**Purpose:** The purpose of this tool is to provide a list of responsibilities commonly assigned to the role of 340B Coordinator, as shared by leading practice sites. This can serve as a resource when developing a job description for staff responsible for oversight of 340B-related activities.

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| **Position Title Examples** | |
| 340B Compliance Coordinator | 340B Compliance Specialist |
| 340B Coordinator | 340B Specialist |
| 340B Program Coordinator | Regional 340B Program Specialist |
| Pharmacy Manager – 340B Compliance and Integrity | Pharmacy Business Operations Manager |
| 340B Program Director | 340B Program Manager |

**340B Program Coordinator General Duties**

* Serves as the covered entity’s compliance expert on 340B Program details, policies, and procedures.
* 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.
* Leads the organization’s 340B oversight committee, which includes members from senior leadership, pharmacy, compliance, legal, and finance.
* 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.
* Actively engages with senior leadership and participates in decision-making processes related to the implementation of new 340B processes.

The following 11 sections include more specific examples of 340B Program Coordinator duties based on area of responsibility.

1. **Policy and Procedure Development**

* Ensures that policies and procedures are developed, implemented, and maintained according to organizational, regional, national, state, and federal requirements and guidelines and are approved by the institution’s legal department.
* 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.

1. **Education**

* Provides ongoing training, education, and communication required for the 340B Program at the organization.
* Develops training/competency materials for all employees who work with the 340B Program.
* Acts as a preceptor to pharmacy students, residents, and others in training.
* 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.

1. **Rules/Guidance Surveillance**

* Monitors and assesses 340B guidance and/or rule changes, including, but not limited to HRSA/OPA rules and Medicaid 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.
* 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.

1. **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 associated sites are within the allowable time frame.

1. **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, when appropriate, to validate internal processes.
* Monitors 340B compliance within workflow processes.
* Responsible for the day-to-day management, compliance review, and operations of clinic-administered medications in eligible locations, 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.
* Ensures that audits follow current regulatory compliance recommendations and are completed at the site level.
* Ensures evaluations are completed for gaps at the site 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.
* Performs 340B purchasing and utilization audits or compliance assessments internally, as needed.
* Routinely audits all 340B programs to ensure compliance with regulations related to 340B purchasing.

1. **External Audits**

* Serves as the point person and coordinator for all audits. Coordinates all requests and responses.
* Maintains a current state of “audit readiness.”
* Provides oversight for all audits performed by independent external auditors.
* Coordinates external compliance assessments with outside firms, when appropriate, to validate internal processes.

1. **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.

1. **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 manufacturers as well as wholesalers to develop strategies for appropriate use of the program.
* 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.
* 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.
* Provides oversight for the implementation of process improvement initiatives and creates an environment that places an emphasis on continuous monitoring and improvement.

1. **Reporting**

* 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.
* Coordinates monthly financial reporting and analysis, including, but not limited to, metric reporting, scorecards, and variance analysis and reporting.
* Ensures that reporting meets organizational, regional, national, state, and federal requirements/guidelines.
* Maintains records related to job function and contributes to reports.
* Routinely communicates any questions, issues, or discrepancies with the appropriate authority.
* Reports monthly savings opportunities.
* Ensures appropriate documentation and audit trail across areas of responsibility.

1. **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.
* 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 and potential alternatives.
* 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.
* 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.
* Ensures compliance with regulations related to 340B purchasing.
* 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.

1. **Third-Party Administrator Software Maintenance**

* Maintains 340B TPA software integrity and reviews 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.
* Works with pharmacy management and 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.

*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.*

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