

## Executive Summary

Medication shortages are an almost never-ending problem in the world of pharmacy, and they are unfortunately a problem that will not be going away anytime soon. Most importantly, what makes this a major issue is that patients that have the unfortunate circumstance of being in this situation may not get their prescription for sometimes months. This brings up the question “*What strategies are there to get around this?*”; the answers however are very few and far in between. One such strategy is the aspect of compounding medications, specifically in an independent community pharmacy setting, that are temporarily recalled off the market or happen to be in a national shortage. This is done utilizing non-sterile compounding as the main method of production. This business plan will provide a brief layout for developing a plan to compound medications that are deemed unavailable due to shortages.

Currently for a southern Illinois independent community pharmacy there has only been one recent example of a medication that is both prescription and over the counter going into a state of national recall as indicated by the FDA. In this instance the FDA considered this medication no longer commercially available and was placed onto the FDA’s drug shortage list. Within this section there will be a brief overview of the current federal and Illinois state laws that guide the ability to safely and properly compound medications.

The operations at this pharmacy will not be drastically changed as there is a dedicated compounding pharmacist at this specific location, as well as an existing compounding space with equipment. The compounding of the medication may be done by a certified technician, as well as the other pharmacists at the location if the dedicated pharmacist is unavailable. Compliance with current United States Pharmacopeia (USP) guidelines will also play an integral role in the guidance of compounding medications in this plan. The changes towards daily operations

include incorporating a screening process for the medications that are stated on the FDA shortage list. This screening of medications would mainly be done by the staffed pharmacists and/or pharmacy manager.

Financing this project would be provided for by the income brought in by the daily operations at the pharmacy itself, as well as the profits made by the compounded medications resulting from the project. Since there is an existing compounding space with proper equipment there is no need to deduct the costs of implementing a new space; only the upkeep of this workspace is to be monitored when undergoing a financial analysis. Each new medication that has started the compounding process will have different prices depending on the ingredients used to make it. Due to state and federal laws marketing for this type of project is severely limited as it cannot pertain to specific medications and may only indicate that compounding is done at this pharmacy. Each medication as stated above must undergo a screening process, this would include a SWOT analysis to determine internal/external factors at the time of discovery on the FDA drug shortage list.

As this project does not have a set duration and is dependent on the duration of the shortage or recall of the medication the exit strategy will vary. The main exit strategy would consist of liquidating the remaining assets of the project to another compounding pharmacy for a set price as determined between pharmacies. This would also include fulfilling the remaining prescriptions for the compounded products, if unable these medications will be disposed of via a licensed waste management service recognized by the FDA and DEA such as Return Logistics International Corporation (RLI).