



CriticalPoint Note on Compendial Applicability September 23, 2019

In 2016 USP revised the General Notices and one of the changes included section 3.10. Applicability of Standards. This section discusses what an “applicable general chapter” is and how these chapters are applied. Unfortunately, many missed the change, resulting in confusion as to which chapters are required to be followed, or in other words, have compendial applicability.

The rule had been that if a chapter was numbered below 1000, it was enforceable, while chapters over 1000 were strictly informational. With the changes to 3.10., now chapters numbered 1000 to 1999 are informational and chapters below 1000 are required from a compendial perspective if the chapter is referenced in:

- a monograph
- another applicable chapter
- the General Notices

USP Chapters <797> and <795> are referenced in the General Notices section 3.10.30. as those chapters which apply to compounding. This means that they are required chapters. You’re probably wondering why USP <800> is not listed. If you look at the General Notices, USP 800 is not listed as one of the standards that apply to compounding. However, the 2019 versions of USP 797 and 795 reference USP 800 and, therefore, when they become official, USP 800 would then have compendial applicability because it is referenced in another applicable general chapter.

With the announced delay of USP 797 and 795, USP still intends for USP 800 to become official on December 1, 2019. This means that USP 800 will be informational as it is not referenced in an applicable chapter and the current versions of USP 797 (2008) and USP 795 (2014) make no mention of USP 800. Be aware, however, that once USP 797 and 795 do become official, USP 800 becomes applicable and enforceable for the sections related to compounding. CriticalPoint recommends that organizations do not simply ignore USP 800 until the other chapters become official, as USP 800 is designed for employee safety.

For more information on compendial applicability, please review the General Notices section 3.10. USP has also published [FAQs](#) on their website.