Quantum 5D Consulting, LLC
Delivering quantum leap ROI

340B Program Compliance Checklist

Comprehensive Audit Readiness and Compliance Framework

340B Program Compliance Checklist

SECTION 1: PROGRAM ADMINISTRATION

Entity Eligibility and Registration

Verify current eligibility status for 340B program

Confirm current OPA database registration is accurate and up-to-date

Maintain documentation of eligibility and registration status

Document any changes in eligibility or registration status

Ensure timely recertification (annually)

340B Program Oversight

Designate 340B program manager/coordinator

Establish 340B oversight committee with clear roles and responsibilities

Document regular oversight committee meetings (quarterly recommended)

Define escalation pathways for compliance issues

Implement process for staying current with 340B program updates

Policies and Procedures

Develop comprehensive, written 340B policies and procedures

Include all operational aspects of your 340B program

Document review and approval of policies by appropriate leadership

Establish regular review schedule (at least annually)

Document employee training on policies and procedures

Maintain policy revision history

Staff Training

Develop structured 340B training program for all relevant staff

Document initial and ongoing training of all staff involved in 340B

Include role-specific training modules

Establish competency assessment process

Maintain training records for all staff

Schedule regular refresher training

SECTION 2: PROGRAM IMPLEMENTATION

Patient Definition Compliance

Document compliance with HRSA patient definition criteria

Maintain auditable records demonstrating provider-patient relationship

Verify patient receives healthcare services from covered entity

Ensure medical records are maintained by covered entity

Confirm healthcare providers are employed by or under contract with entity

Covered Outpatient Drugs

Maintain list of covered outpatient drugs

Document exclusion of inpatient drugs from 340B program

Verify all 340B-purchased drugs meet "covered outpatient drug" definition

Implement process to exclude orphan drugs if applicable

Develop process for identifying and managing drug exclusions

Duplicate Discount Prevention

Document process to prevent duplicate discounts

Verify accurate Medicaid exclusion file reporting

Implement processes to identify Medicaid patients

Maintain auditable tracking system for Medicaid patients

Document state-specific Medicaid requirements and compliance

Verify correct application of Medicaid carve-in or carve-out model

Group Purchasing Organization (GPO) Prohibition (if applicable)

Document compliance with GPO prohibition if applicable

Implement systems to prevent GPO-purchased drugs for outpatients

Establish process for identifying and correcting GPO violations

Maintain accurate tracking of all drug purchasing accounts

Document proper accumulation for split-purchasing sites

SECTION 3: INVENTORY MANAGEMENT

Inventory Tracking and Management

Implement physical or virtual inventory tracking system

Document inventory management processes

Establish process for tracking 340B vs. non-340B inventory

Implement appropriate accumulation/replenishment practices

Document inventory reconciliation processes

Maintain audit trail of inventory transactions

Purchasing Controls

Document purchasing controls to prevent diversion

Implement processes to ensure appropriate 340B purchasing

Verify proper account setup with wholesalers/manufacturers

Maintain separation between 340B and non-340B accounts

Document process for handling drug shortages

Implement controls for split-site purchasing if applicable

Dispensing Controls

Document dispensing controls to prevent diversion

Implement processes to verify patient eligibility at dispensing

Maintain accurate records of all 340B dispensing

Document process for identifying and addressing dispensing errors

Ensure appropriate tracking of 340B drugs through entire process

SECTION 4: CONTRACT PHARMACY ARRANGEMENTS (if applicable)

Contract Pharmacy Agreements

Maintain signed contracts with all contract pharmacies

Ensure contracts include all required elements

Verify contracts are signed by authorized representatives

Document regular review of contract compliance

Maintain record of all contract pharmacy locations

Contract Pharmacy Oversight

Establish oversight processes for contract pharmacy operations

Document regular communication with contract pharmacies

Implement monitoring system for contract pharmacy compliance

Maintain documentation of contract pharmacy performance

Conduct regular compliance reviews of contract pharmacy operations

Contract Pharmacy Data Management

Implement systems for tracking eligible patients at contract pharmacies

Document data exchange processes with contract pharmacies

Establish data validation procedures

Implement process for reconciling contract pharmacy claims

Document process for handling contract pharmacy discrepancies

SECTION 5: AUDIT AND COMPLIANCE

Internal Audit Program

Establish formal internal audit program

Document regular self-audits (monthly recommended)

Conduct comprehensive internal audits (quarterly recommended)

Maintain internal audit documentation

Track resolution of audit findings

Report audit results to leadership and oversight committee

Independent Audit Preparation

Prepare for potential HRSA audit or manufacturer audit

Conduct mock HRSA audit annually

Maintain organized documentation ready for audit

Prepare staff for potential auditor interviews

Document correction of any identified compliance issues

Non-Compliance Management

Establish process for self-disclosing non-compliance

Document any identified instances of diversion or duplicate discounts

Implement corrective action plans for any non-compliance

Track completion of corrective actions

Document self-disclosures to HRSA or manufacturers

Maintain records of any repayment to manufacturers

SECTION 6: PROGRAM OPTIMIZATION

Financial Management

Document 340B program savings calculation methodology

Maintain records of 340B savings

Track utilization of 340B savings

Document how 340B savings support care for vulnerable populations

Prepare regular financial reports for leadership

Performance Metrics

Establish key performance indicators for 340B program

Document regular monitoring of performance metrics

Compare performance against industry benchmarks

Identify opportunities for program improvement

Report performance metrics to leadership

Continuous Improvement

Document continuous improvement initiatives

Establish process for implementing program enhancements

Maintain records of program changes and improvements

Document best practice implementation

Evaluate effectiveness of improvement initiatives

SECTION 7: DOCUMENTATION REQUIREMENTS

Essential Documentation

Maintain patient eligibility records

Document provider credentials and relationships

Maintain accurate drug purchasing records

Document inventory management processes

Maintain dispensing records

Retain all 340B-related contracts

Document self-audits and external audits

Maintain policies and procedures with revision history

Document staff training

Maintain oversight committee minutes

Document corrective actions

Maintain records of any self-disclosures

Document Retention

Establish document retention policy (minimum 7 years recommended)

Implement secure document storage systems

Establish document retrieval processes for audits

Document regular review of retained records

Train staff on document retention requirements

Contact Information

For assistance with 340B compliance, contact Quantum 5D Consulting:

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