Implications of the dramatic changes in 340B reimbursement beginning January 1, 2018

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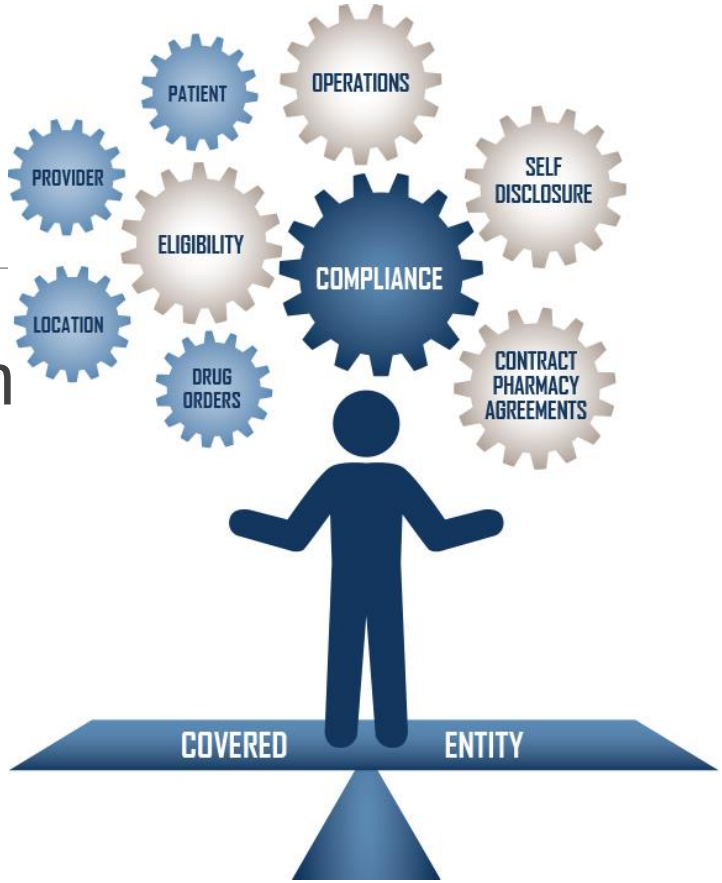
Agenda



- Brief overview of 340B Program
- Reimbursement changes
- Overall effect of changes
- New 340B modifiers
- Ohio Medicaid FAQ Guidance
- Federal lawsuit challenging CMS adjustment
- Q & A

Brief Overview of 340B Program

- Eligible providers (qualifying DSH hospitals, CAHs, SCHs, children's hospitals, PPS-exempt cancer hospitals, various government clinics).
- Enrollment necessary; not automatic participation.
- Allows covered entities (CEs) to purchase drugs at 340B prices (reduction over market price).
- Manufacturers must participate in 340B in order to participate in Medicaid.
- CEs get 340B benefit for drugs ordered from hospital departments (i.e., provider-based locations) for hospital patients.

Motivation for Rulemaking

- Massive growth in 340B program – both in terms of participation and costs.
- Long-term skepticism and scrutiny of 340B program compliance and role.
- House Energy and Commerce Committee report – 1/10/2018.
  - 12,000 entities participating
  - High growth rate in participation
  - No requirement on what CEs do with the savings
  - Recommending more oversight power, audit funding, etc. for HRSA

340B Reimbursement Changes

- 2018 OPPS Final Rule (issued 11/1/2017, eff. 1/1/2018)
- **Note:** not HRSA rulemaking on 340B program
  - CMS changing the reimbursement for drugs
  - Revenue vs. cost adjustment
  - HRSA has limited regulatory authority on 340B
- "…we are exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines)."

340B Reimbursement Changes

- Previous reimbursement: ASP + 6%
- New reimbursement: ASP – 22.5%
- "…we believe this will better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. These changes will lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B program."

ASP = Average Sales Price

340B Reimbursement Changes

The payment changes exclude:

- "Rural" SCHs, children's hospitals, CAHs and PPS-exempt cancer hospitals
- Drugs on pass through payments
- Non-grandfathered provider-based departments

Non-grandfathered PBDs

- These non-grandfathered sites

  (i.e., Sec. 603 Site-Neutral Payments)
- Continue to be paid at ASP + 6%

  (as though in a physician office)
- Change the reimbursement calculus for new PBDs
- "We did not propose to adjust payment for 340B-acquired drugs in non-excepted off-campus PBDs in CY 2018 but may consider adopting such a policy in CY 2019 notice-and-comment rulemaking."

Overall Effect of Changes

- Because changes required to be done in a budget-neutral manner, CMS increased OPPS payments by ~3.2% across the board.
  - 340B changes expected to save $1.6B on their own.
- Redistribution from large urban/suburban to other types of OPPS hospitals.

New 340B Modifiers

Effective 1/1/2018: All 340B hospitals paid under Medicare OPPS must report a modifier:

- **JG** – drug/biological acquired under 340B program and subject to the payment adjustment.
  - Only use for OPPS separately payable drugs (status indicator “K).
  - Do not use for vaccines (status indicator “F”, “L”, or “M”).
  - Do not use for drugs with pass-through payment status (status indicator “G”).

- **TB** – drug/biological acquired under 340B program *and* excluded from payment adjustment.
  - Informational modifier to collect and track 340B claims data.
  - Mandatory but will not trigger payment adjustment.
  - Will continue to receive ASP plus 6% for separately payable drugs in CY 2018.

New 340B Modifiers (continued)

- Non-excepted off-campus provider-based departments of hospitals participating in 340B report TB and PN modifiers.
- Discarded drug amounts ("drug waste") should still be billed with JW modifier plus appropriate 340B modifier (plus PO or PN if furnished in off-campus provider-based department).
- When multiple modifiers are reported, report pricing modifiers first, then descriptive modifiers.
- Dual eligibles – when state Medicaid or commercial plans require reporting of modifiers, CMS says consult Medicaid for guidance.
- CMS published sub-regulatory guidance on the 340B modifiers: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf

Ohio Medicaid FAQ Guidance

- Providers should submit the SE modifier on the 340B drug detail line for dates of service on or after 1/1/18 (delayed from 10/1/17).
- SE modifier should also be submitted on drug detail lines that contain a JW modifier (waste).
- SE modifier must be listed within the first four modifiers submitted for that drug.
- Use of the SE modifier will inform ODM that a 340B purchased drug was used and ODM will automatically exclude those drug details from its rebate request.
- "For those Medicare crossover claims that come directly to ODM from Medicare, we will deal with the 340B reporting to ensure proper drug rebating to ODM. However, if a hospital submits a crossover claim directly to ODM, we will expect proper use of the SE modifier in accordance with our billing guidelines."

https://pharmacy.medicaid.ohio.gov/sites/default/files/2017-12-20%20340B%20FAQ.pdf

Federal Lawsuit Challenging CMS 340B Payment Adjustment

The Plaintiffs:

- American Hospital Association
- Association of American Medical Colleges
- America's Essential Hospitals
- Three hospitals:
  - Eastern Maine Healthcare Systems
  - Henry Ford Health System
  - Park Ridge Health

Federal Lawsuit Challenging CMS 340B Payment Adjustment

Bricker & Eckler ATTORNEYS AT LAW

The Allegations

340B provisions of 2018 OPPS Final Rule violate the law - unlawful under Administrative Procedure Act and in excess of the HHS Secretary's statutory authority.

Court Decision 12/29/2017

- Dismissed the lawsuit as premature since the cuts had not yet gone into effect.
- Comments on proposed rule not enough to give the associations and hospitals standing to sue.
- "Plaintiffs' failure to present any concrete claim for reimbursement to the [HHS] secretary for a final decision is a fundamental jurisdictional impediment to judicial review."
- Opportunity to refile the complaint after the cuts go into effect – must cite specific reimbursement claims affected.
- Judge noted it will be difficult to "unscramble eggs" after the cuts go into effect.

What's Next

On January 9, 2018, the Plaintiffs filed a Notice of Appeal of the lower court's dismissal.

Questions?

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The Complex Balance of 340B Compliance

Bricker & Eckler

- Eligibility and Compliance practices
- Self disclosures to HRSA, drug manufacturers and Medicaid
- Pharmacy Agreements
- Contractual Disputes