Health Resources and Services Administration

340B

Peer-to-Peer Program

340B Compliance Improvement Guide

Strategic Aims

- Leadership Commitment
- Education and Training
- Integrated 340B Systems
- Measurable Improvement

October 1, 2015
Appendices K and L
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The content of this compliance improvement guide was developed by faculty and experts drawn from actual high-performing 340B covered entities that form the Health Resources and Services Administration (HRSA) 340B Peer-to-Peer Program.

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What is the 340B Compliance Improvement Guide?

A larger organizational focus on 340B Drug Pricing Program compliance and integrity is crucial given the complexity of the 340B Program and need for full integration and oversight beyond the pharmacy department. In order to further this effort, 340B compliance must be seen as attainable and offer intrinsic financial or mission-driven benefit to the entity and its leadership.

The content of this 340B Compliance Improvement Guide was developed by faculty and experts and drawn from actual high-performing 340B covered entities that form the Health Resources and Services Administration (HRSA) 340B Peer-to-Peer Program. Improvement concepts and specific action steps represent the collective lessons and practices of Peer Mentors and faculty who are recognized by HRSA as having successfully implemented compliant 340B Programs in their institutions.

The Guide was developed utilizing the Institute for Healthcare Improvement (IHI) Collaborative Model for Achieving Breakthrough Improvement[1], which offers a viable approach to improving 340B compliance and program integrity.

The IHI collaborative model[1] includes three essential components that have been integrated into this Guide:

1. The **proficiency/knowledge** behind the aspects that need to be improved (the key ideas and principles are put into a document called the "Process Improvement Tool").
2. A method for each covered entity to make **improvements** and learn as it makes improvements (called the "Model for Improvement").
3. A method for all the covered entities to **learn** together (the collaborative learning approach).

The 340B Compliance Improvement Model is organized into four strategies designed to achieve accountability and results. Each strategy includes improvement concepts that are accompanied by action items, examples, and potential barriers identified and recommended by Peer-to-Peer faculty and Mentors. The action items are suggestions and are not intended to be an exhaustive list or applicable to all organizations. For example, "Putting the 'Action' into Action" items explain how Peer-to-Peer Leading Practice Sites have applied the associated improvement concept. Potential barriers are also accompanied with suggested actions to overcome them.

Before getting started with this Guide, it is recommended that you view the introductory video for the Compliance Improvement Model as well as the short video on how to use this Guide.

[1] *The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement.* IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2003.

What are the 340B Program strategies and improvement concepts?

LEADERSHIP COMMITMENT: Develop organizational priority focused on compliance with 340B Program guidelines.
A. Foster a culture of compliance with a vision of vertically and horizontally integrated 340B systems.
B. Build the business case and foundation for the sustainability of 340B Program compliance.
C. Integrate 340B compliance with quality improvement and risk management program.
D. Maintain internal and external partnerships to achieve compliance and align resources.
EDUCATION and TRAINING: Develop and maintain staff knowledge and skills related to the 340B Program.
E. Establish minimum 340B knowledge requirements for organizational staff members and leaders.
F. Identify gaps in staff knowledge and skills related to the 340B Program.
G. Establish mechanisms and expectations for staff to attain and maintain their 340B knowledge and skills.
INTEGRATED 340B SYSTEMS: Build an integrated 340B Program across all practice settings.
H. Develop, implement, and maintain comprehensive 340B policies and procedures.
I. Generate auditable records that demonstrate compliance with 340B Program guidelines.
MEASURABLE IMPROVEMENT: Achieve 340B compliance using the value and power of data-driven improvements.
J. Collect, analyze, and disseminate the data to evaluate and guide improvement.
K. Conduct internal and external audits.
L. Utilize "model for improvement" to continually test, track, and study 340B Program enhancements.

How can I use the 340B Compliance Improvement Guide?

The Guide is a dynamic document intended to be used in conjunction with materials developed by the HRSA 340B Peer-to-Peer Program and other resources available from the HRSA Office of Pharmacy Affairs and the 340B Prime Vendor Program managed by Apexus. If you have a comment or question about this Guide, please send an e-mail to p2pcommunication@aphanet.org.

The 340B Compliance Improvement Guide should be used as a complement to the HRSA Compliance Improvement Webinar Series that was recorded November 2015 through March 2016. Each webinar session addresses one of the four strategies and improvement concepts. Go to www.hrsa.gov/opa/ to either register (prior to the scheduled dates) or view the recorded sessions (beyond the live webinar sessions).

The Guide is intended as a tool for covered entities to use at each stage of improving 340B compliance. A short video has been produced to provide further guidance in using the Guide. The Guide and assessments are recommended for use by anyone within a covered entity that is involved in the 340B Program. Not all staff in the covered entity is expected to have knowledge in all proficiencies or be able to complete every assessment component; however, gaps in knowledge and skills can be identified.

The "Readiness Actions" and "Implementation Actions" stages were created to help 340B covered entities advance through the different stages of improving compliance with 340B Program participation. After reviewing the readiness and implementation actions, readers should become familiar with the structure of the Guide.

The appendices include self-assessments for culture, operational elements and processes that might be at risk for 340B compliance, as well as the eight areas of knowledge proficiencies HRSA has identified as critical in maintaining 340B compliance.

Helpful tools, resources, and definitions are also included. Together, these elements provide an easy-to-understand document that will help your organization advance and improve compliance with the 340B Program.

READINESS ACTIONS

Readiness is the first stage for improving organizational compliance with 340B Program requirements. In the readiness stage, the covered entity is committed to improving 340B compliance and allocating resources, but it is not yet ready to fully implement the strategies and improvement concepts or apply the IHI Model for Improvement using the "plan-do-study-act" (PDSA) cycle.

The readiness stage involves carrying out the following actions:

1. View the introductory video for the 340 Compliance Improvement Model.

2. View the video on using the 340B Compliance Improvement Guide.

3. Identify potential high-risk 340B operational elements and processes that may cause the organization to be out of compliance with 340B guidelines. (Complete the 340B Compliance Rapid Self-Assessment found in Appendix A.) The form can be downloaded with this Guide and completed manually or you may go to http://complianceassessmenta.com/form.aspx to complete, save, and download online.

4. Perform a quick self-assessment of your organization's culture of compliance using the 340B Compliance Culture Self-Assessment found in Appendix B. The form can be downloaded with this Guide and completed manually or you may go to http://complianceassessmentB.com/form.aspx to complete, save, and download online.

5. Assemble all existing organizational documents and data related to 340B Program participation.

6. Identify all organizational leaders and business partners that oversee 340B Program processes or influence operational decisions.

7. Allocate resources and staff who will be required to implement the 340B Compliance Improvement Guide strategies.

8. Create and/or formalize a dedicated 340B compliance team.

IMPLEMENTATION ACTIONS

Implementation is the second stage for improving 340B Program compliance. In the implementation stage, the covered entity begins with the first plan-do-study-act (PDSA) cycle. The 340B compliance team for the organization convenes on a regular schedule, working with the 340B Compliance Improvement Guide to implement the improvement concepts.

This stage begins when specific PDSA cycles are being carried out and results are being tracked. Success is highly dependent upon:

1. Having organization leadership in action.
2. Getting staff engaged early.
3. Presenting a picture of compliance as a well-defined process.
4. Integrating through education of department leads/involved internal staff, and external business partner staff.
5. Interfacing between the compliance team and external business partners.
6. Regularly convening the internal compliance team.
7. Speaking of measurable improvement.

STRATEGY 1. LEADERSHIP COMMITMENT

Develop organizational priority focused on compliance with 340B Program guidelines.

IMPROVEMENT CONCEPT A. CULTURE OF COMPLIANCE

Foster a culture of compliance with a vision of vertically and horizontally integrated 340B systems.

Action Items:

A1. Complete the culture of compliance self-assessment for your organization (Appendix B).

A2. Assess organizational needs for compliance improvement by conducting staff and leadership surveys on 340B perceptions and importance to organization.

A3. Set clear organizational goals for 340B compliance.

A4. Provide staff with tools needed to accomplish organizational goals for 340B compliance.

A5. Communicate and reinforce consistent messages regarding goals and expectations for 340B compliance throughout the organization.

A6. Align 340B compliance focus with grant/program, organizational mission, and vision for patient care.

A7. Establish a positive culture of compliance by examining and improving 340B drug acquisition and distribution systems rather than blaming individuals.

A8. Establish an organizational chart that prevents silo management of 340B processes.

A9. Assess the integrity and quality of new leadership for supporting compliance by asking creative and effective questions during recruitment, and build a team that:

- Understands the challenges faced by vulnerable patients in the community.
- Is committed to ensuring 340B compliance that ultimately benefits patients.
- Has a sense of idealism and cooperation.
- Is flexible and willing to work with a variety of people.

A10. Educate senior leadership on importance of 340B compliance and encourage their attendance at state and national 340B conferences and education offerings.

A11. Establish corporate/system leadership oversight of 340B Program.

A12. Provide organizational leadership team with 340B Program updates to ensure decisions align with program requirements.

A13. Ensure 340B team includes authorizing official.

A14. Include 340B compliance topics on monthly meeting agendas throughout the organization.

A15. Obtain support from medical director/staff.

A16. Apply "eight key elements" of compliance program to 340B operations as a foundation:

- Leadership commitment and resources.
- Continuous risk assessments.
- Policies and procedures.
- Compliance training and awareness.
- Adherence to recordkeeping regulatory requirements.
- Compliance monitoring/audits.
- Internal program for handling compliance problems.
- Corrective action.

A17. Ensure pharmacy director and/or appropriate staff are part of senior management team for organization.

A18. Inform and seek guidance from Board of Directors regarding 340B Program compliance efforts of the organization.

A19. Inform provider community at large on 340B restrictions to reduce potential presentation of ineligible prescriptions.

A20. Seek guidance from funding agency (e.g., HRSA) on 340B compliance tools specific to the entity and the grant funding.

IMPROVEMENT CONCEPT B. BUSINESS CASE

Build the business case and foundation for the sustainability of 340B Program compliance.

Action Items:

B1. Estimate direct and cost-avoidance savings that result when patients are able to obtain the medications they need, such as reduced hospitalizations, emergency room visits, and early admissions.

B2. Project the amount of staff resources, equipment, technology, and outsourced services needed to manage the 340B Program in a manner that continually monitors and improves compliance.

B3. Identify and quantify patient care programs supported by realized 340B savings.

B4. Develop and communicate compelling need for investment of resources to maintain 340B compliance to staff, organizational leadership (including Board of Directors), and community at large.

B5. Demonstrate financial savings and patient care contributions of 340B Program participation.

B6. Include projected costs for 340B integrity staff positions and information technology (IT) resources in budget development process.

B7. Establish a process to continually monitor 340B impact on medication budget and patient service delivery.

B8. Outline a decision-making and documentation process for tracking use of 340B savings to improve patient services and access.

B9. Evaluate impact of 340B on revenue and savings for existing and future service expansion.

B10. Establish mechanisms to continuously track patients served, prescriptions filled, and other services or support provided as a direct result of 340B Program participation.

IMPROVEMENT CONCEPT C. INTEGRATION

Integrate 340B compliance with quality improvement and risk management program.

Action Items:

C1. Identify existing compliance and risk management activities that are directly or indirectly affected by 340B Program participation and processes.

C2. Develop or refine ongoing and objective monitoring and assessment methods to integrate 340B processes.

C3. Assign staff with 340B expertise and accountability to provide support and to advise compliance team and risk management personnel.

C4. Incorporate potential impact of continued 340B Program eligibility and participation in risk assessment and decision-making processes.

C5. Develop formal 340B compliance plan for the organization that incorporates health care regulation and grant funding requirements.

C6. Coordinate compliance activities with pharmacy and therapeutics committee decision-making processes and medication formulary recommendations.

C7. Expand 340B compliance committees to include pharmacy representative.

C8. Create a 340B compliance committee as part of organization's overall quality, compliance, and accountability structure.

C9. Incorporate 340B as part of organizational strategic plan.
C10. Dedicate staff (both pharmacy and non-pharmacy) to lead 340B quality and integrity efforts/activities.
C11. Create a management action plan for 340B compliance areas (e.g., diversion, eligibility, audits).
C12. Hold quarterly meetings of operational leaders that procure, dispense, store, administer, or bill 340B drugs.
C13. Integrate specific grant program requirements and systems that apply to 340B compliance.

IMPROVEMENT CONCEPT D. PARTNERSHIPS

Maintain internal and external partnerships to achieve compliance and align resources.

Action Items:

D1. Identify and strengthen communication channels between interdepartmental and organizational units to strengthen coordination of operational functions that require compliance with 340B Program eligibility requirements, prevention of diversion to ineligible patients, and avoidance of duplicate discounts.
D2. Develop professional relationships and affiliations with organizations and business partners that share the organization's 340B Program compliance goals and patient care mission.
D3. Identify all external vendors, contractors, or provider groups that provide services to the organizations that impact 340B Program participation and compliance.
D4. Conduct a comprehensive analysis of all external agreements and terms to ensure that processes support 340B Program compliance and align resource and revenue retention with the organizational mission and vision for providing care to eligible patients.
D5. Initiate strategies to strengthen and modify internal collaboration and external partnerships as required to improve 340B compliance and resource retention.
D6. Participate in a network of other 340B organizations to share effective strategies and operational processes.
D7. Involve the organization in local, regional, or national 340B initiatives that ensure access to accurate and up-to-date 340B information.
D8. Foster relationships with professional education and training programs, including colleges of pharmacy, that will sustain and facilitate organization access to job candidates and individuals with proven 340B knowledge and skills.
D9. Identify and develop relationships with key individuals from applicable regulatory agencies and/or grant funding offices.
D10. Seek opportunities to educate all community stakeholders on value and benefit of 340B Program to patient care service access and quality.
D11. Strengthen providers as partners by continuously informing, educating, and demonstrating ability of 340B Program to support patient care activities and improve patient outcomes.
D12. Gain employee support for 340B compliance by directly linking program compliance with their individual personal and professional goals.

PUTTING THE "ACTION" INTO ACTION ITEMS

Action Examples provided by Community Health Centers or other Grantees:

Arizona Entity

- Formed a 340B compliance committee that includes a compliance officer, clinical pharmacy director, regional nursing managers, health information management, and pharmacy administration team.

Florida Entity

- A Vice President of Pharmacy serves as part of the C-Suite executive team.
- Pharmacy participates in overall organizational compliance activities that include 340B.
- Has adopted an organization-wide management philosophy of doing things right from the start – not just when an audit is pending.

Maine Entity

- Established a 340B compliance subcommittee to health center's compliance committee.

Massachusetts Entity

- Established a 340B compliance committee that reports to a quality council and directly to senior management. Committee includes pharmacy leadership, site operations managers, Medical Director, and senior management team members.
- Expanded 340B compliance staff to include pharmacy regulatory specialist, pharmacy referral representative, and a director of compliance and risk management.
- Incorporate 340B University attendance as part of management training requirement.

Nebraska Entity

- Utilizes a monthly corporate newsletter and group e-mail communications to share information on 340B Program developments and organizational activities.

Ohio Entity – 1

- Pharmacy Director is part of executive management team to ensure compliance is continually considered in strategic and business decisions.
- Appointed an experienced pharmacy technician as pharmacy coordinator with majority of duties focused on auditing and staff training on 340B processes.

Ohio Entity – 2

- Highlights 340B policy and procedures at each staff meeting.
- Tracks utilization of 340B savings.
- Includes a pharmacy representative on clinic program committees to ensure 340B-compliant decision making.

Oklahoma Entity

- Tracks additional services directly resulting from 340B savings and financial impact on client co-payments and out-of-pocket expenses.

Texas Entity

- Presents annually to Board of Directors to ensure they understand what 340B means to the organization and what is required to continue compliant participation.

Utah Entity

- 340B compliance is led by Director of Pharmacy but viewed as an organizational responsibility.
- Self-auditing is viewed as an opportunity to improve and learn, not to identify failures or place blame.
- Both the C-Suite and Board of Directors are kept informed on program requirements and policies that may need to be set in place.
- 340B savings are partially directed to support training as well as to implement and maintain program compliance.

Washington Entity

- Identified a corporate compliance attorney dedicated to 340B issues.
- 340B is included on all meeting agendas and discussed throughout entity.

West Virginia Entity

- Continuous Quality Improvement committee appointed multidisciplinary members to a 340B compliance subcommittee responsible for compliance monitoring, reporting, and training to improve 340B Program integrity.

Action Examples provided by Hospitals or other Non-Grantees:

California Entity

- Allocates resources and has expanded contracted relationships to support 340B compliance activities.

Florida Entity

- Pharmacy leadership meets quarterly with Chief Operating Officer and Chief Financial Officer (CFO).
- Utilizes a separate compliance department to evaluate and ensure 340B compliance.
- Tracks and documents 340B Program savings to justify resources needed for program compliance.

Illinois Entity

- Conducts quarterly meetings with operational 340B leaders to assess changes and status of program.

Minnesota Entity – 1

- Evaluates 340B compliance risks in all business development and service expansion decisions.

Minnesota Entity – 2

- Additional staff hours scheduled to ensure ongoing 340B compliance management.
- Hospital administration is reviewing and revising referral contracts to ensure patient eligibility.
- Serves as a resource for other hospitals in the health system that are implementing 340B Program.
- Meets regularly with providers to discuss 340B Program benefits to facility and importance of compliance to access savings.

Minnesota Entity – 3

- Formed a 340B compliance team that meets quarterly and is composed of health-system Pharmacy Director, CFO, Chief Information Officer, Chief Compliance Officer, and business office staff.

Pennsylvania Entity

- CFO and Chief Medical Officer consider 340B compliance as the highest priority to reduce overall organizational risk.
- Conducts quarterly compliance meetings.
- Meets with contract pharmacy owners as a group to address questions and solve problems.
- Devotes multiple full-time employees to 340B compliance oversight and to performance of ongoing internal audits.
- Schedules monthly meetings with practice management staff to improve communications and streamline processes that align with 340B requirements/guidelines.

POTENTIAL BARRIERS	*SUGGESTED ACTIONS*
Suboptimal relationships between departments and leaders.	Identify interrelated processes and develop options to streamline 340B processes and support functions.
Lack of pharmacy influence on organizational quality and compliance activities.	Assign pharmacy representative to compliance committee.
340B Program viewed as "drug purchasing/pricing" program.	Seek opportunities to inform and educate impact of 340B Program and compliance requirements.
Previous 340B facility experience of leader may not apply to current facility.	Provide information on different entity requirements.

Minimal 340B peer networking and support available among health care leaders in state.	Identify other 340B entities and facilitate outreach and networking opportunities.
Lack of understanding by leaders of need for 340B compliance.	Communicate national HRSA audit results and updates.
Lack of financial resources.	Quantify and communicate financial impact of 340B Program and request allocation of savings to maintain compliance. Demonstrate drug budget impact on top-dollar drugs.
Negative view of pharmacy.	Identify, evaluate, and correct pharmacy service deficiencies.
Lack of compelling "statement of need" for 340B compliance.	Compile and communicate financial and patient care impact of 340B Program. Recruit clinician champion to link 340B Program to patient care and outcomes.
C-Suite does not have or will not prioritize time to 340B.	Customize education and information updates for the C-Suite.
Negative external messaging about 340B Program – financial windfall, program complexity, audit fear, HRSA targeting.	Share accurate and relevant information to organization leaders and department managers.
Suboptimal recognition of program benefit to state's budget and need for compliance.	Educate state lawmakers and health decision-making committee on benefits and impact if program does not remain compliant.

STRATEGY 2. EDUCATION and TRAINING

Develop and maintain organizational knowledge and skills related to the 340B Program.

IMPROVEMENT CONCEPT E. STAFF KNOWLEDGE REQUIREMENTS

Establish minimum 340B knowledge requirements for organizational staff members and leaders.

Action Items:

E1. Identify all individuals that belong to the following groups:
- Organizational leaders that need to understand how the 340B Program impacts organizational mission, financial goals, legal/regulatory requirements, and risk management.
- Operational management staff that have responsibility for establishing and maintaining processes related to 340B drug procurement, inventory management, patient eligibility, and billing.
- Departmental leaders that have responsibility for provider and staff recruitment and performance.
- Staff (including students, temporary, and as-needed personnel) that must carry out policies and procedures at the frontline and patient engagement level.
- Providers and organizations at access points served by eligible patients.

E2. Determine which education knowledge assessment areas relate to each group.

E3. Incorporate 340B knowledge requirements in position descriptions for individuals/staff in each group.

E4. Establish expectation that 340B education and competency is an ongoing process requiring regular updating and verification.

E5. Establish annual competency verification and documentation requirements for all staff and leadership.

IMPROVEMENT CONCEPT F. 340B KNOWLEDGE SELF-ASSESSMENT

Identify gaps in staff knowledge and skills related to the 340B Program.

Action Items:

F1. Have every person identified in Improvement Concept E complete the 340B knowledge self-assessment areas that are relevant to his or her group.

F2. Compile results of all 340B knowledge self-assessments to identify aggregate knowledge gaps of each group and individual staff members.

F3. Utilize audit findings to isolate and close specific departmental, job category, and staff knowledge gaps.

F4. Develop ongoing training plan (at time of hire and annually) for staff at various levels.

F5. Establish mechanisms to monitor, assess, verify, and document staff knowledge and competency to perform 340B critical functions.

IMPROVEMENT CONCEPT G. CONTINUOUS LEARNING

Establish mechanisms and expectations for staff to attain and maintain their 340B knowledge and skills.

Action Items:

G1. Develop and implement an organization-wide education and training strategy to address knowledge gaps identified in the self-assessment.

G2. Establish a convenient mechanism for staff to access and complete the necessary 340B education and training resources.

G3. Create a system to monitor and verify that staff acquire and maintain the 340B knowledge and skills as specified in their position description.

G4. Integrate 340B education and training in new staff orientation processes, performance evaluations, and employment accountability requirements.
G5. Establish methods to communicate regular and relevant updates to leaders, management, and staff on 340B Program requirements, developments that impact organization processes, and required changes in policies and procedures.
G6. Identify and recommend that staff view and complete pertinent education offerings available through the HRSA Office of Pharmacy Affairs website and Peer-to-Peer Program webinars.
G7. Identify and recommend that staff view and complete pertinent education offerings available through the 340B Prime Vendor Program managed by Apexus and the 340B University (live and on-demand modules).
G8. Include 340B policy topics, program updates, and policies and procedures in staff meetings.
G9. Provide opportunities for contracted/vendor staff to access and participate in 340B education offerings.
G10. Establish a regular and consistent communication mechanism and schedule to alert staff to new or existing 340B education offerings.
G11. Develop a plan to train staff in all departments, locations, and child sites.
G13. Send staff to other sites to teach and train on 340B Program management, operations, and compliance improvement.
G14. Conduct regular lunchtime conference calls to provide information and answer questions related to 340B Program.
G15. Build a 340B talent pipeline within the organization to serve as a training and information resource to other staff and leadership.
G16. Evaluate feasibility and create 340B trainer position.
G17. Support attendance of key staff and leaders at national, regional, and local 340B conferences and meetings.
G18. Monitor and document all staff 340B training activities and participation.
G19. Seek opportunities for staff to share and learn best practices related to the 340B Program through speaking and attendance at professional conferences.
G20. Create facility- and procedure-specific learning modules as resources for staff training.
G21. Require regular education and demonstration of 340B knowledge for all contract pharmacy staff.

PUTTING THE "ACTION" INTO ACTION ITEMS

Action Examples provided by Community Health Centers or other Grantees:

Arizona Entity

- Leverages clinical pharmacy programs to facilitate education, communication, and coordination about the 340B Program with medical staff.

Florida Entity

- Utilizes multiple opportunities and methods to educate the state, including meetings, memos, and one-on-one conversations. Compliance activities are further viewed as staff education mechanism.

Maine Entity

- Added a standing agenda item to meetings for review of 340B Program issues.

Massachusetts Entity

- Utilizes staff training as part of the process for resolving or preventing 340B compliance risks.

Nebraska Entity

- New employee orientation includes time spent in pharmacy to learn about the 340B Program.

Ohio Entity – 1

- Devotes a significant portion of new pharmacy staff orientation to 340B before staff actually begin working in the pharmacy.
- Presents an annual report on 340B updates and impact to Board of Directors.
- Developed a program called "Patient Experience" that utilizes a patient scenario to allow new Board members and leadership staff to directly experience the impact of the 340B Program.
- Added 340B University OnDemand to required learning for C-Suite and pharmacy team (director, managers, and coordinators).
- Added 340B modules as required to annual competencies for general clinical, pharmacy, and finance staff training.

Ohio Entity – 2

- Mandatory completion of 340B Prime Vendor tools.
- All pharmacists attend 340B University.

Oklahoma Entity – 1

- Communicate/e-mail information on pertinent webinars and notices to staff on an ongoing basis.

Oklahoma Entity – 2

- Convene entity stakeholders and partners semi-annually to inform and update on 340B developments and requirements.

Utah Entity

- Pharmacy management staff routinely monitor Office of Pharmacy Affairs and HRSA website for policy updates.
- Pharmacy management stays connected with other entities through the HRSA Peer-to-Peer Network to be informed on 340B Program developments and options for compliance improvement.
- Meets with individual providers to educate them on the 340B Program, its benefits, requirements, and importance of maintaining compliance.

West Virginia Entity

- Conduct regular lunchtime conference calls to provide information and answer questions about 340B Program.
- Send pharmacists from primary site to other sites to teach and train on 340B Program policies and procedures.

Action Examples provided by Hospitals or other Non-Grantees:

California Entity

- Encourages new executive management (senior staff) to attend 340B University and other 340B education meetings/conferences.
- Requires all new staff to complete 340B tutorial on Apexus website in order to have a basic initial understanding of the 340B Program.
- Pharmacy leadership participates in the 340B stakeholder opportunities to stay informed and up to date on 340B policy.

Florida Entity

- Hospital legal counsel attended 340B University to better execute contracts with providers and vendors.
- Develops a 340B slide presentation annually for staff review.
- Educates pharmacy residents on the 340B Program using Apexus Basic Five modules.

Massachusetts Entity

- Created a pharmacy trainer position.

- Developed 340B basic training sessions that must be completed annually by all departments.

Minnesota Entity

- Routinely review 340B inventory policy with staff.
- Invite all staff to 340B-related webinars and other education offerings.

Pennsylvania Entity

- Incorporates 340B Program information in all staff orientations. Staff are expected to fully understand the steps in the 340B process to sufficiently resolve problems that may arise with specific patients and prescriptions.
- Print slides of Peer-to-Peer webinars to share with staff and new team members.
- Peer-to-Peer webinars are mandatory for all 340B staff.
- Register staff for Peer-to-Peer webinars that pertain to their specific areas of focus.

POTENTIAL BARRIERS	***SUGGESTED ACTIONS***
New hire orientation further delays employee assumption of duties for vacant positions.	Identify critical functions, conduct knowledge assessment, and identify most short- and long-term educational needs.
Lack of employee accountability for acquiring and maintaining 340B competence/proficiency.	Incorporate 340B knowledge and competence into annual employee performance reviews.
Staff are unable to apply new knowledge and 340B Program updates.	Initiate discussions with department staff to explore operational implications of new program requirements and following staff attendance/completion of 340B training.
Amount of 340B information is perceived as overwhelming.	Establish short- and long-term educational needs.
Incomplete or incorrect 340B Program information is being disseminated among staff and leadership.	Identify critical functions, conduct knowledge assessment, and identify most short- and long-term educational needs.
Inadequate knowledge and misaligned incentives of staff, leaders, and vendors.	Identify and resolve areas where compliance may be viewed as secondary to either patient needs or financial constraints.
Limited funds/resources to allow staff to attend external education offerings/conferences.	Utilize remote learning opportunities and allow staff to complete during work time.
Indirect or only infrequent 340B Program responsibilities.	Conduct regular refresher sessions most critical to those staff.
Multiple sources and duplicative 340B education resources.	Catalog, organize, and simplify accessibility to resources. Evaluate and include comparative assessment of educational options to reduce likelihood of time spent on duplicate/repetitive information.
Frequent rotation of health professional students including pharmacy, nursing, and medical.	Establish comprehensive yet efficient orientation program.

STRATEGY 3. INTEGRATED 340B SYSTEMS

Build an integrated 340B Program across all practice settings.

IMPROVEMENT CONCEPT H. POLICIES AND PROCEDURES

Develop, implement, and maintain comprehensive 340B policies and procedures.

Action Items:

H1. Identify and map all 340B-related processes and determine whether policies and procedures exist or need to be developed for all practice sites/locations including vendors, providers, and contract pharmacies.

H2. Ensure that all 340B policies and procedures are detailed and specific to the organization and will allow staff to carry out work-related functions needed to ensure compliance.

H3. Create one set of policies and procedures that apply to all sites/locations.

H4. Involve all management and staff associated with specific 340B processes in developing policies and procedures.

H5. Review all existing policies and procedures to identify those that directly or indirectly pertain to 340B Program eligibility and compliance.

H6. Revise existing and/or develop new policies and procedures needed to ensure compliance with all 340B Program requirements within all organizational departments and practice sites.

H7. Identify which policies and procedures apply to specific staff positions.

H8. Develop policies and procedures that address oversight and management of all vendors, providers, and contract pharmacies.

H9. Include both internal and external auditing guidelines as part of individual policies and procedures as well as for the overall program, including scheduling and reporting.

H10. Outline a process to continuously assess adherence with policies and procedures and identify barriers preventing policies and procedures from being followed.

H11. Develop and implement a communication and training strategy to alert all staff to changes and expectations related to modified or new policies and procedures.

H12. Identify and catalog policies and procedures that relate to specific organizational groups as identified in Improvement Concept E.

H13. Establish a mechanism to document that each staff member has read, reviewed, and understands policies and procedures applicable to his or her position and area of responsibility.

H14. Maintain all policies and procedures in physical locations or electronic systems for convenient access and reference by staff or compliance reviewers/auditors.

H15. Establish 340B team that meets regularly to update policies and practices and to review compliance.

H16. Establish a non-retributive process to report a breach of policy and encourage staff to report when policies are not being followed.

H17. Establish parameters and methods for ongoing monitoring of contract pharmacy performance and compliance with contractual terms and 340B requirements.

IMPROVEMENT CONCEPT I. AUDITABLE RECORDS

Generate auditable records that demonstrate compliance with 340B Program guidelines.

Action Items:

I1. Identify the data systems or document files that contain all 340B drug procurement, inventory management, patient eligibility, and Medicaid billing records.

I2. Assemble and maintain all documentation and verification of eligibility to participate in the 340B Program.

I3. Maintain records of all registration, change requests, and updates to the HRSA Office of Pharmacy Affairs website.

I4. Test established documentation and record management and reporting systems to ensure that National Drug Code (NDC) specific 340B drug purchases can be traced from order placement/receipt to patient administration/dispensing and eventual billing/reimbursement.

I5. Ensure that record retention policies and procedures are being followed that align with legal and regulatory requirements for operating applicable health care organization legal structure and 340B participation.

I6. Identify and apply information management data systems to collect, store, and report 340B procurement, dispensing, and administration in all practice sites/locations.

I7. Change billing processes from paper to electronic to increase data capture for inventory replenishment and tracking of savings.

I8. Integrate "all" contract pharmacies into single inventory/replacement schedule and tracking system.

I9. Develop standardized reports and data metrics for reporting to entity leadership and management.

I10. Ensure inventory reconciliation is performed and balances.

I11. Create a reporting tool/process that can be used by all staff to report 340B violations/incidents.

I12 Use electronic medical record (EMR) to maintain accurate and up-to-date 340B drug utilization records that span from prescribing to administration to billing.

I13. Include documentation training for staff.

I14. Establish "hard-stops" in electronic data entry to ensure data are accurately and completely collected.

I15. Develop data checklist for each practice site and function.

I16. Adjust data systems as needed to continually monitor and generate required internal reports and contract pharmacy activity.

I17. Utilize both program database and pharmacy system to track data that apply to 340B compliance.

I18. Create Microsoft Excel spreadsheet to track all purchases and dispensing and to true-up inventory.

I19. Engage IT department to develop automated reports within EMR and pharmacy system.

I20. Update pharmacy software systems to allow more complex and relational data functions.

I21. Explore application of Health Level 7 (HL7) interface to link pharmacy system with EMR.

I22. Use database automation to reconcile inventory and reduce risk of human error.

I23. Establish perpetual physical and/or virtual inventory for all 340B medications.

I24. Ensure EMR documentation procedures allow for tracking 340B utilization data and referrals.

I25. Create customized Structured Query Language (SQL) or Microsoft Access reports to improve accuracy of dispensing and inventory reporting.

I26. Ensure different system reports analyze data consistently and show same results.

I27. Develop case scenarios demonstrating impact of erroneous data on compliance requirements.

I28. Establish split-billing tracking systems for all co-payments and rebates, if applicable.

PUTTING THE "ACTION" INTO ACTION ITEMS

Action Examples provided by Community Health Centers or other Grantees:

Arizona Entity

- Employs a 340B specialist as part of the pharmacy management team with primary responsibility to self-audit the 340B Program processes.
- Created electronic versions of all policies and procedures to make sure they are fully and easily accessible to all staff.

Massachusetts Entity

- Regularly meets with medical staff on clinical and 340B-related topics.

Nebraska Entity

- Each month, two staff persons (a pharmacy staff member and the compliance officer) perform contract pharmacy audits.

Ohio Entity – 1

- Utilizes its electronic health record systems to efficiently verify patient 340B eligibility in real time.

Ohio Entity – 2

- Highlights a 340B policy at every staff meeting.

Texas Entity

- Employs a compliance director devoted to 340B Program compliance integration.
- Pharmacy has forged strong partnerships with compliance, finance, and medical staff.
- Maintains comprehensive policies and procedures that are reviewed and revised every 2 years or as new policy clarifications are released by the Office of Pharmacy Affairs.
- Coordinates activities of their grants manager to ensure that 340B registration information is harmonized with HRSA's Electronic Handbook data.

Utah Entity

- Incorporated compliance strategies and auditing processes as part of initial program implementation.

Action Examples provided by Hospitals or other Non-Grantees:

California Entity

- Pharmacy management regularly coordinates and communicates with IT department to ensure access to accurate and timely 340B records and reports.
- Addresses 340B issues during routine daily and monthly pharmacy huddle meetings.

Florida Entity

- Actively works to automate decision making that ensures compliance and consistent decision making related to 340B Program elements.
- Made a deliberate decision to conservatively interpret 340B guidelines in order to reduce ambiguity in patient eligibility.

Minnesota Entity – 1

- Manages 340B compliance in conjunction with business development activities to ensure coordination of internal business and patient care strategies with 340B requirements.

Minnesota Entity – 2

- Utilizes 340B savings to outsource order verification services that help them meet quality measures related to after-hours order checking.
- Started with a limited number of drugs, developed/refined procedures, and expanded the program systematically.

Minnesota Entity – 3

- Participates as HRSA Peer-to-Peer Network Site and uses/adapts tools developed by other peer mentors and sites to maintain and improve 340B compliance.

Pennsylvania Entity

- 340B compliance activities are closely coordinated with accounting department to make sure that Medicare Cost Report aligns with and supports 340B activities.
- Maintains a policy and procedure committee that includes the Medical Staff Director to ensure medical staff awareness and cooperation with 340B policies.

POTENTIAL BARRIERS	*SUGGESTED ACTIONS*
No electronic health record system to match patient care metrics with prescription and inventory procurement data.	Develop a data mapping system using medical record numbers, dates of service, etc.
Vendor does not report needed data.	Review vendor contracts and research alternate vendors.
Multiple 340B processes and methods adapted over time for specific site/location needs.	Establish baseline and standardized metrics and policies that are flexible enough to meet unique care processes at different sites/locations.
Departments have differing needs and processes.	Map 340B processes and apply baseline and standardized metrics and policies.
IT and compliance departments speak different "languages."	Ensure IT staff are fully educated on 340B compliance requirements.
Difficult to fully monitor 340B activity due to extensive number of departments, sites, and locations.	Engage leadership and request allocation of time/resources to fully map and analyze 340B activities at all locations in order to evaluate and revise policies and procedures. Build the business case.
Department management is not fully coordinated or cooperative.	Reinforce financial and programmatic risk of 340B non-compliance on departmental lack of coordination/cooperation.
Leadership view/philosophy is that detailed policies, procedures, and data increase risk exposure.	Engage senior leadership on risk and business case related to 340B non-compliance.
Unable to locate or secure independent external auditor.	Network with other entities. Develop/expand internal auditing procedures that are objective and minimize bias.
Lack of tools for less common 340B entities.	Seek opportunities to collaborate with similar entities at live meetings or via virtual committees.

STRATEGY 4. MEASURABLE IMPROVEMENT

Achieve 340B compliance using the value and power of data-driven improvements.

IMPROVEMENT CONCEPT J. USE OF DATA

Collect, analyze, and disseminate the data to evaluate and guide improvement.

Action Items:

J1. Develop a plan for capturing data on process improvements (computer software or manual).

J2. Analyze self-collected data trends for benchmarking and establishing baselines or trending data over time and after the tests of improvements.

J3. Establish data systems to facilitate identification and reporting of 340B non-compliance.

J4. Practice transparency by implementing a standardized compliance reporting system.

J5. Establish a compliance risk-level classification system to triage and address problems that can and should be immediately addressed or require a "plan-do-study-act" (PDSA) improvement approach.

J6. Continuously review compliance infractions and develop policies to address them within a specified time (e.g., within 5 days).

J7. Use self-audit results to identify areas that need improvement and track performance.

J8. Explore methods to use 340B audit data to conduct drug formulary evaluation and identification of alternatives to maximize savings.

J9. Use audit detail to demonstrate meaning and importance of compliance.

J10. Engage all departments to create reports that demonstrate 340B compliance; report metrics quarterly to senior management and Board of Directors.

J11. Create reporting workgroups and standard set of 340B compliance reports that are reviewed quarterly with senior management.

J12. Report outcomes/findings as part of quality improvement or risk management.

J13. Share data with staff for continued improvement and training.

J14. Maintain and digitize monthly self-audit records based on record retention policies of organization.

J15. Develop complete data-driven plan that focuses on core elements, including interlinked data, analytics, and decision making.

IMPROVEMENTS CONCEPT K. AUDITING

Conduct internal and external audits.

Action Items:

K1. Develop consistent and systematic process to regularly audit 340B procurement, administration/dispensing, and billing transactions at all sites utilizing 340B drugs.

K2. Identify all electronic and paper sources of data required for conducting audits.

K3. Design audit methodologies that reflect organization-specific processes and that will identify specific 340B compliance risks or actual infractions.

K4. Establish internal audit procedures that are conducted and reported objectively and independently from individuals responsible for the processes being audited.

K5. Augment internal audit data with results compiled from external independent auditors.

K6. Select and execute contracts with external auditors with expertise in pharmacy and health care service delivery, 340B compliance, and health care finance/reporting.

K7. Maintain records of all audit results, reporting, and actions taken to correct/improve 340B processes.
K8. Perform random audits for issues or areas for improvement.
K9. Conduct self-audits on patient eligibility and inventory.
K10. Audit outside providers that refer patients to entity.
K11. Conduct self-audits at least monthly.
K12. Assign person to audit/review Office of Pharmacy Affairs database information each quarter.
K13. Review current eligible prescriber list and update EMR and pharmacy systems accordingly.
K14. Audit each 340B unique data set separately.
K15. Establish standing audit program across all 340B areas.
K16. Establish audit frequency and sign-off/approval from compliance oversight committee, management, and Board of Directors.
K17. Establish and deploy standard documentation audit form.
K18. Conduct annual independent audits, including contract pharmacy.
K19. Adapt audit tools available from 340B University.
K20. Audit all 340B purchasing and storage areas (including crash carts and ambulances) in addition to dispensing and care documentation.
K21. Contact Medicaid office annually to confirm compliance with duplicate discount avoidance.
K22. Secure services of external auditor or company.
K23. Integrate second person review for all audits to ensure completeness and accuracy.

IMPROVEMENT CONCEPT L. PLAN-DO-STUDY-ACT

Utilize the "model for improvement" to continually test, track, and study 340B Program enhancements.

Action Items:

L1. Identify specific 340B operational tasks or process changes that should be implemented and outline/describe predicted impact on 340B compliance.
L2. Collect data and information that describe the actual impact on 340B compliance as a result of process changes carried out.
L3. Compare observed results to predicted results.
L4. Modify original change and continue PDSA cycle until desired compliance results are achieved.
L5. Incorporate final changes in organization's 340B policies and procedures.
L6. Repeat audits after corrective action taken to verify improvement.
L7. Identify data required to measure improvements (not just detect non-compliance).
L8. Establish process to review all audit findings and resolve problems areas.
L9. Calculate error rates to track trends and improvement after implementation of solutions/change.
L10. Conduct a root-cause analysis to determine the best course of action to correct compliance infractions.

PUTTING THE "ACTION" INTO ACTION ITEMS

Action Examples provided by Community Health Centers or Other Grantees:

Arizona Entity

- Modifies the audit process every few months to allow for more random record review and reduce the risk of self-selecting and evaluating only compliant records/processes.

Florida Entity

- Views auditing as part of operations and not a separate function.

- Maintains efficient audit process that mirrors specific processes rather than attempting to adapt audit methods from dissimilar organizations.

Massachusetts Entity

- Utilizes IT savvy employees to work with software vendors to maximize reporting and tracking of 340B activities.
- Performs ongoing auditing through daily, weekly, and monthly reports that verify patient eligibility, correct Medicaid billing, and patient referrals.

Ohio Entity – 1

- Established a real-time portal to monitor contract pharmacy prescription activity.

Ohio Entity – 2

- Places all audit result reports in central and easily retrievable location for reference and review.

Texas Entity

- Employs a full-time data analysis person for 340B reporting.
- Audit findings undergo a root-cause analysis to determine individual or system-wide strategies that will improve compliance.

Action Examples provided by Hospitals or Other Non-Grantees:

California Entity

- Depending on issue to be addressed, identifies and engages only those individuals needed to solve or prevent any 340B compliance risk.

Florida Entity

- Designed customized data queries to isolate and identify specific risk activity.

Pennsylvania Entity

- 340B compliance coordinator visits all child sites to observe 340B processes and ensure compliance with established policies.
- External and internal 340B audits are handled outside the pharmacy department with resources expressly allocated by the CFO.
- Audit guidelines are referred to within policies and procedures but maintained as separate approved forms that can be modified without revising policies and procedures.

POTENTIAL BARRIERS	*SUGGESTED ACTIONS*
There is no dedicated IT department, staff, or consultant able to provide needed data.	Identify data sources and develop manual collection and analysis processes using personal computer software programs, such as Microsoft Excel and/or Microsoft Access.
Limited staff resources.	Establish minimal datasets to identify most critical compliance areas and create alerts to compliance risks. Quantify needs and costs to make budgetary case.
Limited staff knowledge of auditing processes and performance improvement.	Outsource/secure external auditor for assistance. Assign staff to attend/complete additional training.
Antiquated technology/software.	Identify needs and research options. Develop and initiate manual processes.
Complexity of program is perceived as unmeasurable and unmanageable.	Use PDSA process to assess and improve smaller components.
Audit process viewed as negative and punitive by staff.	Provide education on purpose and benefit to organization.

APPENDIX A.
340B COMPLIANCE RAPID SELF-ASSESSMENT

NOTE: This form can be printed and completed manually. It is also accessible online at http://ComplianceAssessmentA.com/form.aspx for completion and saving. No personal or entity-specific information will be requested – only your covered entity type will be asked. You will receive a record ID in order to retrieve your completed form at a future date.

Indicate whether your organization is able to document or demonstrate the specified compliance elements. Please note that this assessment is only intended to identify potential areas of compliance risk that may need to be addressed by the covered entity.

ELIGIBILITY – Non-Grantee (Hospital)	RESPONSE		
	YES	NO	UNSURE
1. Legal documents that confirm nonprofit status are available for review.			
2. Governmental ownership documents or contracts with state or local government to provide medical services to indigent or uninsured patients are available for review.			
3. Most recent Medicare Cost Report indicates eligibility of all areas ordering or providing 340B drugs.			
4. Office of Pharmacy Affairs (OPA) database registration information is up to date and accurate.			
5. Entity meets eligibility requirements for participation.			

ELIGIBILITY – Grantee (Non-Hospital)	RESPONSE		
	YES	NO	UNSURE
1. Grant documents or other evidence of eligibility are readily available for review.			
2. All areas that order or use 340B drugs are eligible.			
3. All 340B drugs used are within the covered entity's scope of service.			
4. OPA database registration information is up to date and accurate.			
5. Entity meets eligibility requirements for participation.			

DIVERSION – All Entity Types	RESPONSE		
	YES	NO	UNSURE
1. Entity maintains documented evidence that all 340B-covered outpatient drugs were administered or dispensed only to eligible outpatients.			
2. Entity maintains records of all 340B drugs procured and distributed.			
3. Policies and procedures are in place that detail procurement, inventory management, and dispensing of 340B drugs.			
4. Results of physical or virtual inventory reconciliation are available for review.			
5. Only eligible patients receive 340B medications and meet patient definition as established by OPA.			

DUPLICATE DISCOUNTS – All Entity Types	RESPONSE		
	YES	NO	UNSURE
1. Medicaid billing intent and information on OPA Medicaid Exclusion File is up to date and accurate.			
2. Policies and procedures are in place that specifically address Medicaid billing methods for 340B drugs and prevention of duplicate discounts.			
3. Documented evidence of any special billing arrangements established with state Medicaid agency.			
4. Entity is not billing Medicaid in a manner that would result in duplicate discounts.			

CONTRACT PHARMACY – All Entity Types	RESPONSE		
	YES	NO	UNSURE
1. Current and executed agreements with all contract pharmacy locations are available for review.			
2. OPA database registration information is up to date and accurate.			
3. Policies and procedures are in place that specifically address identification of eligible patients and contract pharmacy oversight.			
4. External and independent audit results of contract pharmacy operations are available for review.			
5. Contract pharmacy does not dispense 340B medications to Medicaid patients (unless agreement with state Medicaid agency and OPA notified).			

APPENDIX B.

340B COMPLIANCE CULTURE SELF-ASSESSMENT

NOTE: This form can be printed and completed manually. It is also accessible online at http://ComplianceAssessmentB.com/form.aspx for completion and saving. No personal or entity-specific information will be requested – only your covered entity type will be asked. You will receive a record ID in order to retrieve your completed form at a future date.

Indicate whether your organization is able to document or demonstrate the specified compliance elements. Please note that this assessment is only intended to identify potential areas of compliance risk that may need to be addressed by the covered entity.

340B COMPLIANCE CULTURE ATTRIBUTE	LEVEL OF COVERED ENTITY OPERATIONAL INTEGRATION		
	FULL	PARTIAL	NONE
1. Executive management and Board of Directors play an active role in 340B compliance.			
2. 340B compliance is a high priority for the covered entity as evidenced by resources, staffing, education, etc.			
3. The covered entity has designated a 340B compliance team that is integrated with quality improvement and risk management functions.			
4. The covered entity provides and maintains clear and comprehensive policies and procedures for each operational unit to ensure 340B compliance.			
5. All business units and processes are included in the 340B compliance policies and procedures.			
6. The 340B compliance efforts are adequately staffed and appropriately structured.			
7. 340B compliance activities are efficiently supported by centrally managed technology tools including databases, processing, monitoring analytics, and reporting.			
8. All staff members are aware of 340B compliance requirements and qualifications for their positions and are kept qualified by educational programs and demonstrated competence.			
9. Adherence to 340B compliance requirements is integral to the covered entity's staff development and evaluation processes (if applicable).			
10. Violations of 340B compliance policy results in punitive measures.			
11. All out-of-compliance conditions and violations are immediately reported, monitored, and corrected.			
12. Compliance with 340B Program requirements is independently assessed by internal and external auditors on a regular basis.			
13. Audit assessments of 340B compliance are planned and coordinated to ensure consistent coverage of areas of greatest risk.			

APPENDIX C.

340B PROFICIENCY SELF-ASSESSMENT – Program Background

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

340B Program BACKGROUND	PROFICIENCY LEVEL		
	Full	Partial	None
1. Describe the pricing implications for a manufacturer relating to the 340B price for covered entities (average sales price, best price, non–federal average manufacturer price).			
2. Summarize the history and intent of the 340B Program.			
3. Describe legislated authority and operational oversight of the 340B Program.			
4. List verified sources of truth regarding the 340B Program.			
5. Regularly review verified 340B Program policy information and sources to remain up to date and knowledgeable of changes to requirements and compliance.			
6. Describe the process and components used for calculating the 340B price.			
7. Discuss 340B pricing and confidentiality.			
8. Discuss penny pricing.			
9. List the steps to verify a 340B price.			
10. List the functions and benefits of the Health Resources and Services Administration (HRSA) Prime Vendor.			
11. Describe resources available to promote and support 340B compliance.			
12. State the definition of 340B-covered outpatient drug.			
13. Define the major 340B compliance cornerstones (eligibility, no diversion, no duplicate discounts, maintenance of records, standard operating procedures).			
14. List the major 340B Program stakeholders and describe their role in the marketplace.			
15. Describe the most common options for delivering 340B drugs to patients.			
16. Describe the process for reporting suspected or confirmed non-compliance (material breach).			
17. Describe manufacturer overcharges and the manufacturer refunds process.			
18. Develop an education/training plan for new and existing staff that demonstrates knowledge proficiency in areas related to each job description.			
19. Establish and maintain a 340B oversight team.			
20. Engage executive staff in the 340B Program.			
21. Write a job description for a 340B manager/coordinator.			
22. Report non-compliance to HRSA and manufacturers.			
23. Resolve non-compliance.			
24. Resolve a 340B price dispute between a 340B-covered entity and a drug manufacturer.			
25. Verify 340B pricing accuracy.			
26. Report a manufacturer to HRSA when a 340B drug does not have a 340B price.			
27. Identify penny-priced drugs.			

28. Document 340B savings.			
29. Describe use of 340B savings in alignment with 340B Program intent.			
30. Determine a threshold for when to report non-compliance to HRSA/manufacturers.			

APPENDIX D.

340B PROFICIENCY SELF-ASSESSMENT – AUDIT PREPAREDNESS

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

AUDIT PREPAREDNESS	PROFICIENCY LEVEL		
	Full	Partial	None
1. List the data reviewed during a Health Resources and Services Administration (HRSA) audit.			
2. Compare the HRSA and manufacturer audit processes and scope.			
3. Discuss the steps in the HRSA audit process.			
4. List the factors that dispose an entity to a higher risk of a HRSA audit.			
5. Identify staff necessary to participate in a HRSA audit.			
6. Identify staff necessary to participate in a self-audit.			
7. Develop and execute a corrective action plan (CAP).			
8. Write standard operating procedures to include self-auditing process, frequency, and actions as a result.			
9. Select tracers for a self-audit.			
10. Develop a request for proposal (RFP) for an independent auditor for a 340B entity.			
11. Select an independent auditor for a 340B entity.			

APPENDIX E.

340B PROFICIENCY SELF-ASSESSMENT – CONTRACT PHARMACY

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

CONTRACT PHARMACY	PROFICIENCY LEVEL		
	Full	Partial	None
1. Explain a ship-to, bill-to arrangement.			
2. Define contract pharmacy arrangements.			
3. Identify the intent of contract pharmacy arrangements.			
4. List the compliance elements outlined in the contract pharmacy guidelines.			
5. Contrast the separate physical inventory versus virtual inventory model in contract pharmacy.			
6. Describe the role, functions, and accountability of a contract pharmacy third-party management company.			
7. Outline the recommended contract pharmacy agreement components.			
8. Describe the requirements for a covered entity to maintain auditable records to support continual oversight and monitoring of contract pharmacy operations and services.			
9. Describe attributes of compliant contract pharmacy/vendor contracts.			
10. Describe the role, functions, and accountability of a contract pharmacy vendor/administrator (third-party management company).			
11. Identify potential contract pharmacy partners.			
12. Establish a request for proposal (RFP) process for selection of contract pharmacy partners/vendor.			
13. Select a contract pharmacy vendor that can support compliance.			
14. Execute a compliant contract pharmacy agreement.			

APPENDIX F.

340B PROFICIENCY SELF-ASSESSMENT – ELIGIBILITY/DATABASE

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

ENTITY ELIGIBILITY and DATABASE ACCURACY	PROFICIENCY LEVEL		
	Full	Partial	None
1. Outline entity eligibility requirements.			
2. Describe the purpose of the Health Resources and Services Administration (HRSA) 340B database.			
3. List the components of the HRSA 340B database record.			
4. State the specific role and responsibilities of the entity authorizing official and primary contact.			
5. Identify which records/documents must be assembled and maintained to certify the covered entity's continued eligibility for participation and compliance.			
6. Outline the registration process for each covered entity type.			
7. List the areas of a covered entity that need to be registered on the HRSA database and explain why.			
8. Describe the validation documentation HRSA uses for different entity types (Medicare Cost Report, Electronic Handbook [EHB], etc.)			
9. Explain the date requirements/windows for the HRSA database registration/recertification.			
10. Outline the recertification process for each covered entity type.			
11. Describe the HRSA 340B database requirements for discontinuing a contract pharmacy.			
12. Explain the registration and recertification attestation of Group Purchasing Organization (GPO) prohibition compliance.			
13. Establish a regular review process (standard operating procedure) to ensure the HRSA database information is accurate and up to date.			
14. Locate the HRSA 340B database.			
15. Verify an entity record is accurate in the HRSA database.			
16. Use the most recently filed Medicare Cost Report to identify information used during registration/recertification.			
17. Use the EHB to identify information used during registration and recertification.			
18. Change entity information in the HRSA database.			
19. Recertify an entity on the HRSA 340B database (including entity, child sites, and contract pharmacy).			
20. Register an entity on the HRSA 340B database (including entity, child sites, and contract pharmacy).			
21. Register a contract pharmacy on the HRSA 340B database.			
22. Register a shipping address on the HRSA 340B database.			
23. Determine the registration options for an entity and its child sites.			

APPENDIX G.

340B PROFICIENCY SELF-ASSESSMENT – DIVERSION

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

DIVERSION	PROFICIENCY LEVEL		
	Full	Partial	None
1. Outline the patient definition.			
2. Discuss the requirement for dispensing 340B drugs only in a registered location.			
3. Write standard operating procedure (SOP) that supports compliance with the prohibition against diversion.			
4. Develop contract terms based on the patient definition guidelines for providers under a referral relationship that could be used to ensure compliance with 340B guidelines.			
5. Develop process of documentation that a covered entity has retained responsibility for the health care services provided to a referred patient.			
6. Address how providers with various medical staff appointments/privileges are handled in the 340B Program written SOPs.			
7. Incorporate patient definition eligibility criteria into split-billing software and test compliance of eligible and ineligible transactions.			
8. Outline approaches to resolve issues specific to multiple covered entities claiming 340B eligibility for a single patient.			
9. Develop an interpretation of the definition of covered outpatient drug that is consistently applied and aligns with regulatory language.			
10. Self-audit the entity's process for compliance with diversion prohibition (including contract pharmacy, if applicable).			

APPENDIX H.

340B PROFICIENCY SELF-ASSESSMENT – DUPLICATE DISCOUNT

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

DUPLICATE DISCOUNTS	PROFICIENCY LEVEL		
	Full	Partial	None
1. Define duplicate discount.			
2. Discuss the purpose, structure, and use of the Health Resources and Services Administration (HRSA) Medicaid Exclusion File.			
3. Discuss the manufacturer's requirement for payment of rebates to state Medicaid programs.			
4. Describe what is meant by the terms carve-in and carve-out.			
5. Outline rationale for making a carve-in/out decision.			
6. Discuss the importance of accurately indicating carve-in/out status on the HRSA Medicaid Exclusion File.			
7. Explain a process for verifying the state's use of the HRSA Medicaid Exclusion File to prevent duplicate discounts.			
8. Describe AIDS Drug Assistance Program (ADAP) duplicate discount scenarios.			
9. Describe the reasons for maintaining and integrating an accurate and current 340B drug acquisition price file and its use in some states for Medicaid billing.			
10. Identify state mechanisms beyond the HRSA Medicaid Exclusion File being used to identify duplicate discounts (in all settings).			
11. Describe a method to avoid duplicate discounts if 340B drugs are provided to Medicaid patients at contract pharmacies.			
12. Identify how to determine state programs that have claims which generate Medicaid rebates.			
13. List resources for identifying state Medicaid 340B contacts.			
14. Write a standard operating procedure (SOP) that supports compliance with duplicate discount prevention.			
15. Determine methods for billing 340B administered or dispensed drugs consistent with applicable state(s) Medicaid requirements.			
16. Self-audit records and processes to prevent duplicate discounts.			
17. Implement, maintain, and verify billing systems that are consistent with entity's response to using 340B drugs for Medicaid patients as indicated in the HRSA Medicaid Exclusion File.			
18. Report to the Office of Pharmacy Affairs any special billing arrangements in place with state Medicaid programs intended to prevent duplicate discounts.			
19. Report the appropriate National Provider Identifier (NPI) and Medicaid provider numbers for all entity sites using 340B drugs for Medicaid patients.			
20. Notify HRSA of the use of 340B for Medicaid in a contract pharmacy.			
21. Determine whether use of 340B for Medicaid in a contract pharmacy is appropriate based on financials and ability to meet regulatory requirements.			
22. Determine whether a vendor's system has the capacity to prevent duplicate discounts.			

23. Write a request for proposal for an auditor that will assess the entity's duplicate discount prevention compliance.			
24. Determine where the entity will use 340B for Medicaid patients.			
25. Verify whether the HRSA Medicaid Exclusion File information accurately reflects practice by documenting an SOP.			
26. Contact the state Medicaid agency and document state process/requirements for preventing duplicate discounts.			
27. Prevent duplicate discounts that may occur between covered entities, ADAP-covered entities, and Medicaid.			

APPENDIX I.

340B PROFICIENCY SELF-ASSESSMENT – INVENTORY

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

INVENTORY	PROFICIENCY LEVEL		
	Full	Partial	None
1. Define Group Purchasing Organization (GPO) prohibition and the covered entities that must meet the requirements.			
2. Outline the flow of data associated with the replenishment model.			
3. Outline the financial flow associated with the replenishment model.			
4. Explain the GPO prohibition.			
5. Discuss how the entity's interpretation of covered outpatient drug impacts the operationalization of the GPO prohibition.			
6. Discuss the GPO prohibition and what violation consequences there are for an entity.			
7. Explain the use of physically separate inventory versus virtual inventory with split-billing software.			
8. Discuss the three account accumulation and replenishment models used with split-billing software.			
9. Explain ways the entity subject to the GPO prohibition can minimize wholesale acquisition cost (WAC) purchases.			
10. Explain the compliant use of GPO private label products in entities subject to the GPO prohibition.			
11. Discuss the Apexus Generics Portfolio and its use by entities subject to the GPO prohibition.			
12. Discuss purchases of drugs for emergency preparedness, crash cart inventory, drug shortages, and retroactive Medicaid eligibility as well as the compliant practices that exist for entities subject to the GPO prohibition.			
13. Describe split-billing software, virtual inventory, and replenishment.			
14. State the role of the Prime Vendor Program regarding compliant contracting for the GPO prohibition.			
15. Identify the necessary purchasing accounts for applicable entities to comply with the GPO prohibition.			
16. Describe contracting that is/is not compliant with the GPO prohibition.			
17. Explain retrospective replenishment.			
18. Discuss replenishment of new National Drug Codes (NDCs) for different inventory models.			
19. Define 11-digit NDC matching.			
20. Discuss situations for 9-digit NDC matching.			
21. Discuss transferring of 340B drugs between entity and sites within the same health care system.			
22. Discuss returning of 340B purchased drugs.			
23. Discuss the inventory management of 340B purchased drugs when entity site or contract pharmacy is terminated.			
24. Discuss chargeback processing.			

25. Discuss the utilization of purchasing agents.			
26. List components of a compliant process for acquiring an initial 340B physical inventory.			
27. Identify the types of purchasing accounts that must be established to ensure entity compliance with GPO prohibition and Medicaid carve-out.			
28. Outline a replenishment model for a single or multiple contract pharmacy(ies) utilizing a central tracking and replacement system.			
29. Select split-billing software for compliance.			
30. Maintain split-billing software for compliance (including crosswalk maintenance).			
31. Audit split-billing software for compliance.			
32. Audit an entity subject to the GPO prohibition that does not include split-billing software.			
33. Establish SOPs for split-billing software compliance/GPO prohibition.			
34. Recognize and take steps to prevent common compliance challenges with split-billing software and its configuration/maintenance (patient eligibility, no exclusive provider lists, patient status classification, manual accumulations, waste billing, lost charges, multi-dose vials, insulin, compounds, etc.).			
35. Write SOPs for transfer of 340B drugs.			
36. Write SOPs for returning expired drugs.			
37. Analyze entity-specific data to evaluate opportunities to minimize WAC exposure.			
38. Verify individual and other contracts are compliant with the GPO prohibition.			
39. Apply best practices in report utilization/customization from a third-party 340B vendor.			

APPENDIX J.

340B PROFICIENCY SELF-ASSESSMENT – PRIME VENDOR PROGRAM

Indicate your level of proficiency in each of the self-assessment areas. For those areas where you identify potential gaps, refer to the education tool index to identify tools and resources to assist you in both increasing and applying your knowledge to develop appropriate job skills consistent with your position description.

PRIME VENDOR PROGRAM (PVP)	PROFICIENCY LEVEL		
	Full	Partial	None
1. Register an entity with the PVP.			
2. Use the PVP public website.			
3. Use PVP education and compliance support resources.			
4. Contact Apexus Answers.			
5. Attend 340B University.			
6. Access PVP contract pricing.			
7. Take action to become a PVP-contracted distributor.			
8. Take action to become a PVP-contracted supplier.			
9. Optimize the use of PVP contracts (vaccines, sub-ceiling, sub–wholesale acquisition cost [WAC]).			
10. Identify new PVP contract opportunities.			
11. Apply best practices in the formulary change process respective of Pharmacy & Therapeutics considerations regarding PVP-contracted items.			
12. Identify specialty pharmacy/distribution concerns.			
13. Apply best practices in specialty pharmacy/distribution.			
14. Confirm compliant distributor purchasing accounts for applicable entities to comply with the Group Purchasing Organization prohibition.			
15. Apply the PVP password protected data/reporting to an entity.			
16. Benchmark entity among peers (total 340B purchases, WAC spend, share back, vaccines, sales) for all entity sites, rolled up and broken down by child sites.			

APPENDIX K.

340B Education Tools and Resources Index

Utilize this index to identify tools and resources in each of the Health Resources and Services Administration (HRSA) 340B proficiency self-assessment areas included in Appendices C through J.

PROFICIENCY AREA	RESOURCE GROUP	REFERENCE NUMBER
Program Background	HRSA Peer-to-Peer Webinars	None current, check for updates
	340B University Tools and Resources	1–5, 10, 12, 15, 17–20, 26, 30, 31
	340B University On-Demand Modules	1, 2, 7, 8, 11, 12, 14-16, 19, 21
Audit Preparedness	HRSA Peer-to-Peer Webinars	1-18, 23–31
	340B University Tools and Resources	5–12, 14, 31, 36, 39
	340B University On-Demand Modules	8, 12, 16, 17-19
Contract Pharmacy	HRSA Peer-to-Peer Webinars	1, 2, 23, 24
	340B University Tools and Resources	5, 11, 14
	340B University On-Demand Modules	2, 13
Eligibility/Database	HRSA Peer-to-Peer Webinars	30, 31
	340B University Tools and Resources	17, 21-25, 33, 35, 36, 38
	340B University On-Demand Modules	3–6, 16
Diversion	HRSA Peer-to-Peer Webinars	25–29
	340B University Tools and Resources	1-4, 6-9, 13, 15, 17, 19, 37
	340B University On-Demand Modules	8
Duplicate Discount	HRSA Peer-to-Peer Webinars	13, 14
	340B University Tools and Resources	1-4, 6-9, 14, 16, 17
	340B University On-Demand Modules	2, 9, 10, 19
Inventory	HRSA Peer-to-Peer Webinars	19–22
	340B University Tools and Resources	13, 28, 32
	340B University On-Demand Modules	7, 11,12, 14, 15, 22
Prime Vendor Program	HRSA Peer-to-Peer Webinars	None current, check for updates
	340B University Tools and Resources	17
	340B University On-Demand Modules	18, 21

APPENDIX L.

340B Education Tools and Resources List

Utilize this list to locate tools and resources in each of the 340B proficiency areas listed in Appendix K.

Ref. No.	**HRSA PEER-TO-PEER WEBINARS** www.hrsa.gov/opa/peertopeer/webinars.html For the current list of webinars, please link to the HRSA Office of Pharmacy Affairs website.
1	Open Office: 340B Compliance Improvement Webinar Series: Measurable Improvement (3/23/2016)
2	340B Compliance Improvement Webinar Series: Measurable Improvement (3/9/2016)
3	Open Office: 340B Compliance Improvement Webinar Series: Integrated Systems (2/24/2016)
4	340B Compliance Improvement Webinar Series: Integrated 340B Systems (2/10/2016)
5	Open Office: 340B Compliance Improvement Webinar Series: Education and Training (1/27/2016)
6	340B Compliance Improvement Webinar Series: Education and Training (1/13/2016)
7	Open Office: 340B Compliance Improvement Series: Leadership Commitment to 340B Compliance (12/09/2015)
8	340B Compliance Improvement Series: Leadership Commitment to 340B Compliance (11/18/2015)
9	Open Office: Identifying Roles, Responsibility and Elements of 340B Risk Management (10/28/2015)
10	Identifying Roles, Responsibility and Elements of 340B Risk Management (10/14/2015)
11	Open Office: From Paper to Practice: Operationalizing 340B Policies and Procedures for Auditable Records (9/23/2015)
12	From Paper to Practice: Operationalizing 340B Policies and Procedures for Auditable Records (9/9/2015)
13	Open Office: 340B Audit Readiness Series: Mechanisms to Prevent Duplicate Discounts (8/26/2015)
14	340B Audit Readiness Series: Mechanisms to Prevent Duplicate Discounts (8/12/2015)
15	Open Office – 340B Audit Readiness Series: Corrective Action Plans (CAPs) from HRSA's 340B Program Audits (7/22/2015)
16	340B Audit Readiness Series: Corrective Action Plans (CAPs) from HRSA's 340B Program Audits (7/8/2015)
17	Open Office – 340B Audit Readiness Series: Developing and Maintaining Auditable Records to Demonstrate 340B Compliance (6/24/2015)
18	340B Audit Readiness Series: Developing and Maintaining Auditable Records to Demonstrate 340B Compliance (6/10/2015)
19	Open Office Managing 340B Inventory and Associated Data Vulnerabilities in a Physical System (5/27/2015)
20	Managing 340B Inventory and Associated Data Vulnerabilities in a Physical System (5/13/2015)
21	Open Office – Managing 340B Inventory and Associated Data Vulnerabilities in a Virtual System (4/22/2015)
22	Managing 340B Inventory and Associated Data Vulnerabilities in a Virtual System (4/8/2015)

23	Open Office – 340B Audit Readiness Series: Contract Pharmacy Arrangements (3/25/2015)
24	340B Audit Readiness Series: Contract Pharmacy Arrangements (3/11/2015)
25	Open Office – 340B Audit Readiness Series: Patient Eligibility – Hospitals (2/25/2015)
26	340B Audit Readiness Series: Patient Eligibility – Hospitals (2/11/2015)
27	Open Office – 340B Audit Readiness Webinar Series: Patient Eligibility – Clinic and Multi Grantee (1/28/2015)
28	340B Audit Readiness Webinar Series: Patient Eligibility (Clinic and Multi Grantee) (1/14/2015)
29	340B Patient Definition and Referral Relationships (12/17/2014)
30	Open Office – 340B Audit Preparedness Webinar Series: Confirming and Documenting Eligibility (11/12/2014)
31	340B Audit Preparedness Webinar Series: Confirming and Documenting Eligibility (10/29/14)
Ref. No.	**340B TOOLS and RESOURCES on the Apexus Website** www.apexus.com/solutions/education/340b-tools Please note that the list below may not be reflective of the latest tool development or modifications as listed on the Apexus website. Please refer to the Apexus website for the most up-to-date list of tools.
1	DSH Comprehensive 340B Policy and Procedure Manual
2	CHC Comprehensive 340B Policy and Procedure Manual
3	HEMOPHILIA TREATMENT CENTER Comprehensive 340B Policy and Procedure Manual
4	FAMILY PLANNING Comprehensive 340B Policy and Procedure Manual –
5	All Entities 340B Compliance Self-Assessment: Vendors
6	CHC 340B Compliance Self-Audit Process (CHC 340B Compliance Self-Assessment Data and Transactions)
7	CHC 340B Compliance Self-Assessment Policy
8	DSH 340B Compliance Self-Assessment Policy
9	DSH 340B Compliance Self-Assessment Policy – Quick (DSH 340B Compliance Self-Assessment Data and Transactions)
10	Defining Material Breach Documentation Tool
11	Contract Pharmacy: Compliance and Self-Assessment
12	FAMILY PLANNING 340B Compliance Self-Assessment: Policy
13	Split-Billing Decision Checklist
14	340B Independent Audit RFP Checklist
15	340B Compliance: For the C-Suite
16	340B and Medicaid

17	All Entities: Getting Started with Compliance Guide
18	340B Glossary of Terms
19	All Entities Self-Disclosure
20	HRSA Notification Template - 340B Price Unavailable
21	New Worksheet A
22	New Worksheet C
23	New Worksheet E
24	New Worksheet S
25	New Worksheet S2
26	340B Benefit and the Use of 340B Savings
27	340B Compliance and the Controlled Substance Ordering System (CSOS)
28	Minimize WAC Exposure
29	340B Acronym Guide
30	340B Manager and Coordinator Job Description Template
31	340B Analyst Job Description Template
32	GPO Prohibition and Wholesaler Non-GPO Account Load Options
33	Hospital Eligibility Criteria
34	Mixed Use Areas: Compliance and Self-Assessment
35	Outpatient and Sub-WAC Areas: Compliance and Self-Assessment
36	HRSA Recertification Attestation Language
37	FP Dispensation and Administration Tracking Log
38	Example Unbundled Trial Balance Sheet
39	Mapping the 340B Drug Operations Environment (Word or Excel)
Ref. No.	**340B UNIVERSITY ON-DEMAND MODULES** www.apexus.com/solutions/education/340b-u-ondemand
1	Introduction to the 340B Drug Pricing Program
2	340B Stakeholder Perspectives
3	Eligibility Overview
4	HRSA 340B Database Navigation

5	Registration for the 340B Drug Pricing Program
6	340B Participant Change Request
7	340B Pricing
8	Compliance Cornerstones
9	340B and Medicaid
10	HRSA's Medicaid Exclusion File
11	340B Drug Delivery Models
12	GPO Prohibition
13	Contract Pharmacy
14	Entity-Owned Pharmacy
15	Mixed-Use Areas
16	Recertification
17	Audit Process & Preparedness
18	PVP Contracting: Maximizing Value
19	340B Hot Topics
20	340B for the C-Suite
21	340B & the Manufacturer
22	340B and the Distributor