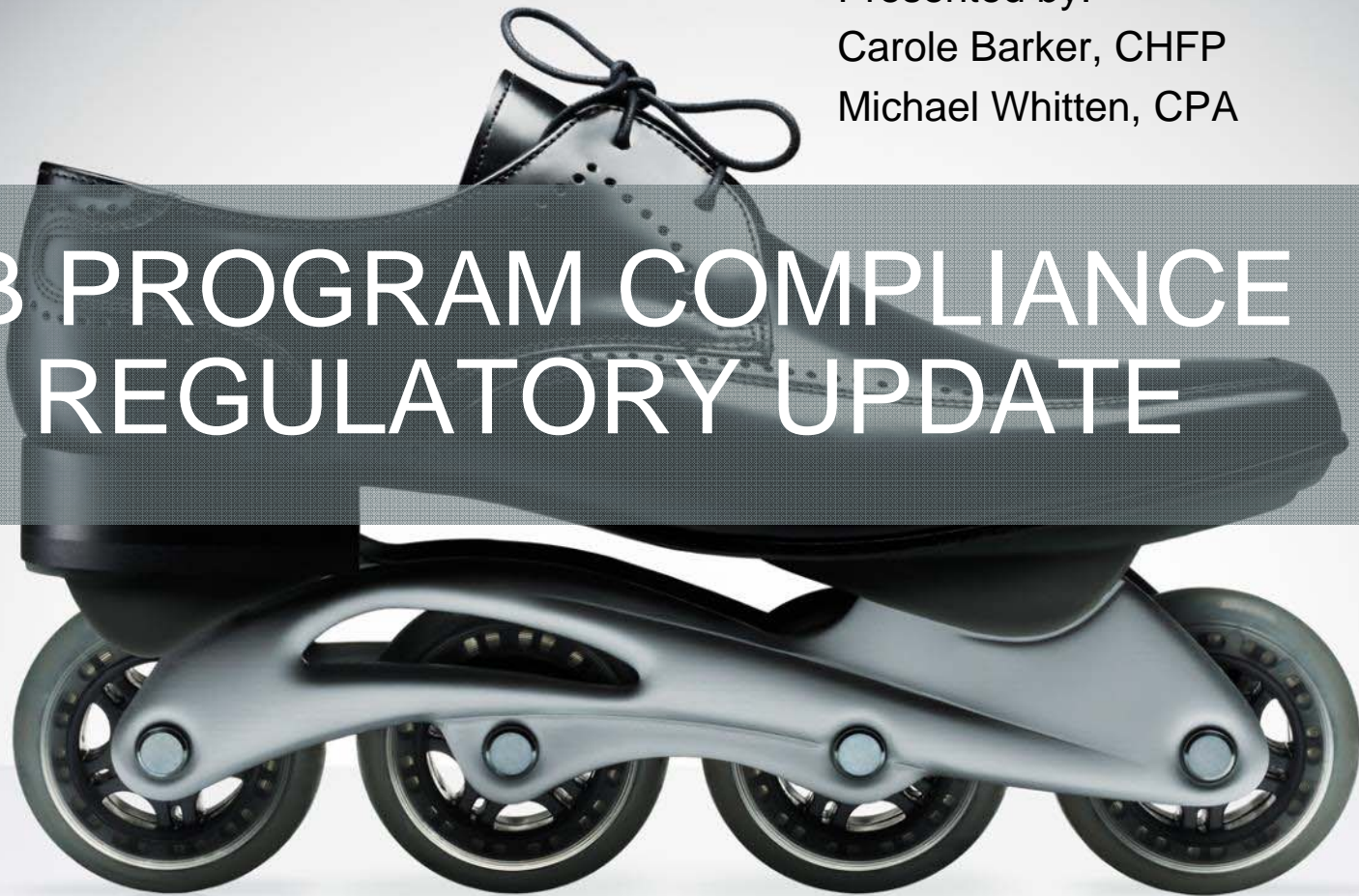


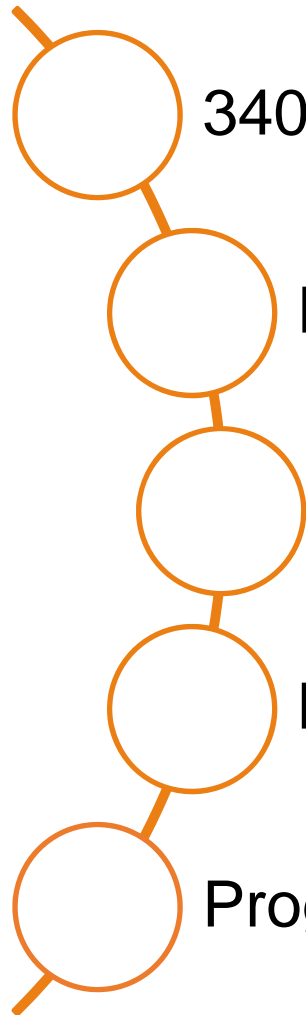


Presented by:  
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# 340B PROGRAM COMPLIANCE AND REGULATORY UPDATE



# AGENDA

- 
- 340B Basics and Program Intent
  - Program Participation Requirements
  - Key Compliance Areas
  - HRSA Audit Findings – common issues
  - Program Update

# 340B PROGRAM BASICS

US federal  
government  
program created in  
1992

Administered by  
the Health  
Resources and  
Services  
Administration  
(HRSA), Office of  
Pharmacy Affairs  
(OPA)

Requires drug  
manufacturers  
participating in  
Medicare and  
Medicaid to sell  
outpatient drugs to  
safety net  
providers at  
significantly  
reduced prices

## 340B PROGRAM INTENT

Support mission

Stretch Federal  
funds

Use drug  
savings to  
benefit more  
patients

Provide more  
comprehensive  
services

# PROGRAM PARTICIPATION REQUIREMENTS

Meet definition of a  
Covered Entity

Capacity to follow  
(and maintain audible  
records documenting  
compliance with)  
program rules

Register on the HRSA  
340B database

Recertify with HRSA  
annually

# KEY COMPLIANCE AREAS



# KEY COMPLIANCE AREAS



# PROGRAM ADMINISTRATION & COMPLIANCE

Multidisciplinary  
team

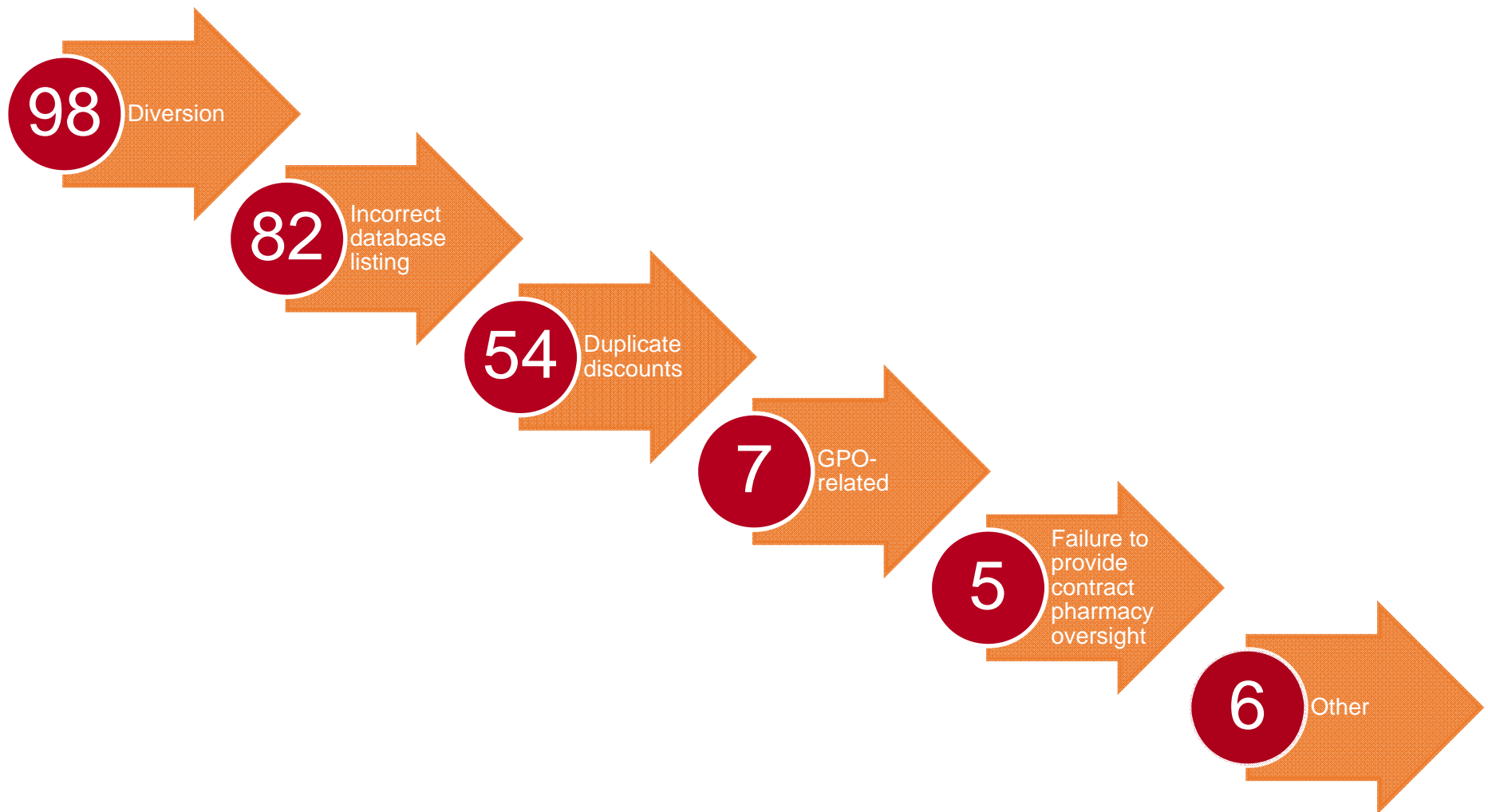
Continuous  
monitoring &  
testing

Documented  
policies &  
procedures

There's NO outsourcing compliance!



# HRSA AUDIT FINDINGS





## PROGRAM UPDATE

### Congressional Hearing Covered

- Oversight and integrity
- Eligible patient definition
- Contract pharmacy use
- Use of program savings by covered entities

## SAVINGS AND SPENDING FOR 340B AND PART B



- MedPac study on Part B reimbursements and 340B acquisition costs
- 2015 OIG study coming



## KEY FOCUS AREAS

- Patient definition
- Hospital eligibility
- Contract pharmacies
- Covered outpatient drug definition
- Annual covered entity recertification
- Audits
- Medicaid duplicate discounts

**340B “MEGA-GUIDANCE”**

Coming in June?

## PROPOSED REGULATIONS & ADDITIONAL REPORTS EXPECTED IN 2015

- HRSA Proposed Regulations
- OIG Reports
- GAO Study

# INTERESTED IN MORE?

We are always available for your questions



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