
I. Purpose

Policy No. 2016-03 sets forth guidance for pharmacies in the implementation of Lean concepts training as stated by Chapter 159 of the Acts of 2014: An Act Relative to Pharmacy Practice in the Commonwealth. Sterile compounding, complex non-sterile compounding, and institutional sterile compounding pharmacies shall ensure their employees are trained in lean concepts before renewing their pharmacy license. See M.G.L. c. 112, §§ 39G(a)(6), 39H(a)(6), and 39I(a)(7).

II. Regulatory Guidelines for the Implementation of Lean Concepts Training

M.G.L. Chapter 112, § 39G (6), §39H (6), §39I (7)
A sterile compounding pharmacy, complex non-sterile compounding pharmacy, and institutional sterile compounding pharmacy license shall not be renewed until the licensee certifies that their employees have been trained in lean concepts, which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency.

III. Introduction to Lean Concepts

Lean is a systematic approach of eliminating and preventing waste in every step of a process, in order to create value. The Lean approach is best implemented via a structured training program designed through careful inspection of current workflow and operational systems to identify points of value and points of waste. Implementing Lean concepts into pharmacy practice will allow pharmacies to improve processes and therefore add value to the service for patients.

Lean principles may be used to identify value in pharmacy processes:
1. Specify value: value from the standpoint of the patient.
2. Identify the value stream: identify all steps and eliminate steps that do not create value.
3. Improve flow: value-adding steps should be in tight sequence.
4. Generate pull: provide services only when they are needed.
5. Perfection: continual attempts to eliminate waste and improve flow and quality.
The following may serve as examples of waste in the pharmacy practice setting:
1. **Correction**: adverse drug events, medication errors.
2. **Overproduction**: drugs returned to pharmacy.
3. **Transportation**: multiple STAT medication deliveries.
4. **Motion**: poor pharmacy layout.
5. **Waiting**: imbalanced workload, low productivity.
6. **Inventory**: excess forms, low inventory turns.
7. **Lack of standardization**: performing tasks differently each time.
8. **Underutilization of skills**: any ideas not considered and implemented.

The “5S” tools of Lean may be used to improve pharmacy efficiency:
1. **Sort**: Remove unnecessary items and/or steps.
2. **Straighten**: Organize the pharmacy so processes flow freely.
3. **Scrub**: Clean the pharmacy area and check equipment; remove clutter.
4. **Standardize**: Set up a system to maintain new flow.
5. **Sustain**: Follow the new standard daily to avoid slips.

**IV. Implementing Lean Concept Training**

The implementation of Lean concepts should be individualized to each particular pharmacy practice setting and the educational material is up to the discretion of the licensee.

Generally, the Lean training should provide an understanding of:
1. The definition of Lean concepts.
2. The concepts of waste and value.
3. The benefits of Lean in pharmacy practice settings.
4. The basic Lean principles and their use to improve pharmacy processes.
5. The use of the “5S” tools of Lean in improving the pharmacy workplace organization.

**V. Manager of Record Attestation**

Upon renewal of the pharmacy license, the Pharmacist Manager of Record shall attest that their employees have been trained in Lean concepts effective December 31, 2017.

For more information, please see:

August, 2016