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340B Drug Pricing Program- Update

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Overview

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- Medicare Payment Cuts for 340B Drugs
  - Scope and Details
  - Litigation Update
- 340B Legislation Update
- State/Medicaid 340B Developments
- 340B Regulations
  - Ceiling Price and Manufacturer Civil Monetary Penalties
- Executive Branch Oversight

340B Program Overview

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- Outpatient drug discount program
- Sec. 340B of the Public Health Service Act
  - Enacted as Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585)
  - 42 U.S.C. 256b
- Establishes ceiling price on "Covered Outpatient Drugs"
- Discounts available to "Covered Entities" for dispensing to "Patients"
- Drug manufacturers that participate in Medicaid are required to participate in the 340B Program

Medicare Payment Cut for 340B Drugs

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- Effective January 1, 2018
- Medicare payments to hospitals for most separately-payable drugs acquired through the 340B Program will be subject to a payment reduction of approximately 30%
  - Payment reduction is only applicable to payments made under the Medicare Hospital Outpatient Prospective Payment System (OPPS)
  - Payment reduction is only applicable to separately-payable drugs
  - Payment reduction is only applicable to "covered outpatient drugs" acquired at or below 340B ceiling prices
  - Payment rate is reduced from ASP plus 6% to ASP minus 22.5%
- Require application of claims modifiers for all 340B-participating hospitals except Critical Access Hospitals and Maryland Waiver Hospitals

Medicare Payment Cut for 340B Drugs

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- Medicare OPPS makes payments to Medicare-enrolled hospitals for outpatient services
  - Does not apply to entities not enrolled in Medicare as a hospital or hospitals/services not paid under OPPS
    - Does not apply to most contract pharmacy arrangements
    - Does not apply to Critical Access Hospitals
    - Does not apply to Maryland waiver hospitals
    - Does not apply to hospital departments excluded from OPPS under the 2015 "site neutral/Section 603" payment methodology (at least for now…)
- Medicare OPPS does apply to rural sole community hospitals, IPPS-exempt cancer hospitals and IPPS-exempt children's hospitals
  - But, CMS excluded these hospitals from the payment cut (at least for now…)

Medicare Payment Cut for 340B Drugs

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- Payment cut does not apply to all 340B drugs dispensed by hospitals subject to the payment cut
  - Payment reduction applies only to separately-payable drugs with status indicator “K”
    - Refer to OPPS Addendum B for status indicators: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html
  - Does not apply to drugs that are:
    - “Packaged” (status indicator “N”- generally drugs less than $120)
    - “Pass-through” drugs (status indicator “G”)
    - Vaccines (status indicator “F”, “L” or “M”)

Medicare Payment Cut for 340B Drugs

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- Payment cut does not apply to drugs that are not "purchased through the 340B Program"
  - "Covered outpatient drug" as defined at § 1927(k) of the Social Security Act
    - Definition is not as clear as might be hoped
    - As a first step, recommend referring to hospital's written policies and procedures
  - Purchased at or below 340B ceiling price, including drugs acquired through the 340B Prime Vendor Program (Apexus)

Medicare Payment Cut for 340B Drugs

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- Payments are reduced from Average Sales Price (ASP) plus 6% to ASP minus 22.5%
- "Savings" generated from the payment cuts are redistributed across all hospitals/services paid under OPPS
  - Therefore, it is possible that some 340B hospitals could see a net gain from the payment cuts
  - All non-340B hospitals will see a payment increase

Medicare Payment Cut for 340B Drugs

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TABLE 88—ESTIMATED IMPACT OF THE CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	340B adjustment	All budget neutral changes (combined cols 2–4) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)	(6)
ALL FACILITIES *	3,878	0.0	0.0	0.0	1.3	1.4
ALL HOSPITALS (excludes hospitals permanently held harmless and CMHCs)	3,765	0.0	0.1	−0.1	1.4	1.5
URBAN HOSPITALS:	2,951	0.1	0.1	−0.3	1.2	1.3
LARGE URBAN (GT 1 MILL.)	1,589	0.1	0.0	−0.2	1.2	1.3
OTHER URBAN (LE 1 MILL.)	1,362	0.0	0.2	−0.3	1.3	1.4
RURAL HOSPITALS:	814	−0.3	0.0	1.4	2.5	2.7
SOLE COMMUNITY	372	−0.2	0.1	2.6	3.9	4.1
OTHER RURAL	442	−0.4	−0.2	0.0	0.8	0.9
BEDS (URBAN):						
0–99 BEDS	1,021	0.0	0.0	1.9	3.3	3.4
100–199 BEDS	850	0.0	0.2	1.2	2.8	2.9
200–299 BEDS	468	0.1	0.1	0.5	2.0	2.1
300–499 BEDS	399	0.1	0.0	−0.4	1.1	1.2
500 + BEDS	213	0.0	0.1	−2.2	−0.7	−0.6
BEDS (RURAL):						
0–49 BEDS	333	−0.5	−0.2	2.1	2.7	2.9
50–100 BEDS	297	−0.2	−0.2	1.9	2.8	3.0
101–149 BEDS	97	−0.3	0.1	1.1	2.3	2.5
150–199 BEDS	49	−0.2	0.1	0.7	1.9	2.1
200 + BEDS	38	−0.3	0.4	0.8	2.4	2.5

Medicare Payment Cut for 340B Drugs

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TABLE 88—ESTIMATED IMPACT OF THE CY 2018 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC recalibration (all changes)	New wage index and provider adjustments	340B adjustment	All budget neutral changes (combined cols 2–4) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)	(6)
DSH PATIENT PERCENT:						
0	10	0.0	0.2	3.2	4.8	4.9
GT 0–0.10	272	0.2	−0.1	2.8	4.4	4.5
0.10–0.16	263	0.1	0.0	2.7	4.3	4.4
0.16–0.23	572	0.1	0.3	2.6	4.4	4.5
0.23–0.35	1,132	0.0	0.1	−0.4	1.0	1.2
GE 0.35	935	0.0	0.0	−2.2	−0.9	−0.8
DSH NOT AVAILABLE **	581	−2.0	0.1	2.0	1.4	1.5
TYPE OF OWNERSHIP:						
VOLUNTARY	1,979	0.0	0.0	−0.3	1.2	1.3
PROPRIETARY	1,293	0.1	0.1	2.7	4.4	4.5
GOVERNMENT	493	−0.1	0.2	−1.6	−0.1	0.0

Medicare Payment Cut for 340B Drugs

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Hospital Type (determined by CMS)	Pass-through Drug (SI "G")	Separately Payable Drug (SI "K")	Vaccine (SI "F" "L" or "M")	Packaged Drug (SI "N")
Not Paid under OPPS				
CAH	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Maryland Waiver Hospital	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Non-Excepted Off-Campus PBD	TB	TB	N/A	TB or JG, Optional
Paid under the OPPS, Excepted from the 340B Payment Adjustment for 2018				
Children's Hospital	TB	TB	N/A	TB or JG, Optional
PPS-Exempt Cancer Hospital	TB	TB	N/A	TB or JG, Optional
Rural Sole Community Hospital	TB	TB	N/A	TB or JG, Optional
Paid under the OPPS, Subject to the 340B Payment Adjustment				
DSH Hospital	TB	JG	N/A	TB or JG, Optional
Medicare Dependent Hospital	TB	JG	N/A	TB or JG, Optional
Rural Referral Center	TB	JG	N/A	TB or JG, Optional
Non-Rural Sole Community Hospital	TB	JG	N/A	TB or JG, Optional

N/A= Not Applicable

Medicare Payment Cut for 340B Drugs

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- Litigation to stop payment cuts filed by hospital associations and 340B hospitals
  - Case was dismissed on December 29, 2017
  - Judge ruled that plaintiffs did not have standing to file the suit
  - Judge did not rule on the merits of the case
  - Appeal filed in early January
- Expect continued litigation following payment of a claim at the reduced rate
- Underlying legal issues are related to administrative law, as well as the intent of the 340B Program

340B Legislation Update

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- HR 4392 would prevent CMS from implementing the payment cuts
  - Significant bi-partisan support (currently 180 co-sponsors)
- HR 4710 ("340B PAUSE Act") would impose a two-year moratorium on new 340B DSH hospitals and locations
  - Would also require for DSH, Cancer and Children's hospitals: (1) additional data reporting; (2) OIG study on charity care; and (3) GAO report on hospital/government contracts and 340B revenue
- S 2312 ("HELP ACT") would also impose a two-year (possibly longer) moratorium on new 340B DSH hospitals and locations
  - Similar to 340B PAUSE Act, but more comprehensive
  - Would establish definition of "child site" for DSH, Cancer and Children's hospitals
  - Some form of claim-level reporting of 340B drugs for all covered entities

340B Legislation Update

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- Highly likely to see additional 340B legislative activity in 2018
  - Legislation would almost certainly be intended to and result in contraction of the 340B Program
- House Energy & Commerce Committee 340B Report
  - Focus on concerns with program growth, oversight and transparency
- Key elements to watch for in 340B legislation
  - Strong focus on 340B-participating hospitals (not on grantees)
    - Limits on definition of patients eligible to receive 340B drugs
    - For example, limiting eligible patients of hospitals to low/income and/or uninsured patients
  - Limits on amounts that could be charged for 340B drugs
    - For example, requiring hospitals to use sliding fee-scales for 340B drugs
  - Limits on contract pharmacies
    - By number and location
  - Required reporting of amount and use of 340B savings

State/Medicaid 340B Developments

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- 340B Program prohibits “duplicate discounts”
  - Manufacturers are not required to provide both a 340B discount and a Medicaid rebate on the same drug
- Federal Medicaid rules require states to request Medicaid rebates on all drugs eligible for rebates- including drugs dispensed to Medicaid managed care enrollees
- So, how do 340B entities, state Medicaid agencies, Medicaid managed care plans, pharmacy benefit managers, contract pharmacies and manufacturers coordinate to identify 340B drugs and prevent duplicate discounts?
- California proposal- prohibit all covered entities from billing any 340B drugs to Medicaid (fee-for-service or managed care)

State/Medicaid 340B Developments

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- Available 340B Program guidance applies only to Medicaid fee-for-service
  - "Carve-in" and "Carve-out" (i.e., dispensing (or not) 340B drugs to Medicaid beneficiaries)
  - Medicaid Exclusion File
  - Contract pharmacy carve-out rules
- But, the duplicate discount prohibition and Medicaid rebate requirements apply to both fee-for-service and managed care
- HRSA audits appear to continue to exclude Medicaid managed care claims
  - But, it is unclear how long that may be the case

State/Medicaid 340B Developments

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- Manufacturers and some states are monitoring 340B purchasing and requesting information/refunds
  - Including as to contract pharmacies, where hospital may have significantly less control over the billing/coding/patient identification
- Recommend reviewing state Medicaid guidance/policies and evaluating hospital and contract pharmacy arrangements
  - Lack of clear/consistent guidance will likely require risk evaluation and legal counsel
- If state Medicaid rules include Actual Acquisition Cost (AAC) billing and payment, risks include overpayments/False Claims Act risks

340B Regulations

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- 340B Statute provides limited opportunities for formal regulations
- Most 340B Program rules and interpretation are provided via less formal guidance documents
  - Federal register notices
  - Policy notices
  - FAQs
  - Audit findings

340B Regulations

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- Regulation governing ceiling prices, “penny pricing” and manufacturer civil monetary penalties was finalized in January 2017
- Effective date was to be March 6, 2017
- Effective date has been pushed back four times:
  - March 21, 2017
  - May 22, 2017
  - October 1, 2017
  - July 1, 2018
- Revised proposed rule currently under review at Office of Management and Budget
- Any significant legislative changes would likely expand the scope of regulatory authority

Executive Branch Oversight

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- Very little policy guidance from HRSA in recent months
- Emergency 340B registration for entities in Public Health Emergency Declaration areas
- Guidance for entities contracting with Rite-Aid pharmacies that are converting to Walgreens pharmacies post-merger
- New 340B Database/on-line registration and recertification system (https://340bopais.hrsa.gov/)
  - New requirements for access to on-line systems
  - New processes for updates to information

Executive Branch Oversight

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- Executive Branch Drug Pricing Initiative
  - White House initiative to address high cost of drugs
  - Concentrated activity in early Summer, not much since
- Series of draft Executive Orders
  - All included policy changes related to the 340B Program
  - White House claimed the drafts were fake
  - Different drafts included different policies, but all would have resulted in 340B Program contraction
  - Requirement that 340B Program directly benefit eligible patients
  - Limits on benefit 340B Program revenue going to entities other than eligible patients or covered entities
  - Rescind 2010 contract pharmacy guidance
  - Delay/withdraw ceiling price/civil monetary penalty rule

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