



Scott Popyk, RPH MBA
Health Dimensions, Inc.
Farmington Hills, MI
Resident: Novi, MI

Hello, I am Scott Popyk and my pharmacy is located in Farmington Hills, MI. Health Dimensions has been operating for 18 years, employs 46 people and is distinguished as a PCAB accredited compounding pharmacy. We tailor medications to specific patient needs when manufactured products do not provide optimal results.

Opportunity for improvement # 1:

Sec. 17709(2) (page 11)

**20 "STERILE PHARMACEUTICAL" MEANS A DOSAGE FORM OF A DRUG
21 THAT IS FREE FROM LIVING MICROBES AND FREE FROM CHEMICAL OR
22 PHYSICAL CONTAMINATION. AS USED IN THIS SUBSECTION, "DOSAGE FORM"
23 INCLUDES, BUT IS NOT LIMITED TO, PARENTERAL, INJECTABLE, AND
24 OPHTHALMIC DOSAGE FORMS.**

Problem: The definition of "sterile" in SB704 requires a sterile drug to be "free of chemical or physical contamination", creating a standard not reflective of any compendial reference.

Sterile dosages should be free of viable organisms. However, complete absence of minute quantities of chemical contaminants and nonviable bacteria or its derivatives is beyond the technological limits of both compounding pharmacy and pharmaceutical manufacturing.

Recommendation: The following definition reflects the industry understanding of "sterile pharmaceutical": "*free from living microbes and essentially free of physical and chemical contaminants in accordance with the standards of USP*".

See attached reference for sterile products manufacturing.

Opportunity for Improvement #2:

Sec 17748B, (page 19)

22 (E) THE CONDITIONS OF OPERATION INCLUDING PRACTICES CONSISTENT
23 WITH USP STANDARDS AND REQUIREMENTS FOR THIRD-PARTY TESTING.

Problem: USP makes no mention of the phrase “third-party testing” but rather the phrase “sterility testing” is the appropriate terminology.

Recommendation: Change to read (E) *the conditions of operation including practices consistent with USP standards and requirements for sterility testing.*

Opportunity for Improvement #3:

177448 (5), (page 20)

(5) EXCEPT AS OTHERWISE PROVIDED IN THIS SUBSECTION, THE
17 DEPARTMENT MAY IMMEDIATELY REVOKE THE AUTHORIZATION GRANTED UNDER
18 SUBSECTION (1) IF THERE IS A CONFIRMED DEVIATION OR VIOLATION OF
19 THE COMPOUNDING PROCESS OR IF AN ADVERSE EVENT ASSOCIATED WITH A
20 COMPOUNDED NONSTERILE OR STERILE PHARMACEUTICAL IS DETECTED. IF THE
21 HEALTH, SAFETY, AND WELFARE OF THE PUBLIC ARE NOT IN IMMEDIATE
22 JEOPARDY, THE DEPARTMENT SHALL PROVIDE AT LEAST 30 DAYS' NOTICE OF
23 THE REVOCATION OF AUTHORIZATION UNDER THIS SUBSECTION.

Problem: “Adverse events” occur with all types of medications, sterile and non-sterile. With sterile preparations, adverse events can result due to mishandling at the user side as well.

Recommendation: Strengthen this section by clarifying (5) except as otherwise provided in this subsection, the department may immediately revoke the authorization granted under subsection (1) if there is a confirmed deviation or violation of the compounding process or if an adverse event directly related to professional malfeasance associated with a compounded nonsterile or sterile pharmaceutical is detected. If the health, safety, and welfare of the public are not in immediate jeopardy, the department shall provide at least 30 days' notice of the revocation of authorization under this subsection.

RATIONALE: attaching “professional malfeasance” clarifies that the adverse events mentioned in this section are not referring to those that are known side effects of a pharmaceutical agent.

PCCA USA
 9901 South Wilcrest Drive
 Houston, TX 77099
 Tel: 281.933.6948

PCCA CANADA
 744 Third Street
 London, ON N5V 5J2
 Tel: 800.668.9453

PCCA Australia
 Unit 1, 73 Beauchamp Road
 Matraville, NSW 2036
 Tel: 02.9316.1500

CERTIFICATE OF ANALYSIS

PRODUCT: POTASSIUM BROMIDE USP
 ITEM NUMBER: 30-4672 - 12,500
 LOT NUMBER: C149975
 MFG. DATE: 03/31/2012
 EXPIRATION: 02/28/2017
 CAS: 7758-02-3
 MW: 119.0000000000
 FORMULA: KBr

10/17/12

TEST	SPECIFICATIONS	RESULTS
Acidity & Alkalinity	<=0.5 ml	0.1 ml
Appearance of Solution	pass	pass
Assay (on dried basis)	98.0-100.5 %	100.06 %
Bromate	pass <i>No blue color or violet color develops</i>	pass
Chloride	<=0.6 %	0.6 %
Description	pass <i>White or almost white crystalline powder or colorless or white crystals; odorless.</i>	pass <i>White crystalline powder</i>
Heavy Metals	<=10 ppm	10 ppm
Identification	pass	pass
Iodide	pass	pass
Iron	<=20 ppm	20 ppm
Loss on Drying	<=1.0 %	0.018 %
Magnesium & Alk. Earths	<=0.02 %	0.02 %
Residual Solvents	pass	pass <i>No potential for presence of any residual solvents</i>
Solubility	pass <i>Freely soluble in water and in Glycerol; slightly insoluble in Alcohol.</i>	pass
Sulphate	<=0.01 %	0.01 %

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 This analysis is not to be construed as a warranty, expressed or implied.