fiscal Note: Not yet determined

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