Purpose: The purpose of this tool is to provide a list of activities commonly assigned to the role of 340B Manager or Coordinator. This list is not exhaustive, rather, it is a compilation of leading practices shared by participating entities with such positions. This list may be used to develop a job description for staff responsible for the oversight of 340B-related activities.

1. **340B Program Coordination:**
   - Serves as primary internal and external program coordinator and liaison for all 340B-related matters.
   - Serves as the institutional "compliance expert or authority" on 340B regarding program details, policies, and procedures of the virtual inventory processes required for mixed-use areas.
   - Serves as primary internal liaison to key stakeholders to help ensure appropriate utilization of the 340B Program and compliance with all program requirements.
   - Acts as the liaison with necessary affiliated departments to ensure 340B Program integrity.
   - Provides oversight and leadership from the department of pharmacy for the 340B Program. Helps lead and assist the organization’s 340B oversight team, which includes representation from pharmacy, legal, compliance, finance, and senior administration.
   - Provides expertise with the 340B Program to staff and participants regarding ongoing compliance.
   - Develops and maintains internal relationships (accounting, legal, national) and external relationships (wholesalers, manufacturers, contract pharmacies, split-billing software vendors, employee benefit pharmacy benefits managers (PBMs), and third-party administrator (TPA) vendors) as needed.
   - Serves as the institutional compliance expert or authority on 340B.
   - Acts as a liaison to the department of pharmacy and regional facilities as well as with the organization’s purchasing office.
   - Actively engages with senior leadership and participates in decision-making processes related to the implementation of new 340B processes.

2. **Policy and Procedure Development:**
   - Ensures that policies and procedures are developed and implemented according to organizational, regional, national, state, and federal requirements and guidelines and are approved by the institution’s legal department.
   - Assists organizational leadership to develop a regular compliance audit program.
   - Contributes processes and materials to promote programs or support the goals of the department and institution.
   - Establishes consistent policies and procedures for 340B that ensure productivity and efficiency so that long-term management of the program does not hamper operations or create unnecessary costs.
   - Develops and modifies 340B policies in accordance with state, federal, and system program requirements.

3. **Education:**
   - Provides ongoing training, education, and communication required for the 340B Program at the organization.
   - Manages health system education, training, awareness, and customer service for all 340B covered entities.
   - Acts as a preceptor to pharmacy students, residents, and others in training.
   - Develops training and competency materials for all staff and leaders who work with the 340B Program.
   - Conducts ongoing 340B Program training for staff.
• May assist in the development, implementation, or promotion of programmatic resources/tools to support staff.
• Regularly communicates with all staff involved with the 340B Program to be sure that processes remain efficient and to address any problems or suggestions for improvement. Establishes a clear way for staff to communicate concerns to the coordinator.
• Provides regular education to staff on policies and procedures related to 340B compliance.

4. Rules/Guidance Surveillance:
• Monitors and assesses 340B guidance and/or rule changes. Attends regular 340B trainings and shares lessons and hot topics with staff.
• Routinely monitors industry publications and websites as well as the professional media, literature, and peers to ensure that the institution has the latest information regarding interpretations, rulings, suggestions, and advanced ideas for improving participation.
• Ensures that the 340B pharmacy program is continuously compliant with 340B federal regulations.
• Maintains knowledge of the policy changes that affect the 340B Program, including, but not limited to, HRSA/OPA rules and Medicaid changes.
• Provides expertise on all 340B Program legislation and policy changes from HRSA and OPA, informing and collaborating with legal and compliance teams.
• Collaborates with the Prime Vendor Program, pharmacy leadership, and other 340B institutions to determine the most appropriate use of the 340B Program staff.
• Develops knowledge and maintains awareness of current regulations, trends, and issues pertaining to the 340B Program.
• Keeps abreast of trends and issues pertaining to the program and relays applications and interpretations to assist departments.

5. Registration/Recertification:
• Responsible for ensuring that the annual HRSA recertification is completed within the allowable time frame.
• Responsible for ensuring that the HRSA 340B OPAIS is accurate for all organization entities.
• Responsible for ensuring registration of any new child site within the allowable time frame.

6. Self-Audits:
• Develops, executes, and documents self-audits of the 340B process. Coordinates and ensures remediation of findings.
• Conducts and/or coordinates an annual audit of all contract pharmacies. Documents results and follow-up on any findings.
• Reviews and monitors all points of service where 340B participation occurs to ensure policy and procedure compliance, covered entity eligibility, and “covered patient” eligibility.
• Responsible for managing and troubleshooting pharmacy billing issues and ensuring that adequate systems checks are reviewed to prevent billing issues.
• Monitors utilization records and 340B purchasing accounts to ensure that software or tools are working properly and accurately, performing audits or compliance assessments internally as needed; coordinates external compliance assessments with outside firms, where appropriate, to validate internal processes.
• Evaluates patient eligibility for qualified and non-qualified patients in hospital-based mixed-use areas and clinics by reviewing patient medical records, insurance plans, and hospital status.
• Monitors 340B compliance within workflow processes.
• Responsible for the day-to-day management, compliance review, and operations of clinic-administered medications in eligible locations, mixed-use areas managed by split-billing software, outpatient prescriptions fulfilled by an owned pharmacy, and outpatient prescriptions fulfilled by a contract 340B pharmacy.
• Conducts monthly audits of all 340B-eligible locations to verify adherence with the 340B Program guidelines and policies.
• Ensures compliance with all aspects of the 340B Program and implements all applicable aspects of HRSA’s Office of Pharmacy Affairs guidance, as well as organizational policies and procedures.
• Responsible for oversight of all audits performed by 340B internal staff.
• Ensures that audits follow current regulatory compliance recommendations and are completed at the facility level.
• Ensures that 340B Program managers are able to complete evaluations of gaps at the facility level and assists in providing the tools necessary to be compliant with the 340B Program.
• Evaluates covered entity compliance at the contract pharmacy, covered entity, and wholesaler levels.
• Performs annual independent compliance audits and reports findings to responsible representatives at the organization.
• Routinely reviews data and related reports from all points of service at which 340B participation occurs to ensure that policies and procedures are followed, entity eligibility requirements are met, and all patients meet patient definition requirements.
• Performs 340B purchasing and utilization audits or compliance assessments internally, as needed.
• Is responsible for the oversight of required 340B audits, both internally and externally.
• Routinely audits all 340B Programs to ensure compliance with regulations related to 340B purchasing.

7. **External Audits:**
• Serves as the point person and coordinator for all audits. Coordinates all requests and responses. Maintains a current state of “audit readiness.”
• Works with medical auditors on third-party payer audits to ensure coordination of efforts and maximum collection.
• Provides oversight for all audits performed by independent external auditors.
• Coordinates external compliance assessments with outside firms, where appropriate, to validate internal processes.

8. **340B Contract Management:**
• Reviews and negotiates any new 340B contracts. Maintains all 340B contracts.
• Manages relationships, billing services, and compliance with contracted 340B pharmacies.
• Evaluates all current and future contract pharmacy opportunities, including contract language, fee structure, data setup, and internal and independent external auditing.
• Works directly with manufacturers, as well as through GPO and peer professional relationships, to determine companies that are contracting with inpatient facilities to offer 340B or equivalent pricing and develops strategies to maximize such participation.

9. **Program Enhancement/Optimization:**
• Assesses opportunities for cost savings and business improvements in 340B contract pharmacy utilization.
• Assesses opportunities for cost savings and system improvements to yield higher compliance.
• Oversees the 340B contract pharmacy marketing program to attract and retain qualified retail pharmacy contracts and serve eligible patients.
• Analyzes utilization of the program and existing software to identify ways to compliantly use the 340B program to its fullest extent to meet the needs of underserved patients.
• Works directly with the manufacturers as well as the wholesalers to develop strategies for appropriate use of the program.
• Participates in projects, councils, and special initiatives related to 340B, compliance, auditing functions, vendor selection, and medication management.
• Develops business plans to prioritize and implement programs related to program services and contract pharmacy agreements.
• Develops action plans to close identified gaps in collaboration with organizational leadership.
• Participates in projects, councils, and special initiatives related to 340B.
• Implements business plans in coordination with organizational pharmacy leadership to help use 340B savings to expand and improve care provided to underserved and vulnerable populations.
• Collaborates with department leadership to improve and enhance service offerings.
• Implements programs that address the programmatic needs of the department and institution.
• Monitors all outpatient points of service to continually check for new areas that may qualify for the 340B Program.
• Provides oversight for the implementation of process improvement initiatives and creates an environment that places an emphasis on continuous monitoring and improvement.
• Provides input and implements business plans in coordination with the organization’s pharmacy leadership for organization facilities to help use 340B savings to expand and improve care provided to underserved and vulnerable populations; assists facilities to prioritize and implement outpatient program development and contract pharmacy agreements related to 340B; and assists the organization’s leadership with program development and optimization.

10. Reporting:
• Tracks and reports program savings on a regular basis; communicates to the leadership team on an ongoing basis.
• Routinely monitors monthly and annual reports on 340B participation that clearly document utilization, savings, problem areas, and exceptions or discrepancies, to be passed on to pharmacy leadership and administration.
• Develops routine reports that are a by-product of the inventory process and software, allowing for concise information to be communicated to the leadership responsible for 340B inventory management.
• Constructs appropriate financial metrics to assess areas of improvement.
• Prepares and assists in the monitoring and various tracking and reporting measurements to ensure compliance with the program.
• Reviews and refines 340B cost savings reports detailing purchasing and replacement practices, as well as dispensing patterns.
• Coordinates monthly financial reporting and analysis, including, but not limited to, metric reporting, scorecards, and variance analysis and reporting.
• Participates in the development and implementation of reports generated on the 340B Program that outline savings, utilization, exceptions, and discrepancies.
• Ensures that reporting meets organizational, regional, national, state, and federal requirements/guidelines.
• Prepares and assists in the monitoring and reporting measurements to ensure satisfaction with the 340B Program.
• Maintains records related to job function and contributes to reports.
• Develops, monitors, and presents reports on 340B participation that clearly document utilization, savings, problem areas, exceptions, and/or discrepancies to pharmacy and administrative leadership.
• Routinely communicates any questions, issues, or discrepancies with the appropriate authority.
• Reports monthly on saving opportunities.
• Communicates key metrics and improvement actions to management.
• Ensures appropriate documentation and audit trail across areas of responsibility.

11. Purchasing/Inventory Oversight:
• Monitors purchasing records for each 340B participant; clearly documents utilization, savings, problem areas, and exceptions or discrepancies. Relays results to pharmacy leadership and administration.
• Monitors for 340B pricing exclusions or shortages and establishes appropriate alternative products that are included when possible, including work with medical staff and formulary to ensure proper position and related use.
• Participates with the prime vendor and routinely reviews 340B formulary pricing, potential alternatives, and possible additional savings as a result of GPO formulary.
• Manages and tracks 340B drug inventory, including proper replenishment.
• Tracks, trends, and reports 340B pharmaceutical sales and purchases data to ensure provider/physician and patient eligibility.
• Manages purchasing, receiving, and inventory control processes.
• Continuously monitors product min/max levels to effectively balance product availability and cost-efficient inventory control.
• Maintains system databases to reflect changes in the drug formulary or product specifications.
• Optimizes purchasing of supplies and medications from the 340 program.
• Ensures compliance with regulations related to 340B purchasing.
• May be required to work on inventory management of the 340B Program and offer input as to the application’s overall functionality and opportunities for improving compliance and efficiency.
• Routinely monitors utilization records and 340B purchasing accounts to ensure that software or tools are working properly.
• Performs thorough quarterly reviews of the new 340B pricing list to search for and quickly address costly changes.
• Oversees 340B regulatory aspects of the inventory purchasing process for outpatient, inpatient, and mixed-use areas.
• Regularly monitors 340B purchasing activity and compliance with established protocols.
• Ensures the effective delivery and distribution of pharmaceuticals and pharmaceutical products as they relate to 340B.

12. Split-Billing Software Maintenance:
• Establishes a routine approach to updating the CDM/crosswalk for new products and product changes to ensure both the accuracy of the utilization report and the efficiency and accuracy of the charge process.
• Maintains 340B split-billing software integrity and reviews applicable reports to identify areas for improvement.
• Assists in implementing new software packages and other changes in business practice based on changing regulations and policies.
• Is responsible for maintenance and testing of tracking software.
• Integrates information from the pharmacy chargemaster system into the 340B split-billing computer system and incorporates that information into auditable and compliant processes.
• Works with outpatient pharmacy management and pharmacy informatics teams to ensure that the organization's clinical information system is coordinated and integrated into the work with the 340B Program. This shall include the electronic interfaces between the EMR and the virtual accumulator and any interfaces between the organization and contract pharmacy providers and/or administrators.
• Ensures split-billing software integrity and reviews applicable reports for areas of improvement.
• Periodically performs spot audits or compliance assessments in specific areas and specific products to ensure that the CDM is accurate, charges are coming across accurately, and the utilization numbers are translating accurately into report for 340B reorders.
• Oversees split-billing software maintenance.

<table>
<thead>
<tr>
<th>Position Title Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>340B Compliance Coordinator</td>
</tr>
<tr>
<td>340B Coordinator</td>
</tr>
<tr>
<td>340B Program Coordinator</td>
</tr>
<tr>
<td>Pharmacy Manager – 340B Compliance and Integrity</td>
</tr>
<tr>
<td>Manager – Pharmacy 340B Program</td>
</tr>
<tr>
<td>340B Program Director</td>
</tr>
</tbody>
</table>

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

© 2018 Apexus. Permission is granted to use, copy, and distribute this work solely for 340B covered entities and Medicaid agencies.