



CHAPTER 7

340B Policies and Procedures

*Lisa N Schatz, PharmD, BCPS and
Fern Paul-Aviles, PharmD, MS, BCPS*

Policies and procedures (P&Ps) govern how a covered entity's 340B program is conducted. It is imperative that the written P&Ps reflect actual practice, because there are many ways to conduct a compliant 340B program in the context of patient care delivery and pharmacy practice in large and complex hospitals. Policy and procedure review is part of the Health Resources and Services Administration (HRSA) audit process with comparisons to the 340B statute, 340B guidance documents, and best practices. Writing and following P&Ps, while conceptually simple, can be a difficult task due to the complexity of the 340B program. It is worth the time and effort to think through 340B processes, even using a process flow diagram, as a preliminary step in drafting P&Ps. When referring to these guidelines in this chapter, the actual policies when written may be more encompassing or more restrictive depending on the covered entity.

The 340B policies and procedures should follow the institution-wide format for P&Ps, including references, pertinent definitions, and review and approval dates. Policies should also consider the broader patient care, regulatory, and other institutional prerogatives.

Several resources are available that support the development of P&Ps so it is not necessary to completely start fresh. HRSA has conducted a peer-to-peer webinar to discuss areas that should be contained in the program P&Ps.¹ Additionally, to assist with appropriate P&P content, Apexus has published sample P&Ps and a set of downloadable tools outlining proper content and compliant 340B operations, available on the Apexus web site.^{2,3}

In constructing policies, the topics in the Apexus sample P&Ps should be included aside from ensuring that all 17 areas recommended by HRSA are covered in adequate detail. Topics covered in the Apexus sample P&Ps include the following definitions:

- Patient eligibility
- Enrollment
- Prevention of duplicate discount
- Education and competency
- Inventory management
- Contract pharmacy operations, oversight, and monitoring
- Noncompliance and material breach
- Program compliance that contains an audit plan

Table 7-1 provides a more comprehensive list of topics. The tool in **Table 7-2**, adapted from a HRSA document, lists the 17 elements HRSA recommends. Not all elements apply to every

Table 7-1. Example of Policy and Procedure^{3,4}**POLICY TOPIC**

- Background on the 340B Program
- Definitions
- References
- Covered Entity Eligibility
- 340B Program Enrollment, Recertification, and Change Requests
- Patient Eligibility/Definition
- Prevention of Duplicate Discounts
- 340B Program Roles and Responsibilities
- 340B Program Education and Competency
- Inventory Management
- Contract Pharmacy Operations
- 340B Non-Compliance/Material Breach
- 340B Program Compliance
- Contract Pharmacy Oversight and Monitoring
- Prime Vendor Program (PVP) Enrollment and Updates
- Suggested Appendices

Source: Adapted with permission from sample P&P courtesy of Apexus LLC, Irving, Texas.

covered entity; therefore, the covered entity should review the list for their entity type, contract pharmacy participation, and physical versus virtual inventory.

The Apexus tools include sample P&Ps for disproportionate share hospitals (DSHs) and community health centers.^{3,4}

KEY POINT

Ensure that all HRSA-recommended areas are included in P&Ps.

The samples should be used as a starting point, and the P&Ps should be customized to your institutional P&P format. Copying and pasting the Apexus sample policies is not recommended, as it will indicate that the 340B program team has neither given much thought as to how the program is conducted nor devised policies to reflect specific operational practice variations. Further, template policies may conflict with regular practices and activities at the covered entity.

It is important to keep P&Ps accurate and up-to-date. A covered entity should have a formal process for P&P review for all policies, not just 340B policies. A covered entity may need a more flexible, separate process for 340B P&P review on a more frequent basis, so that policies and procedures are an accurate reflection of current practices. Because of the intensive scrutiny of the 340B program and the more flexible and current nature of 340B guidance, 340B program managers at the covered entity may need to employ more diligence than is normally necessary to ensure that policies are amended, edited, and approved in a timely fashion. 340B program leaders are encouraged to stay current with HRSA audit practices and with changing guidance and frequently asked questions (FAQs) on the HRSA and Apexus/340B Prime Vendor web site as sources for continuing review and updates.