

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
AUDIT & ADVISORY SERVICES**

**UCSF Health  
Specialty Pharmacy  
Project #20-054**

**November 2020**



University of California  
San Francisco

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November 17, 2020

**Desi Kotis**  
Chief Pharmacy Executive  
UCSF Health

**SUBJECT: Specialty Pharmacy Review  
Project # 20-054**

Audit & Advisory Services (“A&AS”) conducted a review of UCSF Health Specialty Pharmacy. The purpose of this review was to assess the processes and internal controls in place for Specialty Pharmacy inventory management.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the “IIA Standards”).

Our review was completed and the preliminary draft report provided to department management in October 2020. Management provided final comments and responses to our observations in November 2020. The observations and corrective actions have been discussed and agreed upon with department management and it is management’s responsibility to implement the corrective actions stated in the report. A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

Irene McGlynn  
Chief Audit Officer  
UCSF Audit and Advisory Services



## EXECUTIVE SUMMARY

### I. **BACKGROUND**

As a planned audit for Fiscal Year 2020, Audit & Advisory Services (A&AS) conducted a review of the UCSF Health Specialty Pharmacy (“Specialty Pharmacy”) to assess internal processes for inventory management.

Specialty Pharmacy manages chronic and complex diseases and conditions that require specialized therapies and customized pharmacy services. In 2017, UCSF Health began offering specialty medications through the Liver Disease and Liver Transplant Clinic, where embedded clinical pharmacists helped ensure safe and appropriate use of Hepatitis C medications. Integration with UCSF Health Ambulatory Clinics resulted in improved quality of care by customizing pharmaceutical services to meet patient needs. The Specialty Pharmacy care team is made up of clinical pharmacists, technicians and patient care coordinators specially trained in varying patient conditions.

Specialty medications may be expensive, require extra attention from a patient’s health care team such as special storage or handling not readily available at other pharmacies, treat rare, serious or chronic conditions, be given orally or by injection or have side effects that require monitoring by a trained pharmacist. Due to the nature of specialty medications, pharmacists in Specialty Pharmacy have access to patients’ complete medical records, allowing them to function as part of the clinical team. Customized services such as reduced prior authorization time, education on administration techniques and management of side effects and drug interactions support the goal of achieving the best outcomes for patients.

All Specialty Pharmacy inventory is tracked in Willow Ambulatory, the outpatient pharmacy module created by Epic, from the ordering and receiving of inventory to dispensing inventory to patients. Specialty Pharmacy migrated from using QS1 to Willow in January 2020. When creating orders in Willow, additional approval must be given in AmerisourceBergen (“ABC”), the wholesaler platform. Functions performed to account for inventory include cycle counting, removing expired drugs or recalled drugs from inventory, and reviewing negative balances. Per the Specialty Pharmacy Operations Policy 310.101 (revised in June 2020), both pharmacists and pharmacy technicians (“technician”) are involved in inventory functions as follows:

| <b>Function<sup>1</sup></b>                           | <b>Responsible Staff</b> |
|---|--------------------------|
| Prescription drop off                                 | Technician               |
| Data Entry  | Both                     |
| Prescription data verification                        | Pharmacist               |
| Prescription filled                                   | Technician               |
| Product verification                                  | Pharmacist               |
| Review for any available financial assistance options | Both                     |
| Prescription filled or sold                           | Both                     |
| Patient counseling                                    | Pharmacist               |

See Appendix B for a more detailed Specialty Pharmacy workflow.

<sup>1</sup> These are patient facing functions. Back end functions, such as reconciliation of invoices is performed by Specialty Pharmacy management.

## II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to assess internal processes for inventory management for Specialty Pharmacy.

The scope of the review covered transactions and activities for February – April 2020 at the Specialty Pharmacy located at the UCSF Parnassus Campus. The transactions in focus include those made via Wholesale Acquisition Cost (WAC), for processes that could be assessed remotely due to COVID-19 related limitations in performing reviews on-site.

Procedures performed as part of the review included a review of inventory processes, including how product is received and how to determine what product is needed to optimize expense opportunities. For more detailed steps, please refer to Appendix A.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in September 2020.

## III. SUMMARY

Based on work performed, many processes surrounding inventory control have been refined as evidenced by updated comprehensive policies and procedures for Specialty Pharmacy, which is notable especially as a newer department. The implementation at Specialty Pharmacy of a perpetual inventory system using the Willow Ambulatory module and structure surrounding the new system is a model that can be leveraged in other areas. Furthermore, Specialty Pharmacy is continually evaluating and improving processes as issues are identified.

Opportunities for improvement exist in the areas of cycle counting inventory and securing and monitoring expired drugs or other drugs to be returned to the reverse distributor.

The specific observations from this review are listed below.

1. Cycle counting is not performed in a consistent manner, which may prevent a comprehensive and accurate accounting of all drugs in Specialty Pharmacy.
2. Controls regarding expired drug management are not sufficient, creating the potential for diversion.
3. The reason for adjusting inventory is not regularly provided in the Willow comments field, preventing thorough trending and analysis of inventory.

Additionally, there was an opportunity for improvement noted where drugs may show negative balances, indicating inaccurate inventory records.

**IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (MCA)**

| <b>No.</b> | <b><u>Observation</u></b>  | <b><u>Risk/Effect</u></b>            | <b><u>Recommendation</u></b>             | <b><u>MCA</u></b>  |   |       |   |       |   |  |   |   |
|------------|--|--------------------------------------|--|--|---|-------|---|-------|---|--|---|---|
| 1          | <p><b><i>Cycle counting is not performed in a consistent manner, which may prevent a comprehensive and accurate accounting of all drugs in Specialty Pharmacy.</i></b></p> <p>A cycle count is an inventory management auditing procedure where a small subset of inventory in a specific location is counted on a specific day. The purpose of cycle counting is to verify the accuracy of inventory and is performed to identify the root causes of inventory errors. The report being used for this purpose by Specialty Pharmacy is the Inventory Balance Report.</p> <p>A review of cycle counting performed February – April 2020 identified that an inconsistent number of cycle counts were being performed, and there were times when a cycle count did not occur at all. The number of cycle counts ranged from zero to 49 per day.</p> <table border="1" data-bbox="172 803 844 977"> <thead> <tr> <th>Month</th> <th>No. of Days Zero Cycle Counts Occurred</th> </tr> </thead> <tbody> <tr> <td>February</td> <td>2</td> </tr> <tr> <td>March</td> <td>3</td> </tr> <tr> <td>April</td> <td>1</td> </tr> </tbody> </table> <p>Since Specialty Pharmacy migrated from QS1 to Willow in January of 2020, adjustments were still being made to internal inventory processes. However, by June 2020, the requirement that 10 random drugs being counted per Specialty Pharmacy Operations Policy 310.101 (in effect beginning June 2020) was still not implemented, with 17 days having fewer than 10 drugs counted.</p> <p>The inconsistency in number of drugs chosen for cycle counting indicates that the existing methodology may not account for all inventory. Not doing enough cycle counts, manual or otherwise, could lead to inaccurate inventory.</p> | Month                                | No. of Days Zero Cycle Counts Occurred   | February   | 2 | March | 3 | April | 1 | <p>Without choosing enough drugs to cycle count at random, Specialty Pharmacy may not be accounting for all inventory on hand.</p> | <p>The policy should be updated to reflect actual processes if they account for all the inventory in stock. An updated methodology on cycle counting to account for all inventory should be included in the updated policy.</p> | <p>During this review, Specialty Pharmacy updated its policy to reflect the current, risk-based approach to cycle counting and methodology to ensure all inventory is accounted for on an annual basis.</p> |
| Month      | No. of Days Zero Cycle Counts Occurred   |                                      |  |  |   |       |   |       |   |  |   |   |
| February   | 2  |                                      |  |  |   |       |   |       |   |  |   |   |
| March      | 3  |                                      |  |  |   |       |   |       |   |  |   |   |
| April      | 1  |                                      |  |  |   |       |   |       |   |  |   |   |
| 2          | <p><b><i>Controls regarding expired drug management are not sufficient, creating the potential for diversion.</i></b></p>  | <p>Allowing drugs that have been</p> | <p>Expired, recalled and other drugs</p> | <p>Specialty Pharmacy began reconciling expired drug</p> |   |       |   |       |   |  |   |   |

| No. | Observation  | Risk/Effect  | Recommendation   | MCA   |
|-----|--|--|--|---|
|     | <p>Expired drugs, recalled drugs, or other drugs to be returned to the reverse distributor, Inmar, are not kept in a locked or otherwise secured location with limited access within the Specialty Pharmacy.</p> <p>Additionally, Inmar is scheduled to pick up drugs from Specialty Pharmacy once a month; however, not all of the drugs scheduled for pick up are actually picked up upon each visit at Inmar’s discretion. There is a control gap which could allow drugs that are marked as being returned to potentially be diverted; however, Specialty Pharmacy contacted Inmar during the course of this review to resolve the inconsistent pick-up of expired drugs.</p> <p>There is a further control gap in that expired drugs are not being monitored on a regular basis for discrepancies. Though there is an existing expired drugs report, containing a date of service and expiration date, it is not being monitored for accuracy or discrepancies.</p> <p>Review of the report from Inmar for February – April 2020 identified two instances where a drug was pulled before the 120-day expiration window, which Specialty Pharmacy investigated and attributed to staff error, and one instance where an expiration date was recorded incorrectly. These errors had not been identified prior to this review.</p> <p>Monitoring of expired drugs is a crucial process in maintaining accurate and safe inventory and should be performed on a regular basis. Misidentification of expired drugs affects usable stock inventory.</p> | <p>removed from inventory to be kept in an unsecured location, especially high value drugs or controlled substances, creates the opportunity for diversion.</p> <p>There is a risk of dispensing expired drugs when not monitoring for the accuracy of expiration dates or loss in revenue by pulling drugs earlier than needed.</p> | <p>needing to be returned should be kept in a secured, locked location, with limited access and a log of expired drugs should be maintained.</p> <p>The expired drugs report should be monitored on a regular basis to ensure that there are no inaccuracies or discrepancies.</p> | <p>reports in August 2020 and has updated its policy to include the reconciliation.</p>   |
| 3   | <p><b><i>The reason for adjusting inventory is not regularly provided in the Willow comments field, preventing thorough trending and analysis of inventory.</i></b></p> <p>Specialty Pharmacy management requires that comments be included when adjusting inventory in Willow. For the inventory in scope, comments were sporadically provided, though the Specialty Pharmacy</p>   | <p>Without more specific reasoning as to why inventory is adjusted in Willow, challenges</p>   | <p>Specialty Pharmacy should remind staff to include comments when adjusting inventory and monitor to validate that comments are</p>   | <p>Specialty Pharmacy leadership reiterated the necessity of including comments when adjusting inventory and will begin monitoring compliance and provide feedback.</p> |

| No. | Observation  | Risk/Effect   | Recommendation                       | MCA  |
|-----|--|---|--------------------------------------|--|
|     | <p>manager stated that staff were told they were required to input data in the comment field when adjusting inventory.</p> <p>Without having this important information, reasons for adjustment of inventory is harder to determine, and monitoring inventory is thus made more challenging.</p> | <p>arise in capturing a full picture of inventory, and diversion may go undetected.</p> | <p>included on an ongoing basis.</p> | <p><b>Responsible Party:</b><br/>Manager, Specialty Pharmacy Services<br/><b>Target Completion Date:</b><br/>November 2020</p> |

**V. OPPORTUNITY FOR IMPROVEMENT**

| No.    | Observation   | Risk/Effect            | Recommendation                 |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
|--------|---|------------------------|--------------------------------|------------------------|---|----|---|---|----|---|---|---|---|---|---|---|---|----|---|---|---|---|---|---|---|---|----|---|---|---|---|----|---|---|---|---|
| 1      | <p><b><i>Drugs may show negative balances, indicating inaccurate inventory records.</i></b></p> <p>Review of the inventory balance changes report for February – April 2020 showed 44% of the inventory items had a negative starting inventory balance.</p> <p>Specialty Pharmacy management stated that negative balances may occur if a drug has been prescribed but is on order and not yet filled. For 10 drugs sampled with a beginning negative balance, the balance remained negative for over a day, and took up to over a month to return to positive as shown below:</p> <table border="1" data-bbox="170 873 842 1292"> <thead> <tr> <th>Sample</th> <th>Length Negative Balance (days)</th> <th>Resolved by June (Y/N)</th> </tr> </thead> <tbody> <tr><td>1</td><td>37</td><td>Y</td></tr> <tr><td>2</td><td>32</td><td>Y</td></tr> <tr><td>3</td><td>3</td><td>N</td></tr> <tr><td>4</td><td>2</td><td>Y</td></tr> <tr><td>5</td><td>41</td><td>Y</td></tr> <tr><td>6</td><td>6</td><td>N</td></tr> <tr><td>7</td><td>2</td><td>Y</td></tr> <tr><td>8</td><td>23</td><td>Y</td></tr> <tr><td>9</td><td>1</td><td>Y</td></tr> <tr><td>10</td><td>4</td><td>N</td></tr> </tbody> </table> <p>The reasons for negative inventory balances for multiple days in a row are due to a prescription going into “ready to fill” status, deducting from inventory, being ordered that day, and then being filled once the order comes in. For the samples tested, the March and April fills were due to staff error in not updating the inventory when the drugs arrived. In</p> | Sample                 | Length Negative Balance (days) | Resolved by June (Y/N) | 1 | 37 | Y | 2 | 32 | Y | 3 | 3 | N | 4 | 2 | Y | 5 | 41 | Y | 6 | 6 | N | 7 | 2 | Y | 8 | 23 | Y | 9 | 1 | Y | 10 | 4 | N | <p>Specialty Pharmacy’s inventory control may potentially be adversely affected by inaccurate inventory records stemming from negative inventory.</p> | <p>Specialty Pharmacy is compensating for the system limitation by ensuring that drugs with negative balances are included in the cycle count for review. Specialty Pharmacy should continue to work with Clinical Systems to discuss the need for updating the Willow Ambulatory module to provide accurate inventory information.</p> |
| Sample | Length Negative Balance (days)  | Resolved by June (Y/N) |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 1      | 37  | Y                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 2      | 32  | Y                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 3      | 3   | N                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 4      | 2   | Y                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 5      | 41  | Y                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 6      | 6   | N                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 7      | 2   | Y                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 8      | 23  | Y                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 9      | 1   | Y                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |
| 10     | 4   | N                      |                                |                        |   |    |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |   |   |   |   |    |   |   |   |   |    |   |   |   |   |

| <u>No.</u> | <u>Observation</u>  | <u>Risk/Effect</u> | <u>Recommendation</u> |
|------------|---|--------------------|-----------------------|
|            | <p>June, the reason for the outstanding negative balances were due to drop ship workflow, in which there can be a delay for a drug to arrive at Specialty Pharmacy. Until there is an update to the Willow Ambulatory module, there will continue to be negative balances on a regular basis.</p> |                    |                       |

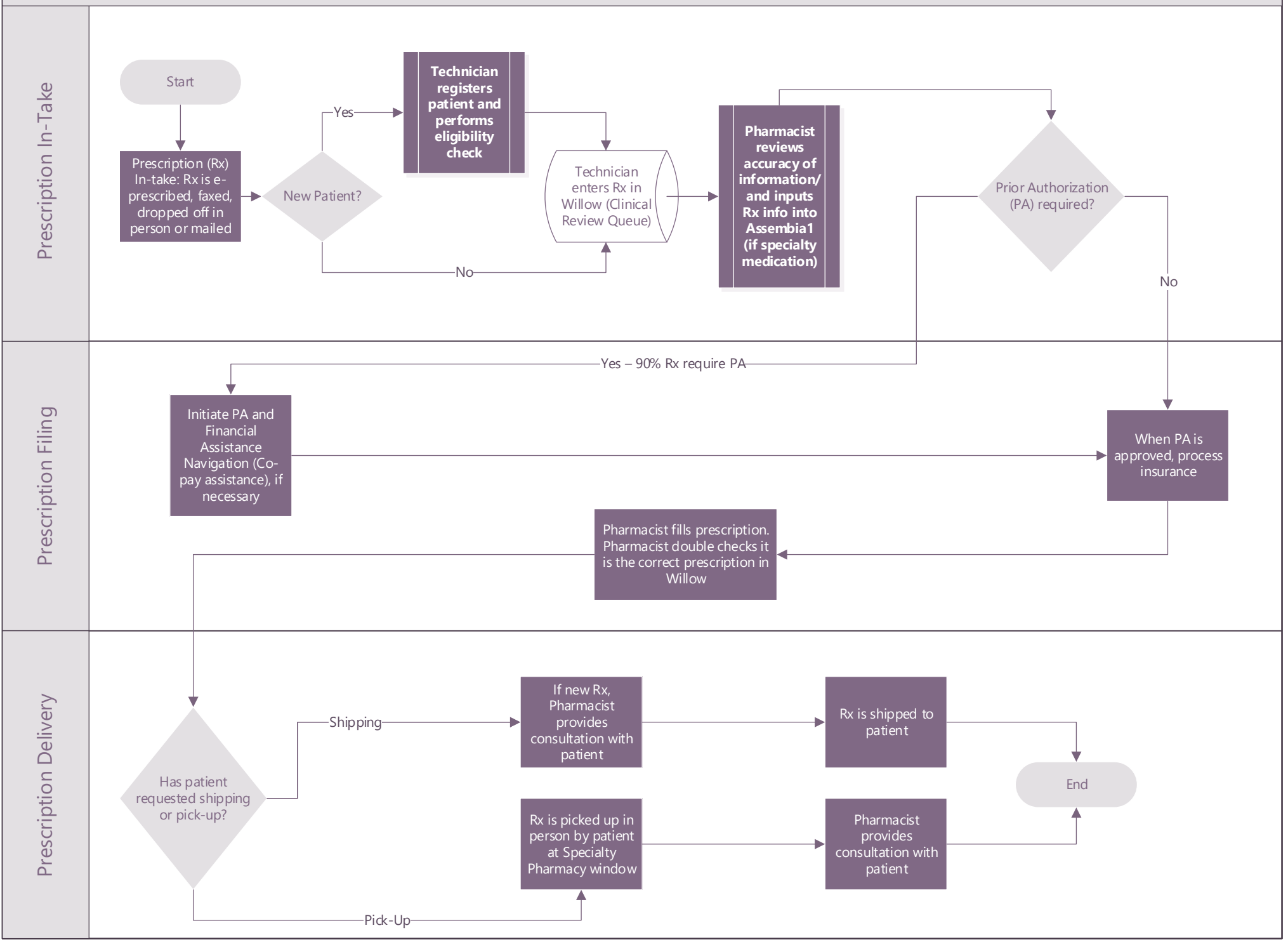


**APPENDIX A**

To conduct our review the following procedures were performed for the areas in scope:

- Reviewed relevant regulations, policies and procedures for inventory processes, including how product is received and how to determine what product is needed to optimize expense opportunities
- Interviewed key department personnel and the management team within Specialty Pharmacy, as well as analysts who are involved in Accounts Payable and Willow
- Evaluated processes for receiving, dispensing, charging and managing inventory in Willow
- Reviewed a sample of invoices to validate proper inventory cycle

# Appendix B - Specialty Pharmacy Inventory Management Work Flow



# Specialty Pharmacy Inventory Management

