

# 340B UPDATE

**HIGHLIGHTS FROM THE  
340B COALITION CONFERENCE  
WASHINGTON DC JULY 2016**



# AGENDA

- Proposed Rules and Guidance
- Hot Topics
- 340B Best Practices



## **PROPOSED RULES AND GUIDANCE**

- Proposed 340B mega guidance
- Proposed rule on manufacturer civil monetary penalties and 340B ceiling price calculations
- Proposed rule on administrative dispute resolution process

# MEGA GUIDANCE

- Patient definition
- Hospital eligibility
- Contract pharmacies
- Covered outpatient drug definition
- Medicaid Managed Care
- Reporting requirements

Provides clarification but threatens 340B benefits

## **PROPOSED 340B MEGA GUIDANCE**

- HRSA received 1,264 comments from 340B stakeholders
- Target for final release December 2016

# PROPOSED RULE ON MANUFACTURER CIVIL MONETARY PENALTIES AND 340B CEILING PRICE CALCULATIONS

- Sets standards for calculating ceiling prices
- Implements civil monetary penalties for manufacturers that knowingly and intentionally overcharge





## **PROPOSED RULE ON MANUFACTURER CIVIL MONETARY PENALTIES AND 340B CEILING PRICE CALCULATIONS**

- HRSA reopened the comment period in April 2016
- Expect final rule release this year

# PROPOSED RULE

## ADMINISTRATIVE DISPUTE RESOLUTION (ADR)

- Released August 12, 2016 by HHS
- Three member ADR Panel to resolve and review claims
- Members will be from CMS or Department of Veterans Affairs and have knowledge of 340B program
- On *ex-officio* member from Office of Pharmacy Affairs staff
- Claims related to:
  - Claim by covered entity (CE) for being overcharged by manufacturer
  - Claim by manufacturer, after audit, for resolution if CE violated duplicate discount or diversion provisions



## **PROPOSED RULE**

### **ADR (CONCLUDED)**

- Must submit written claim within three years of sale (payment)
- Allows for consolidation of claims process
- Must provide documentation to move forward
- Allows CE an info request process
- HHS developing system to verify ceiling price of a 340B drug and allow CE to access and verify ceiling prices

## HOT TOPICS

- Politics and 340B
- Medicare and 340B
- Medicaid and 340B
- HRSA 340B Initiatives



# POLITICS AND 340B

## HIGH DRUG PRICES & SPECIALTY DRUGS

- 2015 total drug spending \$425 Billion per IMAS Health (12% increase from 2014)
- Of total 2015 drug spend – Specialty drugs were \$150 Billion (22% increase from 2014)

- 2017 Industry projections – Specialty drugs 44% of total spend
- Recent high profile price increases



# MEDICARE AND 340B

**GROWTH IN 340B PROGRAM**

**MEDICARE PART B DRUG  
SPENDING AT 340B HOSPITALS**

**MEDICARE PROGRAM AND  
BENEFICIARIES PAY SAME RATE  
FOR PART B DRUGS AT 340B AND  
NON 340B HOSPITALS**

**340B HOSPITALS DRUG  
ACQUISITION COSTS ARE MUCH  
LOWER**

**MEDICARE PAYMENT ADVISORY  
COMMISSION (MPAC)  
RECOMMENDATION**

**ALLOW BENEFICIARIES AND  
HOSPITALS PROVIDING THE  
MOST UNCOMPENSATED CARE  
TO SHARE IN SAVINGS**

- **REDUCE MEDICARE RATES BY 10% OF AVERAGE SALES PRICE (ASP) – LOWERS COST SHARING BY 10%**
- **REDISTRIBUTE PROGRAM SAVINGS TO THE HOSPITALS PROVIDING THE MOST UNCOMPENSATED CARE**

# MEDICAID AND 340B

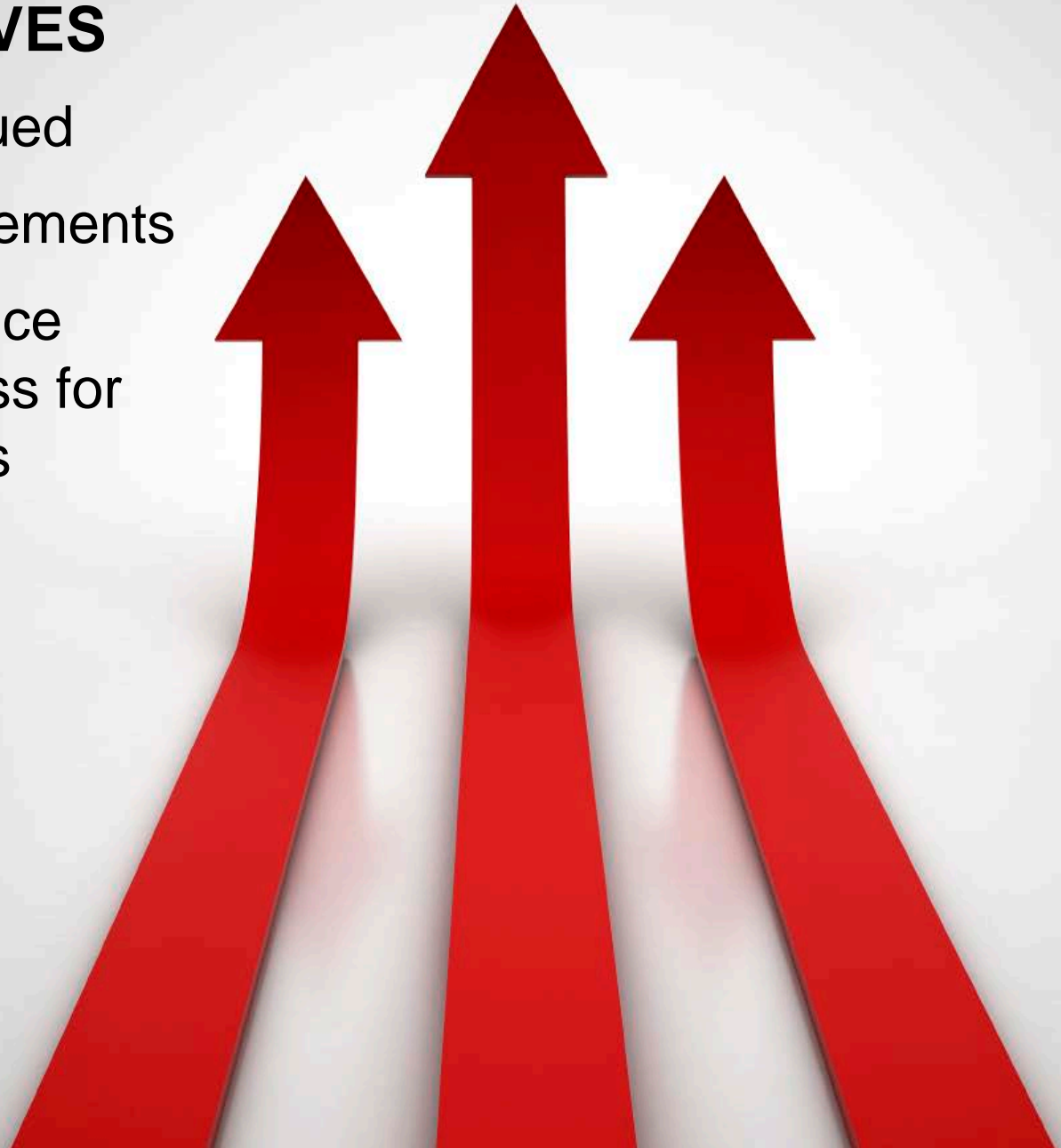


Establish procedures to exclude drugs utilized in 340B program



# HRSA INITIATIVES

- Audits...continued
- System improvements
- 340B ceiling price database access for covered entities



# BEST PRACTICES

- Provider based status and child site registration
- Preparing for an audit
- Contract pharmacy checklist



# PROVIDER-BASED STATUS AND CHILD SITE REGISTRATION

- Clinics must be on a reimbursable line of the Medicare cost report (Worksheets A & C)
- Register all “off-site” outpatient locations using 340B
- Register separately
- “Off-site” for 340B refers to outside hospital’s four walls
- Within the four walls if share same physical address
- Proposed site neutral payment – impact on eligibility



# TIPS ON PREPARING FOR AN AUDIT

## Self Audit

- Multi-disciplinary team involved
- Several times a year
- Medicare Cost Report – child sites reviewed
- 340B Database profile reviewed
- Keep connected – how will decisions made in the organization impact 340B
- Educate on 340B program

## Policies and Procedures

- Contract pharmacy eligibility and oversight
- Prevention of diversion
- Prevention of duplicate discounts

## Example of Self-Audit Schedule

<b>MONTHLY</b>	<ul style="list-style-type: none"><li>• Test Split billing software</li><li>• Test 340B transactions for compliance</li></ul>
<b>QUARTERLY</b>	<ul style="list-style-type: none"><li>• Review OPA Database</li><li>• Formal meeting of Compliance Oversight Committee</li></ul>
<b>ANNUALLY</b>	340B training

# CONTRACT PHARMACY CHECKLIST

Contract covers all HRSA's essential elements

Contract includes the appropriate responsibilities of each party

Compensation arrangements are compliant with fraud and abuse laws

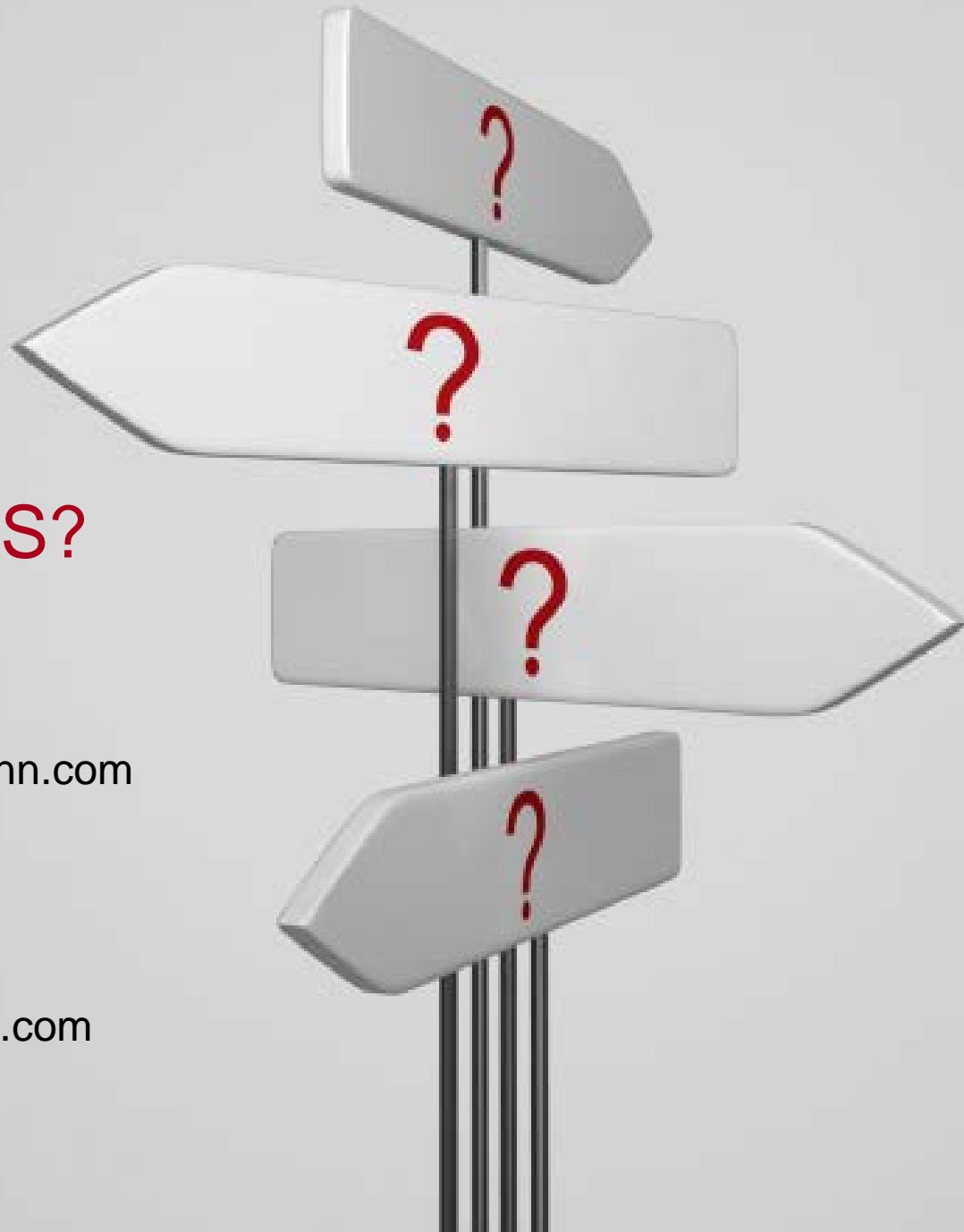
Contract is fully executed by both parties

Appropriate business associate agreements are executed

Accurate registration on HRSA OPA database

Written and followed policies and procedures on contract pharmacy operations

- Carve out on FFS Medicaid
- State policy addressing Medicaid MCO duplicate discounts
- Adequate process for determining patient eligibility
- Adequate process for oversight



## QUESTIONS?

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