Drug Reimbursement Trends & 340B Updates

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Disclaimer

Information provided as part of this presentation is not intended to be utilized as consulting advice for an individual practice or facility.

No legal advice is provided as part of this presentation; Revenue Cycle Coding Strategies recommends that providers review legal issues with healthcare regulatory counsel.

Reasons for Increasing Costs

Overall increase in spending for cancer care reflects increases in both price and quantity of care

The increases in price and quantity reflect the introduction of new medical technology

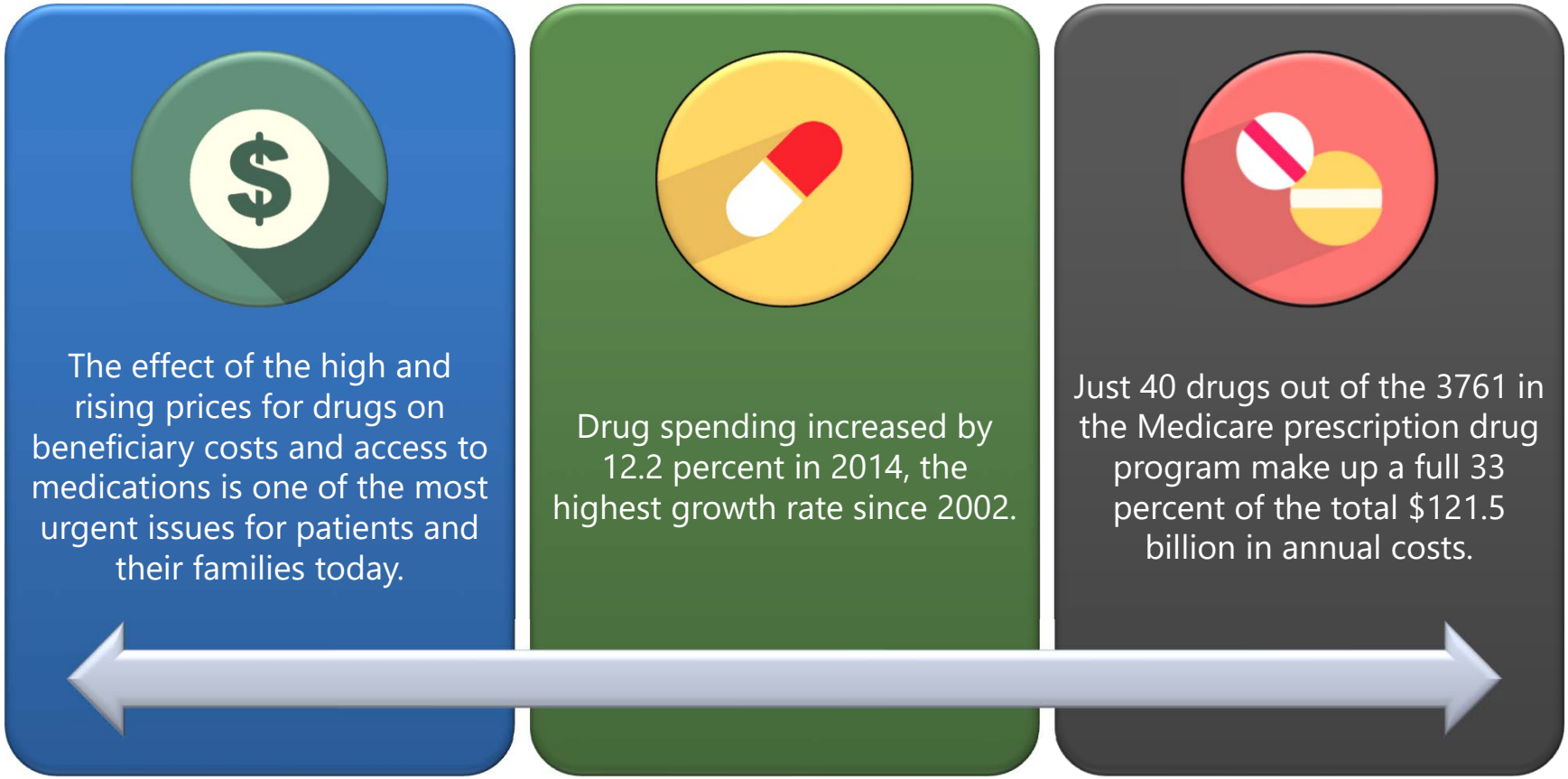
Newer cancer therapies are more expensive than the prior standard of care; they also expand the pool of treatment candidates (e.g., because of broader indications, reduced side effects).

Drug Reimbursement Trends

2018 MPFS Final Rule

CMS wants to promote innovation, provide more options to patients and providers and encourage competition.

HHS FY 2017 Budget in Brief – Medicare



HHS FY 2017 Budget in Brief – Medicare Goals

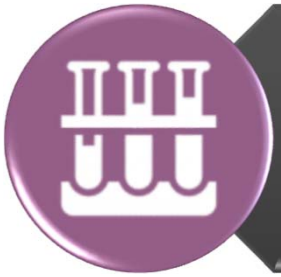
- Align Medicare Drug Payment Policies with Medicaid Policies for Low-Income Beneficiaries
- Accelerate Manufacturer Drug Discounts to Provide Relief to Medicare Beneficiaries in the Coverage Gap
- Modify Reimbursement of Part B Drugs
- Require Mandatory Reporting of Other Prescription Drug Coverage
- Allow the Secretary to Negotiate Prices for Biologics and High Cost Prescription Drugs
- Establish Authority for a Program to Prevent Prescription Drug Abuse in Medicare Part D
- Require Evidence Development for Coverage of High Cost Drugs

HHS FY 2017 Budget in Brief – Medicare Goals

Increase the Availability of Generic Drugs and Biologics

HHS FY 2017 Budget in Brief – Medicare Goals

Prohibit Brand and Generic Drug Manufacturers from Delaying the Availability of New Generic Drugs and Biologics



Modify Length of Exclusivity to Facilitate Faster Development of Generic Biologics

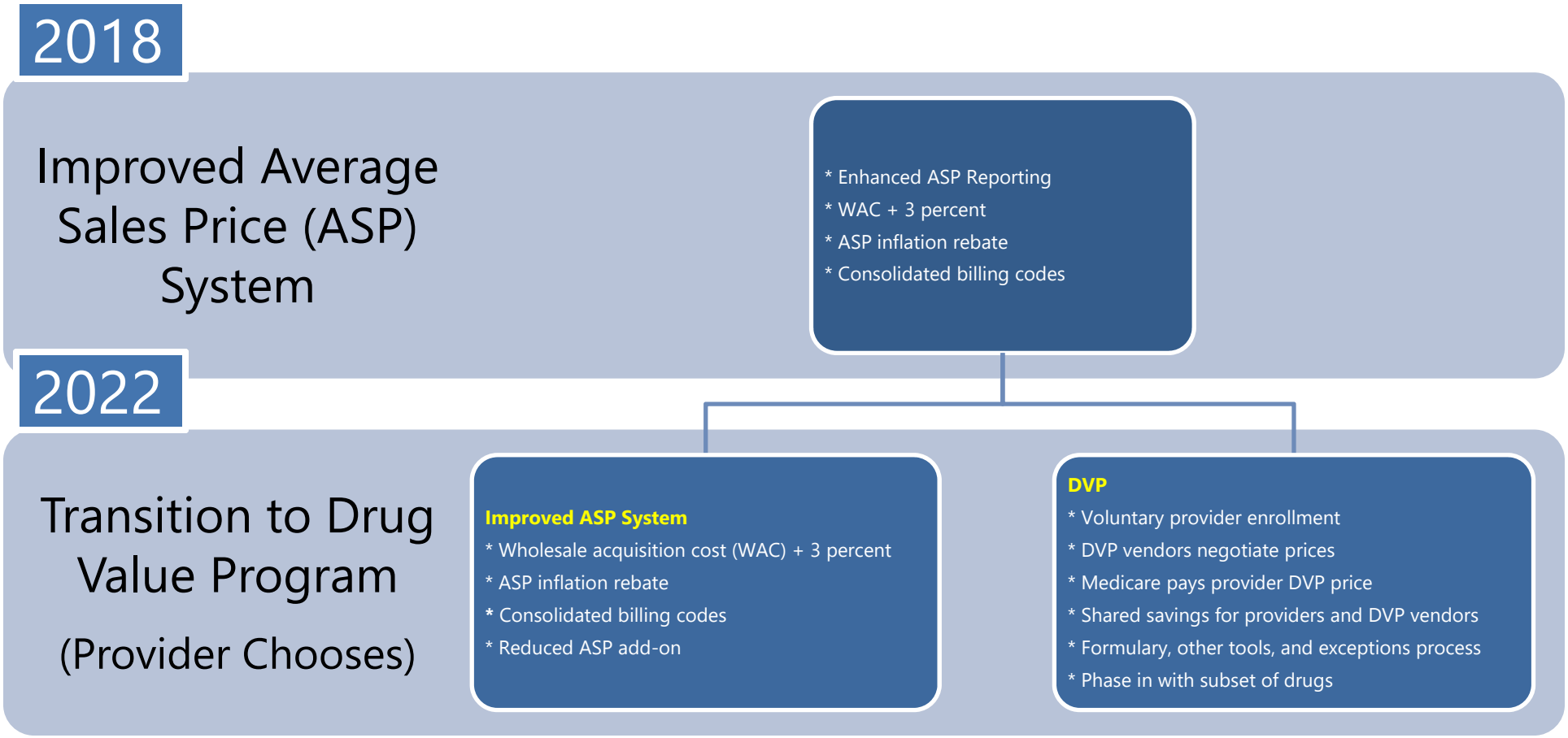
Establish Transparency and Reporting Requirements in Pharmaceutical Drug Pricing

MedPAC Proposals

On April 6 2017, the Medicare Payment Advisory Commission (MedPAC) voted to include in its June Report to Congress a package of proposals to change Medicare Part B drug reimbursement.

Under the proposal, no later than 2022, clinicians would have a choice to remain in the ASP system or move over to the DVP (Drug Value Program).

MedPAC Proposals



MedPAC – Improved ASP System

- Changes to ASP methodology – phase down to WAC + 3% & set ASP inflation limit
- Consolidated billing codes for reference products and biosimilars
- New payment formula for drugs with no ASP data
- Require manufacturers to report ASP data & implement penalties for non-reporting

MedPAC – Drug Value Program (DVP)

- A voluntary market-oriented alternative to ASP system
- Use private vendors to negotiate prices and offer providers shared savings opportunities
- Permits an option for binding arbitration between vendors and manufacturers for certain single source drugs
- Vendors paid fixed administrative fee, and would be able to utilize a formulary with an exceptions and appeals process

MedPAC Recommendations

MedPAC's recommendations would require BOTH new legislation and rulemaking.

However, the recommendations serve as an important starting point for policy makers when considering needed reforms, especially as the conversation in the US about high drug prices and high Medicare spending continues.

National Academy for State Health Policy

Responding to rapidly rising drug costs, **30 states across the country have drafted more than 60 drug price transparency bills** designed to:

- Identify the costs that contribute to drug manufacturer expenses and list prices
- Unveil the often opaque business practices of pharmacy benefit managers (PBMs).
- States are large purchasers of prescription drugs for a number of programs and agencies, such as Medicaid, prisons, and state employee benefits. Escalating drug prices have put pressure on states to create legislation to improve the sustainability of their budgets and ensure health care access for their residents.
- Some of the more ambitious proposed legislation requires manufacturers to justify prices, particularly for new drugs or for large year-after-year increases for older drugs that strain state budgets.
- Other states plan to use their authority to take action under long-standing "unfair business practices" laws.

Proposed Transparency Legislation

Vermont

Nevada

Maryland

California

Pennsylvania

Oregon

Oncology As The Forerunning Model

ASCO Projections From 2010 To 2020

13.8 to 18.1 million cancer patients	• 45% increase in new cases annually • Cancer becomes the leading cause of death in US
$104 billion to $173 billion annual cost of cancer drugs	• Associated drug therapy costs rise 27% • > 400 drugs in oncology related pipeline • Most new drugs are biologic with genetic target

Remember: These are recommendations and projections!

340B Updates

340B Drug Discount Program

The 340B drug discount program mandates the sale of outpatient prescription drugs to safety-net providers at reduced prices.

340B Program

Named for the legislation that created it in 1992 (section 340B of the Public Health Service Act).

Requires manufacturers to sell products to safety-net providers and programs identified in statute at a discounted price.

A price no higher than the net price paid by Medicaid, after rebates.

- Manufacturers can sell to 340B-eligible purchasers at even deeper discounts if they choose, without triggering a new Medicaid "best price."

Drug Discount

The discount is required for all outpatient prescription drug products – a designation that encompasses more than the traditional retail pharmacy medicines, such as infusion therapies, provided they are not part of an inpatient stay.

Purpose is to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Participants

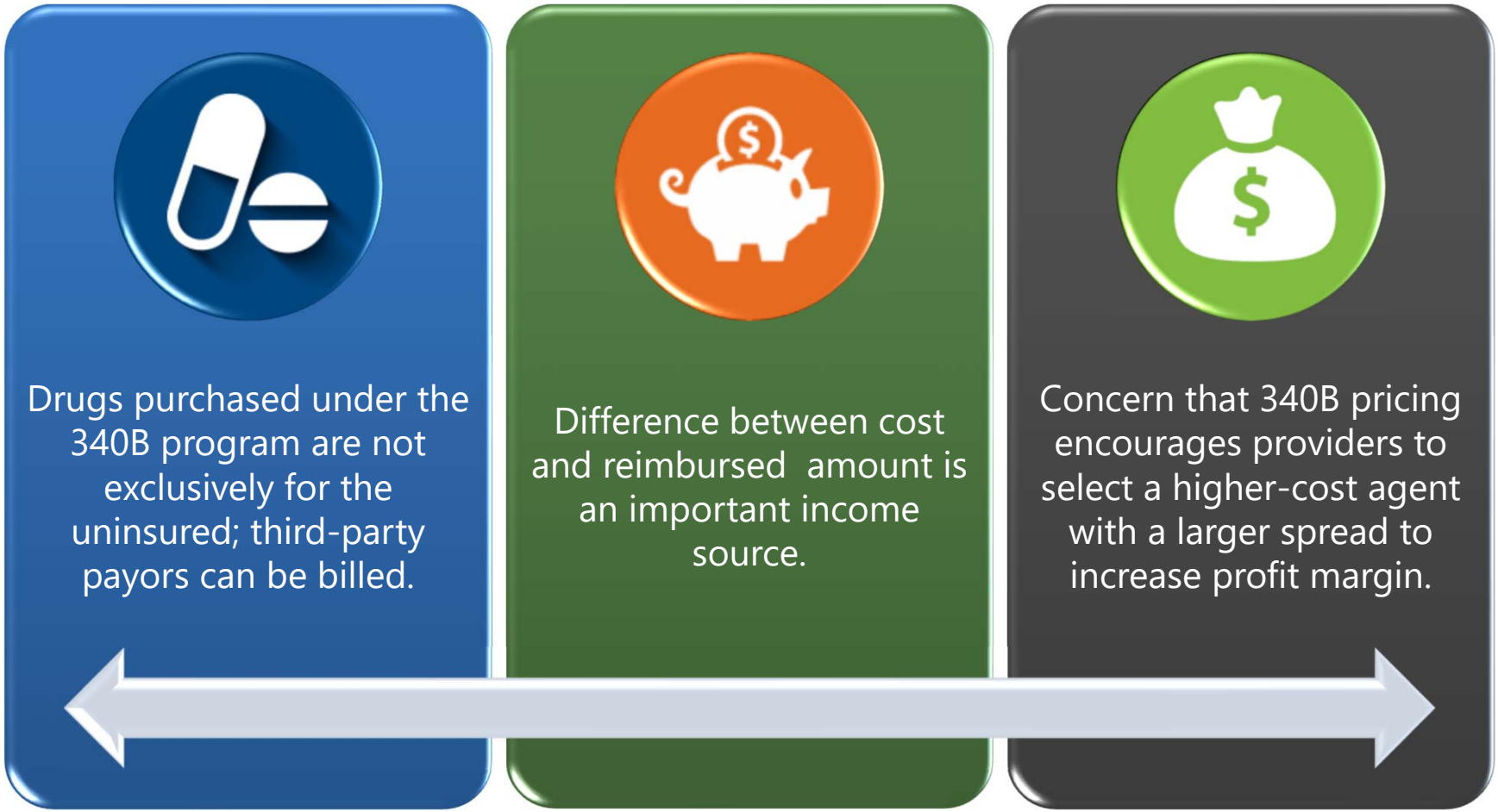
As of 2016 there were almost 35,000 individual sites registered by the Health Resources and Services Administration (HRSA) as eligible for the discount.

As of January 1, 2017 over 12,000 entities participate in the 340B program.

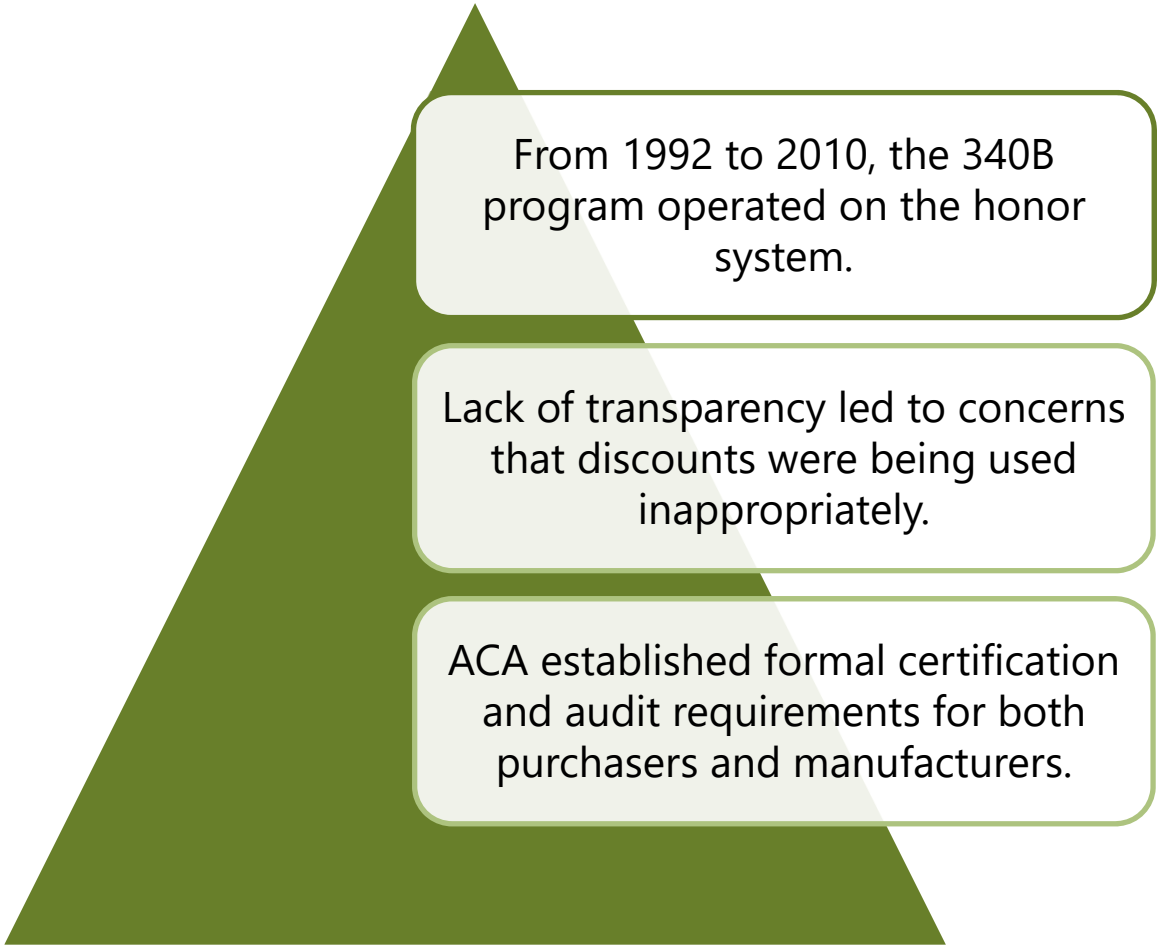
According to HRSA, drug purchases at 340B prices totaled about $12 billion in 2015.

Assuming a 25 – 50 percent discount on those purchases, HRSA estimates savings of $6 billion for covered entities.

340B – Things to Know



340B Program



340B Program

The program has grown rapidly, and the use of the discount by a relatively small set of large public hospitals has raised questions about whether the 340B discount is having unintended ripple effects on patient care and provider markets.

House Republicans Urge Greater Transparency for 340B Hospitals

Representative Chris Collins (R-NY) asserted that hospitals were acquiring oncology clinics solely to reap the profits under 340B.

2018 OPPS Final Rule – 340B Program

CMS adjusted payment for drugs and biologicals acquired under the 340B problem:

- From: ASP+6%
- To: ASP -22.5%

No Reduction

Vaccines and drugs on pass-through payment status.

2018 OPPS Final Rule – 340B Program

MedPAC and GAO studies

Estimated covered entities saved $3.8 billion on drugs purchased through 340B in 2013

OIG report – Part B payments averaged 58% more than 340B ceiling prices

In at least one quarter of 2013, beneficiary coinsurance alone was greater than the amount spent to acquire the drug

In 2018: 340B drugs require a modifier!

340B Modifiers

TB
Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

Effective January 1, 2018 this informational modifier will facilitate collection and tracking of 340B claims data for OPPS providers that are **excepted** from the payment adjustment.

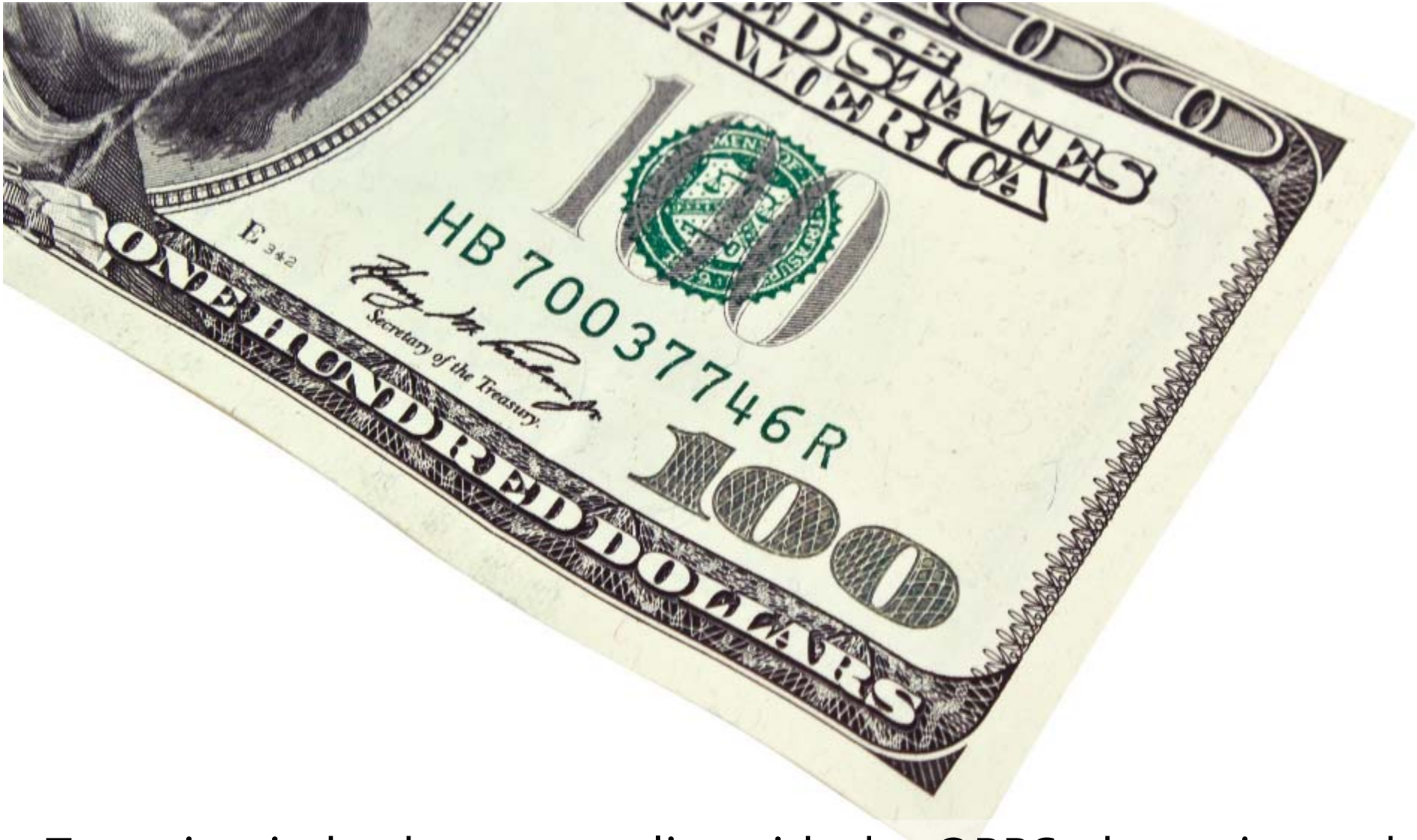
- Rural sole community hospitals (SCHs)
- Children's hospitals
- PPS exempt cancer hospitals

340B Modifiers

JG
Drug or biological acquired with 340B drug pricing program discount

Effective January 1, 2018 providers who are subject to the 340B payment adjustment will report this modifier to identify that a drug was acquired under the 340B program.

This drug will be paid by Medicare at ASP-22.5%



To maintain budget neutrality with the OPPS, the estimated $1.6 billion in reduced drug payments will be distributed in an equal offsetting amount to all OPPS hospitals, increasing the payment rates by 3.2% for non-drug items and services.

Drug Companies May Be Fined?

Federal Register, January 5, 2017

- Final Rule, effective April 1, 2017
  (Currently DELAYED until July 1, 2018)
- Requires manufacturers to provide a ceiling price report for covered outpatient drugs, which will be verified by CMS
- Will impose Civil Monetary Penalties (CMP) against manufacturers who "knowingly and intentionally overcharge a covered entity"

Final Thought

America's Health Insurance Plans (AHIP)

To improve access to prescription drugs and to make new treatments more affordable, health care stakeholders should promote policies that preserve needed innovation and competition, while also promoting greater transparency to improve the value of prescription drugs for patients.

Thank You!

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