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USP 797 Compliance with USP 797 is our DUTY because: 1. It improves the health and well-being of our patients AND 2. In New Mexico, it is the law (NMSA 26-1-16. and NMAC 16.19.6.11). A healthy patient is a happy patient!

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Developing USP General Chapter <797> USP is a not-for-profit, science-driven organization that has an established process for convening independent experts in the development and maintenance of healthcare quality standards. The process is public health focused, leveraging current science and technology, and draws on the expertise of scientists and healthcare practitioners while providing ...

General Chapter <797> Pharmaceutical Compounding - USP
USP Chapter <797>, Pharmaceutical Compounding: Sterile Preparations, became effective January 1, 2004 6. USP Chapter <797> is a set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP) that set the standards that apply to all settings in which sterile preparations are compounded. 7.

Introduction to USP General Chapter 797
By the end of this presentation you should be able to: 1. Identify the proposed changes to USP Chapter <797> that will most impact home infusion providers. 2. Understand how to provide comments to USP regarding the proposed revision to Chapter <797>.

USP <797> Pharmaceutical Compounding - Sterile ...
Specifically, USP published the final revised version of general chapter <797> (Pharmaceutical Compounding of Sterile Preparations) to accompany the previous released general chapter <800> (Hazardous Drugs Handling in Healthcare Settings). Due to pending appeals, the effective date of USP <797> remains postponed

USP Chapters <797> and <800> New and Revised Compounding ...
In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, USP is postponing the official date of Pharmaceutical Compounding—Sterile Preparations <797>. After publication of the . revised <797> on June 1, 2019, USP received appeals on certain provisions of the chapter.

797 PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS - USP-NF
797 □ Pharmaceutical Compounding — Sterile Preparations . Revision Bulletin . level for air, surface, and personnel gear are not exceeded for a specified cleanliness class. Compounding Aseptic Containment Isolator (CACI) —A compounding aseptic isolator (CAI) designed to provide worker protection from

(797) PHARMACEUTICAL COMPOUNDING—STE RILE PREPARATIONS
USP <797> and <800> Changes in USP-NF Compounding Guidelines ... 2016 –USP <800> Final draft is published 2018 –Implementation delayed to coincide with release of revised USP <797> December 1, 2019, USP <800> Scheduled to go into Effect. ... USP 800 Presentation 3.9.2019 Jered Pasay - Read-Only ...

USP 800 Presentation 3.9.2019 Jered Pasay - Read-Only
the requirements and recommendations of the USP General Chapter. The author is a member of the USP Compounding Expert Committee, but this publication is not endorsed by or affiliated with USP. Comments in this book are related to USP <795> and <797> from USP 39—NF 34, 2016. Revisions to those documents must be considered when designing ...

The Chapter <800> Answer Book - ASHP
The United States Pharmacopeia (USP) was created nearly 200 years ago, dedicated to instilling trust where it matters most: in the medicines, supplements and foods people rely on for their health. The quality standards we develop help manufacturers deliver on their promises of safe products, while building confidence among healthcare ...

U.S. Pharmacopeia
Missing from the immediate-use provisions of USP <797> are guidelines—provided in USP <825>—for the qualifications for personnel who prepare these sterile drugs; USP <825> incorporates guidance on completing a sterile radiopharmaceutical preparation, including directions for hand hygiene, gloving, garbing, and the required aseptic technique ...

USP General Chapter <825> Impact on Nuclear Medicine ...
The United States Pharmacopeia Appeals Panel today remanded the revised USP General Chapter standards <795> for nonsterile compounding and <797> for sterile compounding to an expert committee "for further engagement on the issues raised concerning the beyond-use date provisions." USP last year postponed the effective dates for these standards and for the new General Chapter <825 ...

USP panel remands revised compounding standards for ...
As of February 1, 2016, USP <800> is approved and final. 3,7-9 Enforceability and Key Changes Due to provisions of USP numbered below 1000 being legally enforceable, following the adoption of these rules by individual state boards, USP <800> may subject pharmacies to both state board and FDA inspections.

USP <800>: Key Changes and Additions to USP <797>
Only being used for Emergency Purposes as defined by USP 797. Aseptically compounded Simple transfer ≤ 3 commercially manufactured non-hazardous products. Not > 2 entries into any container Administration begins ≤ 1 hour from start of compounding. Comments B. High Risk Compounding. High Risk Compounding performed? (if no, skip this section ...

DCP.DrugUSPCompounding@ct.gov www.ct.gov/dcp/dcd Pharmacy ...
Pre-Presentation Question 1 USP released the most recent version of USP Chapter 800 in: A. 2008 B. 2016 C. 2018 D. 2019. ... United States Pharmacopeia ... certification in USP 797 and 795, maybe USP 800 ...

USP Chapter 800 Hazardous Drugs – Handling in Healthcare ...
USP <797> published (2004) USP 797 updated (2008) 2010s NIOSH list updates 2010, 2012, 2014, 2016 pending USP <800> published (2016) USP <800> ... (i.e. final dosage forms) NIOSH List Table 2-3 agents New medications post NIOSH list that meet HD criteria but are not APIs or antineoplastics requiring

USP <800>: What you need to know - IPhA
The revisions to USP 797 and new USP 800 standards will go into effect December 1, 2019. Over the course of 2018, the Henderson Engineers' team of experts has evaluated nearly a hundred facilities across the country to prepare their pharmacies for this deadline. During this time, we've discovered the only way to make these projects successful is to not just to understand the content of ...

USP 797 and USP 800 - 8 Common Mistakes To Avoid When ...
These standards are taken directly from www.usp.org document 2017 USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings and are reflective of all required and must standards. Important Dates: USP <800> and the revised <797> chapter will become final in June of 2019 and are set for implementation in December of 2019.

USP <800> Hazardous Drugs Risk Readiness Checklist
Note: There appears to be conflict here between 800> and the current 797>. USP 800> allows for the compounding of low- and medium-risk sterile compounds in the C-SCA, while the current USP 797> only allows low-risk sterile compounding to occur in the C-SCA. This is likely to be addressed by the revision of USP 797>.

PCCA | A Helpful Guide to USP <800> Compliance
USP 797, USP 795 and USP 800 have been going through revisions and will be mandated to be in place by December 1, 2019. The final versions will be in hand by April 1, 2019. The purpose of this session is to review these changes and provide a background to address the client's needs.