

340B

Where Have We Been and Where Are We Going

Douglas Wong, Pharm.D.
Vice President, Pharmacy Practice
Pharmacy Healthcare Solutions

Disclosures

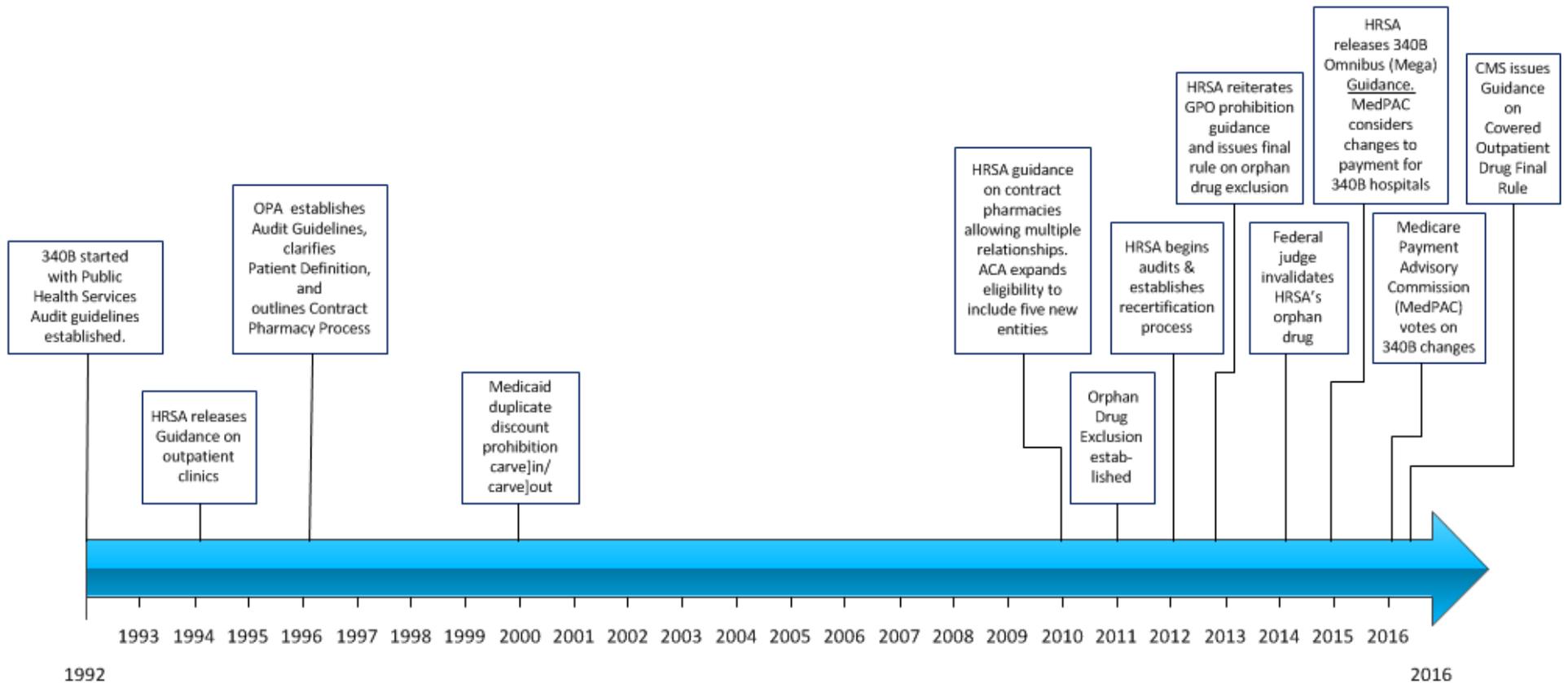
Doug Wong is an employee of Pharmacy Healthcare Solutions. The conflict of interest was resolved by peer review of the slide content. He declares no other conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Learning Objectives

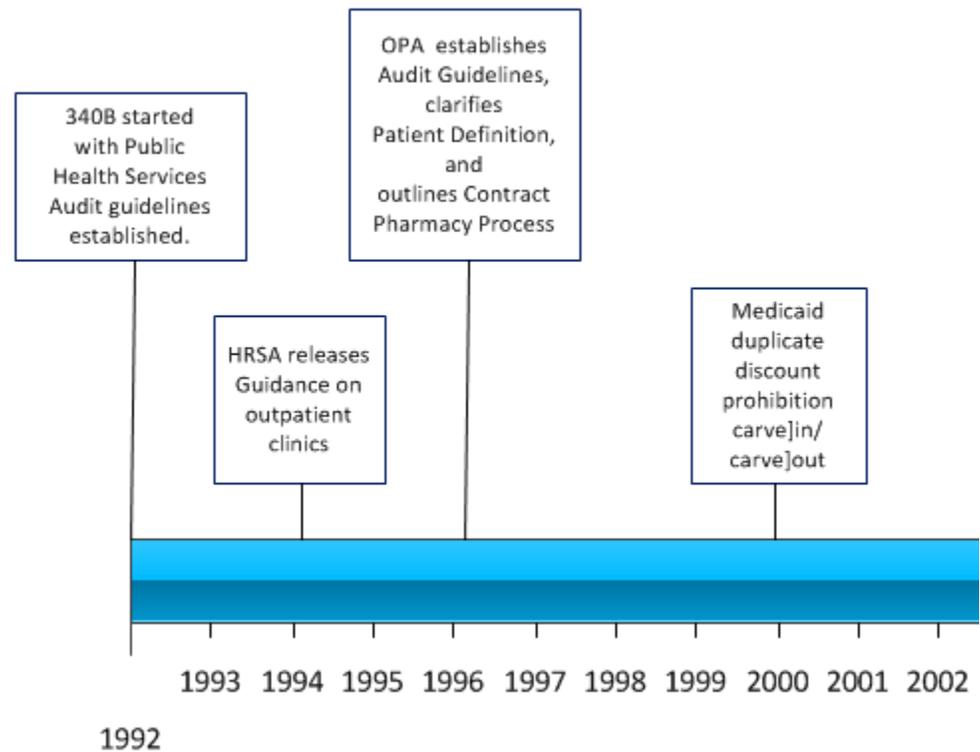
Following this presentation, attendees should be able to:

- Identify key events in 340B landscape that occurred in 2015 and 2016.
- Identify critical components of a compliance plan.
- List the different types of non-compliance in OPA findings during their audits
- List elements of a corrective action plan (CAP).
- List elements of proposed six part test for patient definition

Progression of 340B

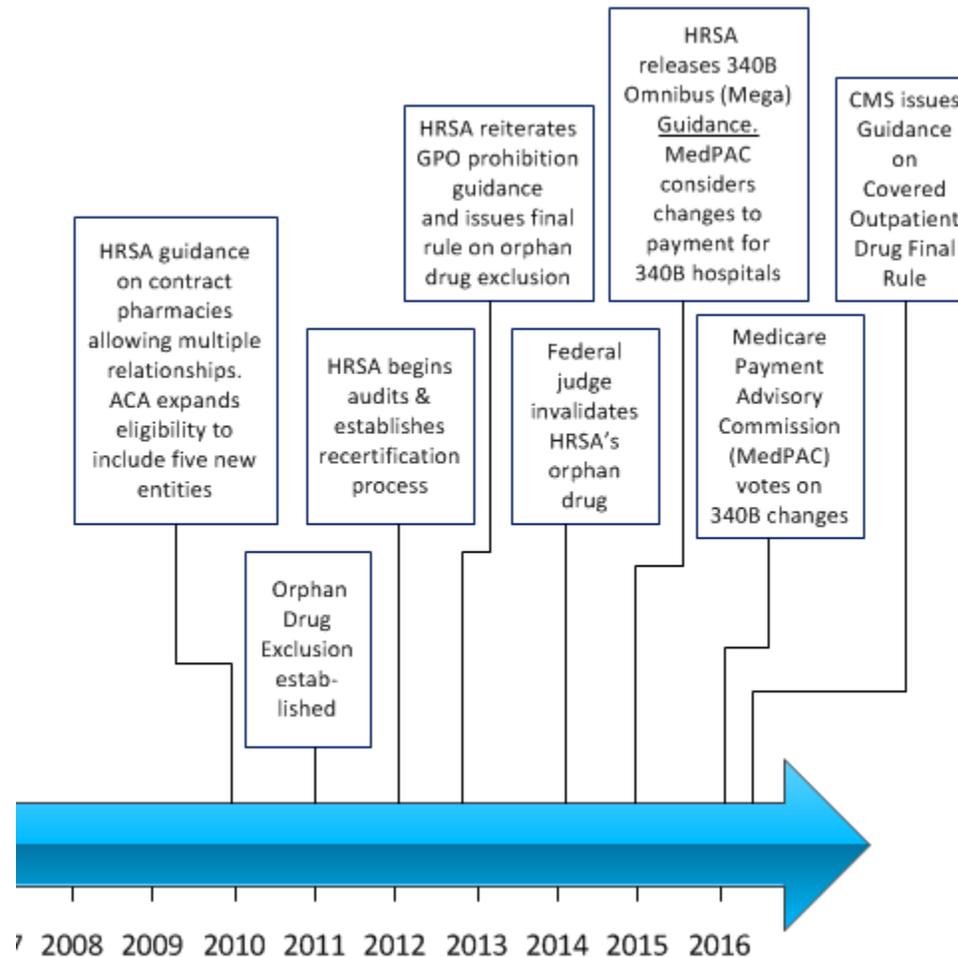


Formative Years



American Society for Automation in Pharmacy
2016 Midyear Conference
June 16–18 • Louisville, Ky. • www.asapnet.org • #ASAPMidyear

Influential and Pivotal Years



American Society for Automation in Pharmacy
2016 Midyear Conference
June 16–18 • Louisville, Ky. • www.asapnet.org • #ASAPMidyear

What's in the future

- Mega-guidance finalized?
 - Entity restrictions/areas
 - > Hospital eligibility
 - > Covered outpatient drug
 - > Patient definition (discharge, referral, self-insured plans, infusion “only,” billed as outpatient)
 - > Records retention
 - > Improper accumulation could be diversion
 - > Contract pharmacy annual and quarterly audits (expectation)
 - Medicaid
 - Manufacturer restrictions/areas

What's in the future

- FY17 Budget provides funding for New Guidance on Key 340B Program Areas
 - Manufacturer and Entity Civil Monetary Penalties Ceiling Price Rules
 - Amendment to grant new authority
 - Enhanced Audit Activity
 - Information Technology
 - Compliance Management Tool

Corrective Action Plan Elements

- Covered entities (CEs) must initiate correction action in two situations:
 - As a result of an adverse audit by Health Resources and Services Administration (HRSA) or manufacturer
 - As a result of discovering a use of the 340B program that is non-compliant

Corrective Action Plan - HRSA

- If there is an adverse audit by Health Resources and Services Administration (HRSA) or manufacturer
 - Corrective Action Plan (CAP) is due within 30 days of either an uncontested adverse audit report or a Notice of Disagreement
 - HRSA is generally willing to grant one extension
 - Audit results are posted on the website of the Office of Pharmacy Affairs (OPA)

Corrective Action Plan - Entity

- Covered entities (CEs) discovers use of the 340B program that is non-compliant
 - Contact OPA as soon as reasonably possible if a “material breach” of program requirements
 - Corrective action may include repayment to manufacturers, payment of interest and/or removal from the program
 - Corrective action is required even if self disclosure is not

Elements of CAP

- Manufacturer repayment
- Reinforce or improve policies and procedures
- Targeted self-audits with description of audit process, sampling, frequency, etc.
- Describe compliance oversight activities
- Implementation dates
- Responsible individuals
- Internal communication and education strategy

Patient Definition

- The covered entity has a patient relationship with the individual, such that it maintains records of the individual's care
- The individual receives services from a professional who is either employed by or under contract with the covered entity, such that responsibility for the individual's care remains with the covered entity
- The individual receives care or services from the covered entity consistent with the services or range of services for which the covered entity receives federal funding (this requirement does not apply to hospitals)

Patient Definition-Mega Guidance

1. The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B Program database;
2. The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider;
3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug;

Patient Definition-Mega Guidance

4. If applicable, the individual receives a health care service that is consistent with the covered entity's scope of grant, project or contract;
5. The individual is classified as an outpatient when the drug is ordered or prescribed;
6. The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for that care is with the covered entity, and that each element of this patient definition is met for each 340B Drug.

Questions

American Society for Automation in Pharmacy
2016 Midyear Conference
June 16–18 • Louisville, Ky. • www.asapnet.org • #ASAPMidyear