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"You are never wrong, if you do the right thing."



Expertise - Commitment - Integrity

340B Policies & Procedures: Building a Foundation for Program Integrity

A GCA 340B Educational Webinar



COMPLIANCE



OPERATIONS



AUDIT
READINESS



STAKEHOLDER
ACCOUNTABILITY



PROGRAM
INTEGRITY



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Virtue 340B



GCA 340B Educational Webinar



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Why 340B Policies & Procedures Matter

Policies & Procedures as the Foundation of Program Integrity

INCREASING PROGRAM SCRUTINY



Heightened manufacturer scrutiny



Increased HRSA audit sophistication



Contract pharmacy complexity



Ongoing legal and operational volatility



Greater expectations for audit readiness and internal oversight



 Strong policies and procedures are essential to safeguarding the 340B program, protecting patients, and demonstrating our commitment to compliance and integrity.

POLICIES AS THE COVERED ENTITY'S INTERPRETATION



Policies document how we interpret and operationalize:

- HRSA guidance
- 340B statute requirements
- Internal compliance expectations



They create consistency across operational stakeholders

POLICIES AS OPERATIONAL GUIDANCE



A roadmap for internal stakeholders



A reference point for day-to-day administration



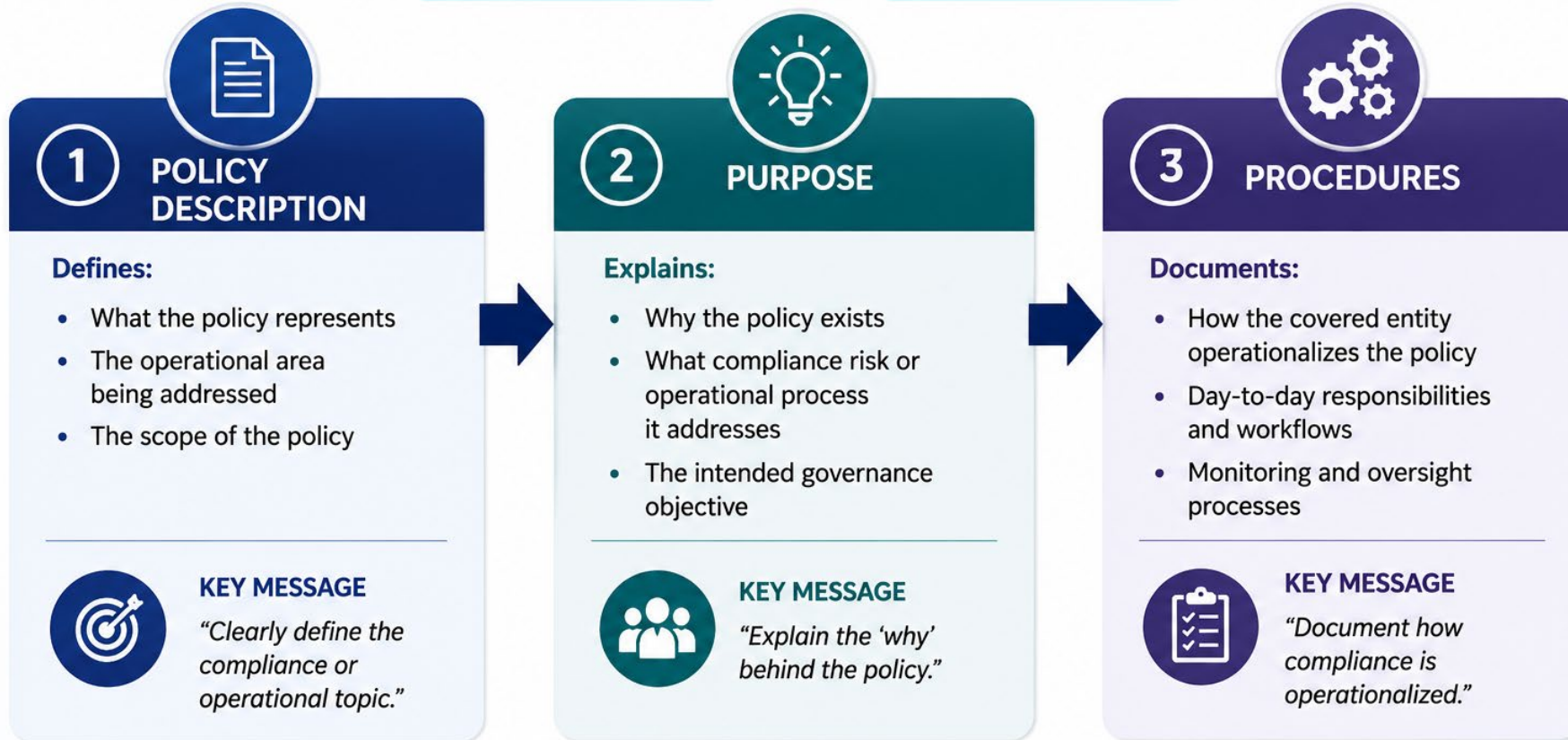
A tool supporting consistency and accountability



A framework for training and oversight

The Three Core Elements of an Effective Policy

Building Policies That Are Functional and Defensible



When these three elements work together,
POLICIES BECOME A FOUNDATION FOR PROGRAM INTEGRITY.



HRSA CORE POLICY EXPECTATIONS

Core Policy Elements Expected by HRSA



These core policy elements are required by HRSA and address the key operational risk areas covered entities must actively govern and document.



PROGRAM GOVERNANCE

- Registration & Recertification
- 340B OPAIS Maintenance
- Eligible Site Determination
- Self-Disclosure & Material Breach



PURCHASING & INVENTORY CONTROLS

- Purchasing Process
- GPO Prohibition Prevention
- Inventory Methodology
- Excluded Drug Definitions



DIVERSION PREVENTION

- CE Diversion Prevention Controls
- Pharmacy Diversion Prevention Controls
- Patient Eligibility Validation
- Provider Eligibility Validation



DUPLICATE DISCOUNT PREVENTION

- CE Duplicate Discount Prevention
- Contract Pharmacy Duplicate Discount Prevention
- Medicaid Billing Controls



OVERSIGHT & AUDIT READINESS

- Contract Pharmacy Oversight
- Internal Audits
- Independent Audits
- Special Circumstance Site Eligibility



These are not simply policy topics — these are operational risk areas HRSA expects covered entities to actively govern and document.

Best Practice Policy Opportunities

Beyond Compliance: Strengthening Program Integrity



These elements may not always be explicitly required by HRSA, but they represent strong governance practices that support long-term sustainability and defensibility.

THE MATURITY JOURNEY

Moving from compliance to best-in-class program integrity



BEST PRACTICE POLICY OPPORTUNITIES

	340B Savings Utilization Statements	Document how savings are reinvested to support patient care and mission.
	Program Roles & Responsibilities	Clearly define ownership and accountability across the 340B program.
	Education & Competency Expectations	Ensure staff have the knowledge and training needed to operate the program effectively.
	Prime Vendor Program (PVP) Governance	Maintain oversight and alignment with PVP requirements and updates.
	Auditable Record Retention	Retain and maintain records to support compliance and audit readiness.
	Referral Capture Eligibility	Define and document criteria for referral capture and patient eligibility.
	Affordable Insulin & Injectable Epinephrine Program Policies (FQHC Specific)	Ensure low-income patients have access to affordable insulin and epinephrine as required by HRSA.



Moving beyond compliance to operational excellence builds a stronger, more resilient, and mission-driven 340B program.



Drafting Recommendations & Virtue 340B Methodology

Creating Policies That Reflect Real Operations

1 DRAFTING RECOMMENDATIONS



POLICIES SHOULD BE LIVING DOCUMENTS

- Annual review at minimum
- Leadership approval and governance oversight
- Periodic updates as operations evolve



POLICIES MUST REFLECT ACTUAL OPERATIONS

Policies should be written such that:

- an external reviewer
- HRSA auditor
- manufacturer
- consultant

“Policies should reflect operational reality — not idealized workflows.”

could evaluate operations against documented processes



BALANCE DETAIL WITH OPERATIONAL FLEXIBILITY

- Provide clear guidance
- Support consistency
- Avoid becoming overly rigid
- Remain realistically operationalizable

2 VIRTUE 340B AUDIT METHODOLOGY



FRONT-END POLICY ASSESSMENT

Evaluate:

- Inclusion of core HRSA policy elements
- Inclusion of best practice elements
- Structural completeness
- Governance alignment



OPERATIONAL VALIDATION DURING AUDIT

Validate whether:

- Actual workflows align with written policies
- Staff operationalize procedures consistently
- Documentation supports policy statements
- Controls are functioning effectively



Our approach ensures that policies are not only complete on paper, but **effective in practice**.



“Strong policies and procedures are not simply compliance documents — they are evidence of intentional program governance.”



We're Here to Help!



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