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340B historical timeline

2021 Special Committee on Federal 340B Drug Program
December 8, 2021

today's agenda



Introductions



**History of 340B
policy and guidance**



Decade review



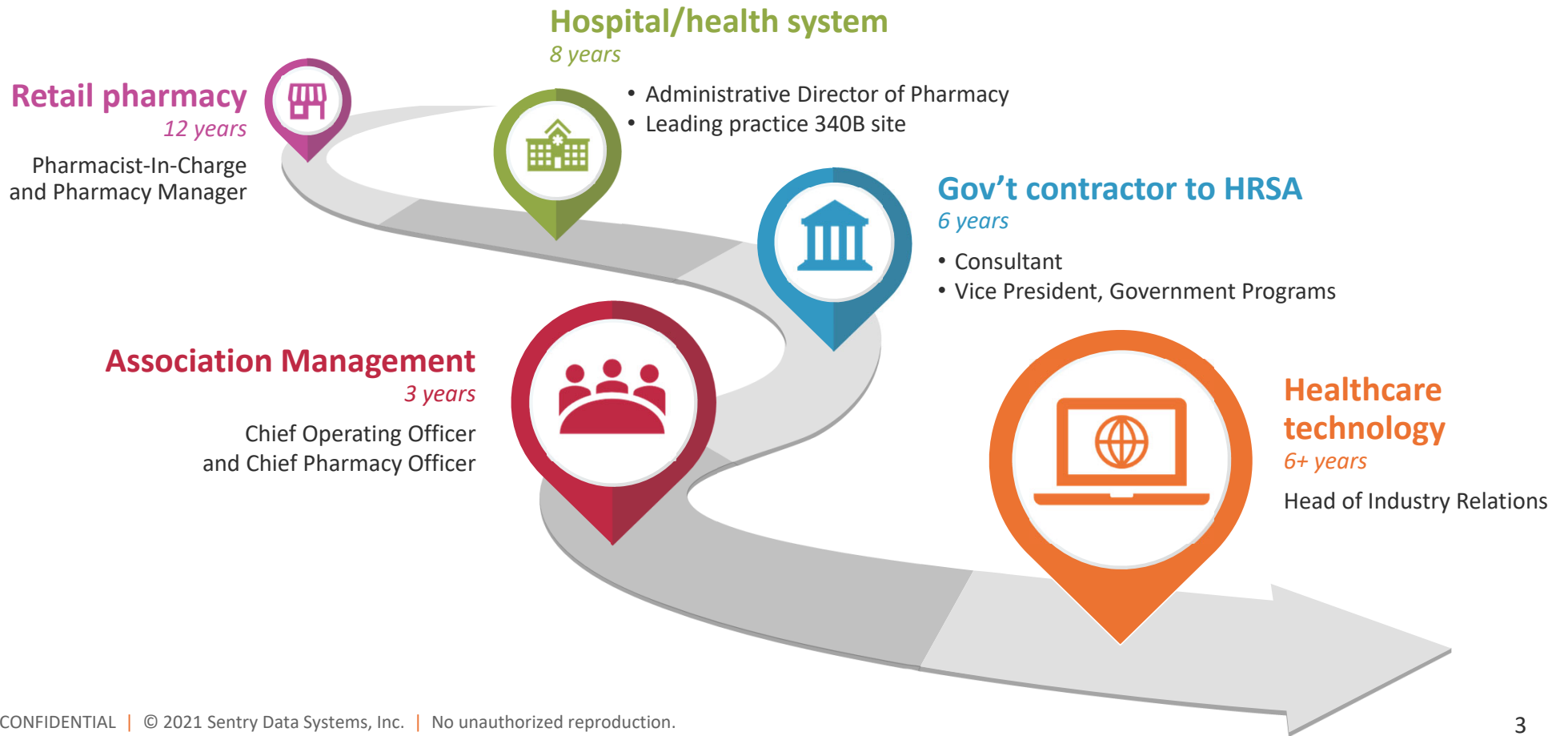
Q/A

today's presenter



Lisa Scholz PharmD, MBA, FACHE
Head of Industry Relations

my 340B journey





History of 340B policy and guidance

what is happening in 340B and why?



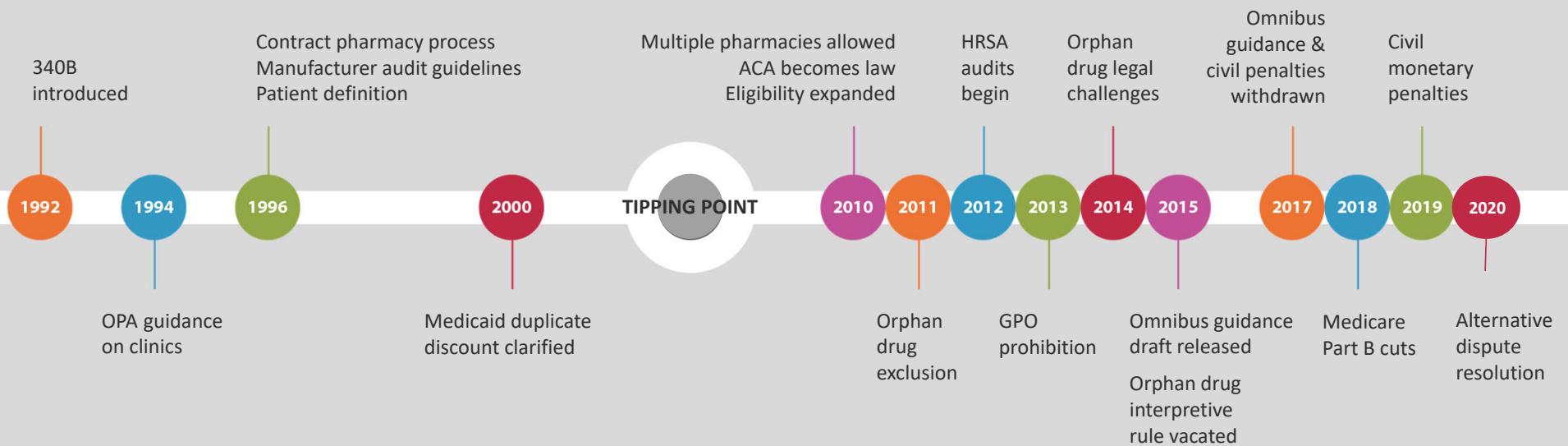
*A market shift by
manufacturers
AND pharmacy
benefit managers*



340B history



Over the years, a number of challenges have emerged regarding new program requirements, prohibitions, and integrity provisions





Decade review



340B trends over the decades:



Guidance, oversight and the beginning of “self-policing”

> Guidance

- Hospital outpatient facilities
- Patient definition
- Manufacturer audit guidelines
- ADAP
- Duplicate discounts
- One-to-one contract pharmacy

> Oversight

- OIG Audit: AIDS Drug Assistance Program and use of 340B encouraged to optimize usage

> Miscellaneous

- No Wholesaler Acquisition Cost (WAC) accounts exist
 - Purchase at 340B or GPO

340B trends over the decades:



Education, guidance and oversight

> Guidance

- WAC requirement (340B, GPO, and WAC)
- Duplicate discounts

> Education

- HRSA call center managed by American Pharmacist Association-Pharmacy Services Support Center
- 340B University started by Apexus

> Oversight

- OPAIS database changes to expand on child site listings
- OIG audit: Mashantucket Pequot Tribal Utilization of 340B
- OIG testimony to House E&C Committee (Subcommittee on Oversight and Investigations)

340B trends over the decades:



Education, guidance, judicial intervention, oversight, and regulations

> Judicial

- Orphan Drug
- Medicare Part B

> Oversight

- HRSA audits begin (2012)
- GAO Studies (9)
- Congressional committee reports (3)
- “Policy releases” 2011-2014
- “Program updates” 2014-2019
- HRSA call center managed by Prime Vendor Program
- State law: PBM anti-discriminatory language

> Regulations

- Orphan Drug (2014)
- Civil monetary penalties (final in 2019)
- Alternative dispute resolution (final in 2020)

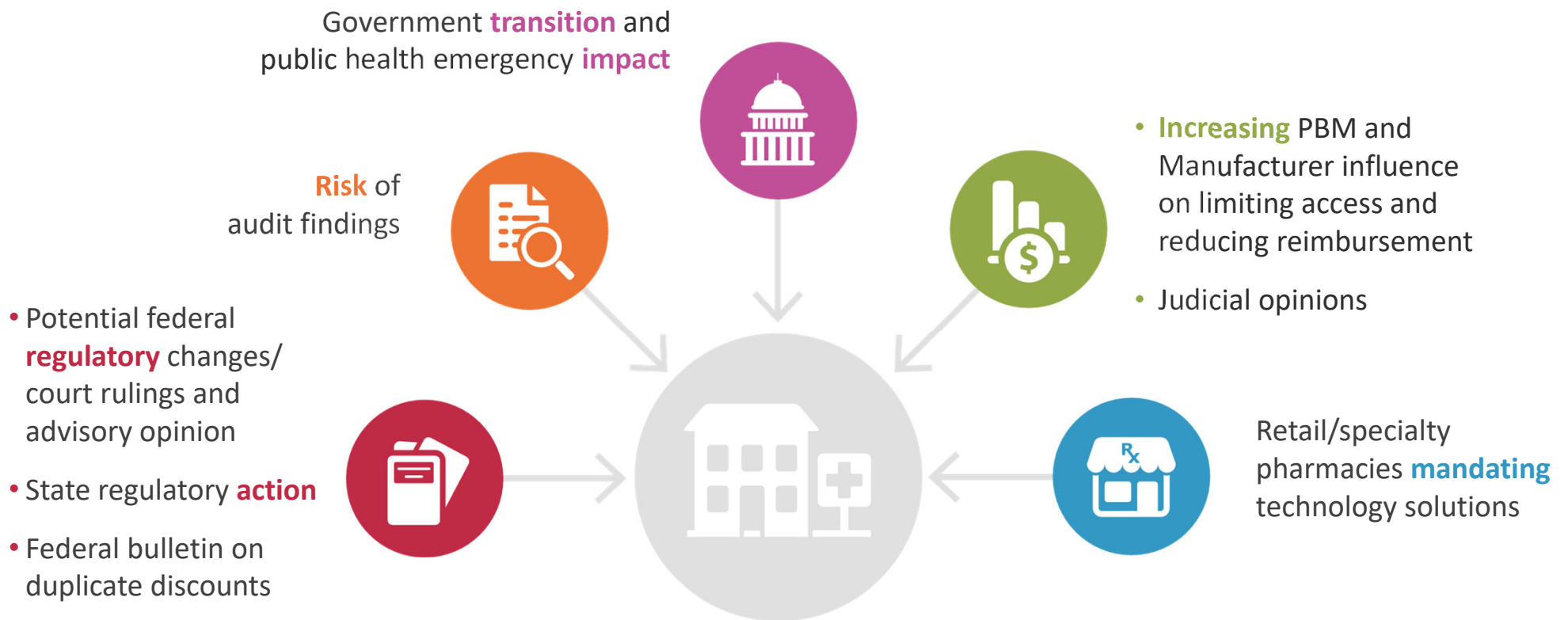
> Guidance

- Multiple contract pharmacy
- Proposed Omnibus guidance not successfully launched

> Education

- Apexus individualized certificate program
- HRSA 340B Peer to Peer Program
- 340B software certificate programs

340B trends over the decades: **2020s**



questions?



thank you



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