

PSSNY Mid-Winter Meeting January 2020 Student Business Plan Competition Case

Authored by PSSNY 2020 Mid-Winter Student Business Plan Competition Committee [Updated: 8-13-19]

Disclaimer: This case was developed solely by the committee and any similarities to other cases or work is coincidental. This case shall not be recreated or used for the purposes of curriculum at any New York State School of Pharmacy

Background:

Community pharmacies around the nation have been evolving to take a lead role in patient care activities which include CLIA-Waived Testing. These tests are waived under the Clinical Laboratory Improvements Amendments (CLIA) of 1988¹. The CDC, in partnership with CMS and FDA, supports the CLIA program and clinical laboratory quality. “Waived” testing, as defined by CLIA, are simple non-invasive tests with a low risk for an incorrect result. For example, CLIA-waved tests:

- Screen to monitor/diagnose various disease/conditions, such as diabetes or Hepatitis C;
- Monitor blood glucose levels and cholesterol levels;
- Screen for the presence of drugs.

Laws in most states permit pharmacists to perform FDA-approved CLIA-waived tests consistent with manufacturer’s instructions.

Over the past few years pharmacists have proven to have a positive impact on population health with their quick call to action during recent flu epidemics; this has certainly gained recognition by legislators in New York. CLIA-wave testing presents as an opportunity, similar to vaccination expansion, for pharmacists to broaden their role in NY State. This would improve the management of patient outcomes by delivering important health status information in a timely manner.

Business Plan Case:

For the purposes of this case we are going to assume that the attached legislation A3867-A McDonald/S5092 Rivera (Appendix I) will be passed and signed into law effective August 1st of this year (2019). Hypothetically, you are an owner of a community pharmacy in NYS tasked to make a business case for starting CLIA-waived testing in your pharmacy. You are a PGY-1 trained pharmacist who fully understands the clinical impact of such services. You must prove that it is cost-effective to provide these services within your pharmacy. In addition, you have a local independent primary care physician who fully supports this idea, as s/he can potentially outsource these tests to your pharmacy.

It will be imperative to address potential safety concerns, patient consent, costs to your pharmacy, electronic medical record dimensions, and potential savings to the healthcare system or provider’s office. Additionally, you must be prepared to act on test results accordingly. Design a Collaborative Practice Agreement (CPA) which outlines a plan to help the doctor’s office with Collaborative Disease State Management. This must include a prioritization of disease states, program design, and program initiatives within a detailed timeline.

You must disclose the location of your pharmacy within NYS and use these location details to outline a market analysis which includes your partnership with stated independent primary care physician. Due to this recent legislation change, you and your business partners (group members) must move quickly to capitalize on this opportunity and expand your patient care services.

It will be up to your team to create a staffing model which compares your previous business model to the one you plan to pursue. This should include: pharmacists, technicians, cashiers, hours of operation, your current patient care services, immunizations and your current retail model. Whether or not you plan to sustain your current model must be addressed.

Current Pharmacy Staff Details:

- *Two full time pharmacists (both of whom are immunizer certified)*
- *One part time pharmacist*
- *One full time pharmacy technician (CPhT)*
- *Two part time pharmacy technicians (non-certified)*
- *One cashier*
- *One stockperson/delivery driver*

Description of Business (current services offered):

- *Hours: M-F, 8AM-7PM, Sat and Sun 9AM-3PM*
- *Prescription dispensing*
- *Patient home delivery*
- *Medication Therapy Management (e.g. – personalized medication records, resolution of drug therapy problems)*
- *Immunizations*
- *OTC*

Location of Pharmacy:

- *Community Pharmacy located in New York State. Any location chosen by the participant group. This should be a fictional pharmacy.*

Below are further deliverables which must be included with the business plan/proposal:

1. Current Mission & Vision Statement of pharmacy
 - I. Identify how this aligns with the new potential service
2. SWOT Analysis
 - I. Identify potential barriers to POCT/CLIA that could affect your participation in this service
 - II. Identify which tests your pharmacy plans to offer
 - III. Identify how your pharmacy will handle *all* results
3. Operational Considerations
 - I. Staffing changes to accommodate new service
 - II. Layout changes to accommodate new service
 - III. Process Mapping Chart (must identify updates from original workflow in chart)
 - IV. Timeline and scale of project (i.e. GANTT Chart or project chart)
 - V. Clinical and operational objectives on proposed service
4. Program economics, budget and financial projections
 - I. Define the economics of the program which include potential revenue and all expenses
 - i. Direct/indirect expenses
 - ii. Sources of generated revenue
 - iii. Personnel costs (e.g. training, addition staffing requirements)
 - II. Include Return on Investment (ROI) chart to highlight projected value
 - i. Break even analysis

- ii. Time to profitability
 - iii. Service Pro forma (three years)
- 5. Marketing/Advertising
 - I. How program will be marketed
 - i. Current customers/patients
 - ii. Potential customers/patients
 - iii. Healthcare providers
- 6. Appendices
 - I. References
 - II. Pharmacy Layout
 - III. Collaborative Practice Agreement(s)
 - IV. Other supporting documentation

The competition is open to individuals or teams of up to four students enrolled at colleges of pharmacy in New York State. Any questions should be directed to the committee as outlined in the guidelines.

Additional/suggested resources:

1. How to develop a Business Plan for Pharmacy Services, Third Edition (ACCP)
2. APhA Point-of-care testing: https://www.pharmacist.com/point-care-testing-emerging-market-opportunity-pharmacists?is_sso_called=1
3. Pharmacy Today: [https://www.pharmacytoday.org/article/S1042-0991\(16\)00228-0/fulltext](https://www.pharmacytoday.org/article/S1042-0991(16)00228-0/fulltext)
4. CMS CLIA Regulations: <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/research-testing-and-clia.pdf>
5. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to optimize Patient outcomes: <https://www.pcpcc.org/sites/default/files/media/medmanagement.pdf>

General Guidelines: The submitted document should be in PDF or MS Word Format no more than twenty-five pages in length (minimum of 12 point font, single spaced, and one-inch margins) including tables/graphs/photos. Further information on Guidelines is in Appendix II of this document.

Appendix I:

Pharmacists Society of the State of New York
Community Pharmacy Association of New York State
New York State Council of Health System Pharmacists
New York State Chapter of the American Society of Consultant Pharmacists

**MEMORANDUM IN SUPPORT
A3867-A McDonald/S5092 Rivera**

An ACT to amend the public health law and the education law authorizing pharmacists to perform certain CLIA-waived tests'

Obtaining a simple test for the flu or strep throat should not be complicated. In most states members of the public can walk into any pharmacy, ask the pharmacist to perform a simple test and receive the results quickly.

Pharmacists in New York look forward to the day when state law will permit them to perform safe, non-invasive tests that are listed as “waived” tests by the U.S. Centers for Disease Control and the Food and Drug Administration as initiated by a patient. “Waived” tests are simple and standardized. As such they are excluded from the strict requirements of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 that establishes rigorous standards for any test on a person that assesses health or diagnoses disease. Waived tests are FDA-approved non-invasive tests that are readily available and routinely performed in physician offices and clinics. In more than 39 states laws authorize pharmacists to administer CLIA-waived tests. New York should no longer be an exception that places both pharmacists and the public at a distinct disadvantage.

Improving accessibility to CLIA-waived tests such as the rapid HIV test, or tests for flu or strep will improve public health. A positive test result will prompt an individual to seek care, thereby reducing the number of untreated individuals who will inevitably become sicker and require higher more costly levels of care. Untreated infections lead to greater incidence of disease.

It is important to point out that the bill does not authorize pharmacists to perform every CLIA-waived test on the CDC-FDA list. The legislation requires the Commissioner of Health to develop the list of CLIA-waived tests that pharmacists would be authorized to perform here in New York. In other states pharmacists commonly test for A1C, blood glucose, strep, flu, HIV, opioids and hepatitis C.

Pharmacies provide devices such as glucometers. Under current law a pharmacist is not authorized to provide a hands-on demonstration of glucose testing devices that involve piercing the skin as most do. The bill removes this barrier, another aspect of the bill that has the potential to significantly improve the care that diabetic patients and their families receive from pharmacists.

As public health officials and private insurers grapple with the increasing cost of healthcare, they have come to recognize the value that pharmacists bring to patient care. Adding pharmacists to the healthcare delivery team makes the system more efficient and cost-effective, improves therapeutic outcomes and is well received by consumers.

This legislation is reasonable and delivers a clear public health benefit.

Appendix II:

PSSNY Mid-Winter Meeting Student Business Plan Competition Student Business Plan Competition Rules and Guidelines

1. The competition will take place at the PSSNY Mid-Winter Meeting between January 25 – 27, 2019. Date, time and location will be communicated once meeting scheduled is finalized.
2. The competition is open to individuals or teams of up to four students enrolled at colleges of pharmacy in New York State.
3. All participants must be registered for the PSSNY Mid-Winter Meeting no later than Sept. 30, 2019; pre-registered for the competition, and current SPSSNY members (unless no chapter exists at their School of Pharmacy). Note: meeting registration opens in September; competition registration is open now.
 - a. To register for the PSSNY Mid-Winter Meeting, please go to: www.PSSNY.org
 - b. Pre-register for the competition via this link: www.pssny.org/2020MWBusinessPlan
 - c. The case will be presented to the contestants upon receipt of letter of intent.
4. Students are expected to form teams and align with a faculty mentor, at their School of Pharmacy who will provide guidance, assist in the learning process, and help connect students with community contacts who can provide additional support/guidance. In addition, teams must name a PSSNY member who will serve the team as a consultant for questions or guidance.
5. A letter of intent to join the competition is due to the business plan panel by the end of day on October 1, 2019. At a minimum, please include in this letter: names of group members (maximum 4), pharmacy school or college name, name of faculty mentor, and name of community pharmacy PSSNY member (consultant). There are all required.
6. The deadline for submission is November 27, 2019 (by 11:59:59 p.m.). There are no exceptions for late submissions. Submissions can be made via [this link](#).
7. All questions about the case should be sent to Kara Wilcox at klw01143@sjfc.edu no later than November 1, 2019 (by 11:59:59 p.m.). Answers to those questions will be sent to all contestants to see to ensure fairness. The committee will answer no questions about the case after this time.
8. The deliverable includes a response to the case question(s) and submission of a concise business plan to the judges.
9. The business plan should be in PDF or MS Word format no more than twenty-five pages in length (minimum 12 point font, single spaced, one-inch margins, including tables/graphs/photos).
10. Judges will review and score the submissions. The top three (3) ranking teams will be invited to present their summaries live at the Mid-Winter Meeting. Guidelines for the live presentation will follow submissions.
11. Participants are not limited with regard to the resources utilized to create the response and the summary (e.g. websites, reference books, live interviews with mentors/employers/wholesalers, etc.)
12. Participants shall not receive assistance or advice from the PSSNY BPC Committee members. If a committee member is contacted by a student then the member should respond accordingly.
13. Case studies, documents or any materials that have been previously submitted to local or national competitions (e.g. NCPA) or as part of course work for class will not be accepted.
14. This case was produced by the business plan committee and cannot be used as part of coursework, or curriculum at Schools of Pharmacy (past and present).
15. Monetary prizes will be awarded to the teams that come in 1st / 2nd / 3rd place and be presented at the Mid-Winter Meeting.