3163

RECEIVED
IRRC

2017 APR -6 PM 12: 25

Patricia Clancy Kienle
106 Elmwood Drive
Laflin, PA 18702
pkienle@comcast.net – Cell 570-947-4271

March 19, 2017

Board Counsel, State Board of Pharmacy
P.O. Box 69523
Harrisburg, PA 17106-9523

RE: Reference No. 16A-5419 (Compounding)

To Whom It May Concern:

I am a Pennsylvania-registered pharmacist who has been involved in sterile compounding for over 40 years. I am a member of the USP Compounding Expert Committee, but these comments are my own, not those of USP or my employer.

I am pleased that the State Board of Pharmacy has proposed compounding regulations as published in the March 11, 2017 *Pennsylvania Bulletin*. In particular, the language in §27.601 ("the compounding of sterile and nonsterile preparations shall be done in accordance with the current version of the USP chapters governing compounding") provides the clarity necessary.

Since the USP chapters will be used, I would recommend removing some of the other sections which are detailed in the USP chapters <795> Pharmaceutical compounding – nonsterile preparations, <797> Pharmaceutical compounding – sterile preparations, and <800> Hazardous drugs – handling in healthcare settings. (USP <800> has been published; the official date for implementation of that chapter is July 1, 2018.) As USP chapters are updated (which always occurs with a public comment period), there would be no situation where the state and federal requirements would differ; there might be if specific wording is included in the Pennsylvania regulations.

There are some terms which could be particularly problematic if they are not removed or clarified:

- Bulk – This term seems to be used to describe Active Pharmaceutical Ingredients (APIs), which are the raw chemicals used in some nonsterile or nonsterile-to-sterile compounding. However, it is also used to refer to batches. Batches are routinely prepared in health-system pharmacies from commercially-available sterile FDA-approved products. The batches are used for patients within the health-system over a several-day period defined by the beyond-use dates permitted in USP <797>. In the proposed regulations, the term "bulk" should either be eliminated (since the situations are defined in USP <795> and <797>) or the distinction between API and sterile products needs to be defined.
- Formula record and production record – USP defines two types of records for this: Master Formulation Record and Compounding Record. Use of "formula record" and "production record" is confusing. Use of the terms as they are defined in the USP chapters provides the clarity needed.
- Resale – Clarify that distribution within a health-system is not resale.
- Prohibited compounding – There are situations where products that have been removed from the market for safety reasons may be included (and need to be compounded) for investigational purposes, based on an Institutional Review Board's protocols. This is not common, but could occur.

Please consider the following changes in the document proposed in the March 11, 2017 *Pennsylvania Bulletin*:

- Remove the following sections since they appear in the USP compounding chapters <795> and/or <797> which provide greater detail
  - § 27.618 Accuracy
  - § 27.619 Production record (but list the 2 year record retention in another section)
  - § 27.620 Label information required
  - § 27.621 Compounding records (but list the 2 year record retention in another section)
  - § 27.622 Master formulation record
  - § 27.623 Production record for drugs compounded in bulk quantities
  - § 27.624 Label information

- § 27.603 – Bulk drug substances (Active Pharmaceutical Ingredients) that are used in compounding, must ...

  Note: Active Pharmaceutical Ingredient is defined in USP as: Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

- § 27.604, last sentence – Compounding from API shall comply ...
- § 27.617
  - (a) Delete the second and third sentences. This is detailed in the USP chapters. Additionally, it applies primarily to compounding from API, but not from commercially-available products.
  - (b) Delete the phrase "including validation of any sterilization process" since this is described in USP <797>. USP <797> does not require every sterile preparation to be tested.
  - (c) Delete the last sentence and the numbered bullets. This is detailed in USP chapters. Also, "must include all" and "as appropriate" conflict.

I would be happy to work with the State Board and a group of practitioners to develop further documents that support this effort to keep the citizens of Pennsylvania safe.

Sincerely,

Patricia Clancy Kienle

Patricia Clancy Kienle

Pennsylvania Registered Pharmacist RP028405L