

340B Survival Kit

Table of Contents

1. OVERVIEW OF THE 340B DRUG DISCOUNT PROGRAM	1
1.1. <i>Background</i>	1
1.2. <i>Program Eligibility</i>	2
1.3. <i>How Does the 340B Program Operate?</i>	4
1.4. <i>Program Restrictions</i>	7
1.5. <i>Savings</i>	9
1.6. <i>Information Resources</i>	11
2. HOSPITAL ELIGIBILITY	1
2.1. <i>Criterion One: Government Function</i>	1
2.2. <i>Criterion Two: Medicare DSH Adjustment Percentage Above 11.75</i>	5
2.2.1. <i>Determining the Medicare DSH Adjustment Percentage</i>	7
2.2.2. <i>Strategies for Maintaining a 340B-Eligible Medicare DSH Adjustment Percentage</i>	10
2.3. <i>Criterion Three: Purchase No Covered Outpatient Drugs Through GPOs</i>	12
2.3.1. <i>Scope of the GPO Exclusion</i>	13
2.3.2. <i>Application to Drugs Dispensed to Non-340B Outpatients</i>	17
2.3.3. <i>Compliance with the GPO Exclusion</i>	19
2.4. <i>DSH Hospital Enrollment Process</i>	20
2.5. <i>Children’s Hospitals</i>	23
3. DEFINING THE SCOPE OF AN ELIGIBLE DSH HOSPITAL	1
3.1. <i>Medicare Cost Report Test</i>	1
3.2. <i>Medicare Provider-Based Test</i>	3
3.3. <i>Home Health Agencies, Long-Term Care Facilities, Etc.</i>	8
3.4. <i>Enrollment Process For New Outpatient Sites</i>	11
4. WHAT DRUGS ARE ELIGIBLE AND AT WHAT PRICE?	1
4.1 <i>Medicaid Definition of Covered Outpatient Drugs</i>	1
4.2 <i>Application to 340B Program</i>	6
4.3 <i>340B Price Calculations</i>	10
4.3.1 <i>Formula and Its Components</i>	10
4.3.1.1 <i>AMP</i>	11
4.3.1.2 <i>Unit Rebate Amount</i>	12
4.3.1.3 <i>“Best Price”</i>	13
4.3.2 <i>Calculation Process and Timing</i>	14

4.4	<i>New Drugs</i>	16
4.5	<i>Confidentiality of 340B Prices</i>	18
4.5.1	<i>AMP and “Best Price”</i>	19
4.5.2	<i>340B Ceiling Prices</i>	21
4.5.3	<i>340B Actual Prices</i>	22
5.	WHO MAY RECEIVE THE DISCOUNTED DRUGS?	
6.	MEDICAID BILLING REQUIREMENTS	
7.	MEDICARE PRESCRIPTION DRUG BENEFIT AND 340B	1
7.1	<i>Part D Basics</i>	2
7.1.1	<i>Program Administration and Access</i>	3
7.1.2	<i>Standard Benefit</i>	4
7.1.3	<i>Part D Drug Coverage</i>	6
7.1.3.1	<i>Medicare Part D v. Medicare Part B</i>	7
7.1.3.2	<i>Plan Formularies</i>	8
7.1.4	<i>Eligibility and Enrollment</i>	10
7.1.4.1	<i>Auto-Enrollment of Low-Income Beneficiaries</i>	11
7.1.4.2	<i>Long Term Care Residents</i>	12
7.1.4.3	<i>Medicare Advantage Enrollees</i>	13
7.1.5	<i>Provider Marketing Guidelines</i>	14
7.1.5.1	<i>What Activities Are Permissible</i>	15
7.1.5.2	<i>Prohibited Activities</i>	15
7.1.6	<i>Medication Therapy Management</i>	17
7.2	<i>The Low-Income Subsidy</i>	18
7.2.1	<i>Dual Eligibles</i>	21
7.2.2	<i>Point of Sale Facilitated Enrollment</i>	22
7.3	<i>Formulary Safeguards</i>	23
7.3.1	<i>Restrictions on Formulary Changes</i>	23
7.3.2	<i>Transitioning to the Part D Plan Formulary</i>	26
7.4	<i>TrOOP and Other Coverage Gap Issues</i>	27
7.4.1	<i>What Qualifies As TrOOP?</i>	28
7.4.2	<i>Pharmacy Waiver/Reduction of Cost-Sharing and Applicability Toward TrOOP- General Overview</i>	29
7.4.3	<i>Cost-Sharing Subsidies by DSH Hospitals</i>	31
7.4.4	<i>Anti-Kickback Concerns</i>	32

7.4.5	<i>Manufacturer Patient Assistance Programs</i>	33
7.4.6	<i>State Pharmacy Assistance Programs</i>	36
7.5	<i>Contracting with a Medicare Part D Plan</i>	37
7.5.1	<i>Contracting Strategies</i>	38
7.5.2	<i>Any Willing Pharmacy Requirement</i>	39
7.5.3	<i>Model Safety Net Pharmacy Contract Addendum</i>	40
7.5.4	<i>Key Contracting Issues</i>	41
7.5.4.1	<i>Discounts to Uninsured/Underinsured</i>	41
7.5.4.2	<i>Reimbursement Rates</i>	42
7.5.4.3	<i>Medicare and Duplicate Discounts</i>	42
7.5.4.4	<i>Unique 340B Contracts</i>	43
7.5.4.5	<i>Preferred Pharmacy Status</i>	44
7.6	<i>SNHPA’s Advocacy Efforts on Medicare Part D</i>	44
7.6.1	<i>Pharmacy Networks and 340B Pharmacies</i>	45
7.6.2	<i>Payment Rates</i>	46
7.6.3	<i>Medication Therapy Management Plans</i>	47
7.6.4	<i>Co-Branded Drug Cards</i>	48
7.6.5	<i>TrOOP</i>	49
8.	INVENTORY MANAGEMENT	1
8.1	<i>Relevant 340B Standards</i>	2
8.2	<i>Stock Replacement</i>	4
8.2.1	<i>NDC-by-NDC Substitution</i>	5
8.2.2	<i>Reverse Substitution</i>	7
8.3	<i>Meeting the Challenge of NDC-by-NDC Substitution</i>	8
8.3.1	<i>Inadequate Tracking Systems</i>	9
8.3.2	<i>Unavailability of Replacement Product</i>	10
8.3.3	<i>Generic Substitution</i>	12
8.4	<i>Emergency Room Drugs</i>	13
8.5	<i>Cherry Picking</i>	14
8.6	<i>Future Considerations</i>	15
9.	CONTRACT PHARMACIES	