Centralized Repackaging of Medications

Edward Timm¹

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It was with great interest that I read the article “A Financial Evaluation of the Centralized Repackaging of Intracameral Moxifloxacin for Cataract Surgery and Its Impact on Cost Reduction” in the October 2018 issue of *Hospital Pharmacy*. There are points which I do not understand and would ask for guidance to achieve clarification.

In the article, it is stated that “The Aurora Pharmacy Packaging Center (APPC) is a 503a compounding pharmacy within Aurora Health Care that repackages bulk pharmaceuticals into unit doses for distribution within the health care system.” Such a statement disclaims status as a hospital pharmacy, rendering production at the facility subject to regulations defined by the Drug Quality and Security Act (DQSA).

A hospital pharmacy may compound and repackage for its affiliates, if said affiliates are within a 1-mile radius of the repackaging site. If the affiliate is outside of this range, it must observe regulations defined by the DQSA. However, APPC is a self-defined 503a pharmacy.

A 503a pharmacy requires an advance individual patient-specific prescription before dispensing. A review of your text and process documentation (Figures 1-3) is absent process or documentation for the inclusion of a patient name. Indeed,

the text states that, like a manufacturer, production is based on projected patient volume, not patient specific need.

With this in mind, how is the APPC able to claim status as a 503a compounding pharmacy, yet produce in a manner akin to that of a manufacturer or a 503b outsourcing facility? Is it receiving individual patient-specific prescriptions prior to dispensing to its affiliates?

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¹Mobius Therapeutics, Saint Louis, MO, USA

Corresponding Author:

Edward Timm, Mobius Therapeutics, 1000 Executive Parkway, Saint Louis, MO 63141, USA.

Email: ed.timm@mobiustherapeutics.com