

Update on 340B Drug Pricing Program

LCDR Joshua E. Hardin MBA, RN/BSN, MLT
Donna Murray

Office of Pharmacy Affairs

U.S. Department of Health and Human Services
Health Resources and Services Administration
Healthcare Systems Bureau



Principal Covered Topics

- What is the mission of OPA and the programs it leads
- What is the Intent of 340B Program and Eligible Entities
- Recent Legislation and its affects on HRSA/OPA
- Program Integrity and Recertification
- Patient Safety and Clinical Pharmacy Services Collaborative (PSPC)

Office of Pharmacy Affairs Mission:

Promote access to clinically and cost effective pharmacy services



**340B Drug
Pricing Program**



**Patient Safety
and Clinical
Pharmacy Services
Collaborative**

Program Administration

- Three Legs of the OPA
 - Federal Team
 - Pharmacy Services Support Center (PSSC/PharmTA)
 - 340B Prime Vendor Program (PVP)



Intent of 340B

Permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

H.R. Rep. No. 102-384(II), at 12 (1992)

340B Eligible Entities

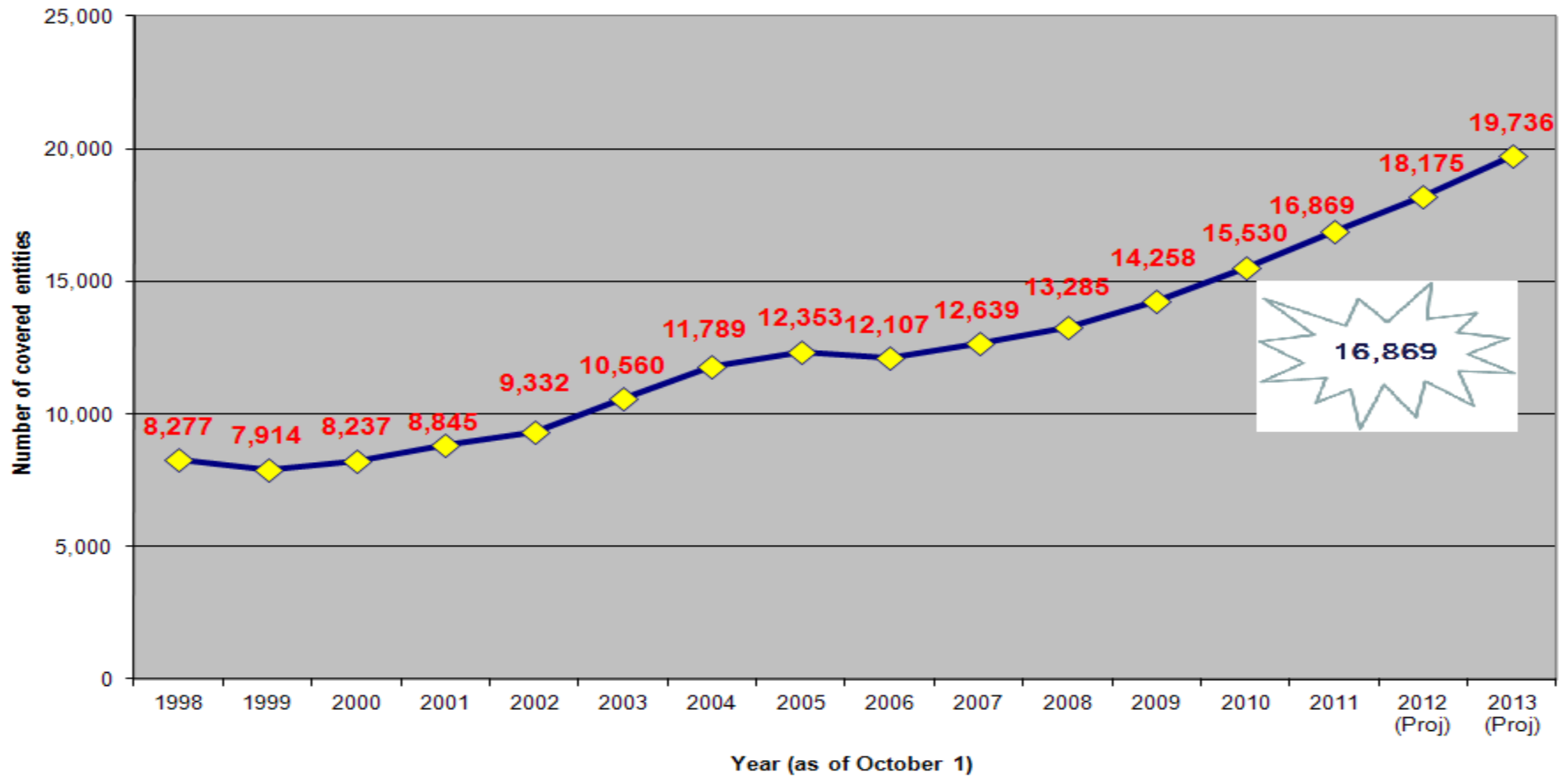
- Federally Qualified Health Centers (FQHC)
- Comprehensive Hemophilia Treatment Centers
- Ryan White Programs (Parts A, B, C, D)
- Sexually Transmitted Disease/Tuberculosis Programs (STD/TB)
- Title X Family Planning Clinics
- Urban / 638 Tribal Programs
- Federally Qualified Health Center Look-Alikes (FQHC-LA)
- Disproportionate Share Hospitals (DSH)
- Children's Hospitals
- Free Standing Cancer Hospitals
- Critical Access Hospitals
- Sole Community Hospitals
- Rural Referral Centers

Why “Definition of Patient”?

- Statute does not define “patient”
- Necessary to provide clarity on who is and is not a patient for the purposes of 340B
- Ensures against diversion and supports 340B program integrity
- 1996 FR Notice is current guidance
- New Guidance Under Development
 - Clarifies previous FR Notices of 1996 and 2007

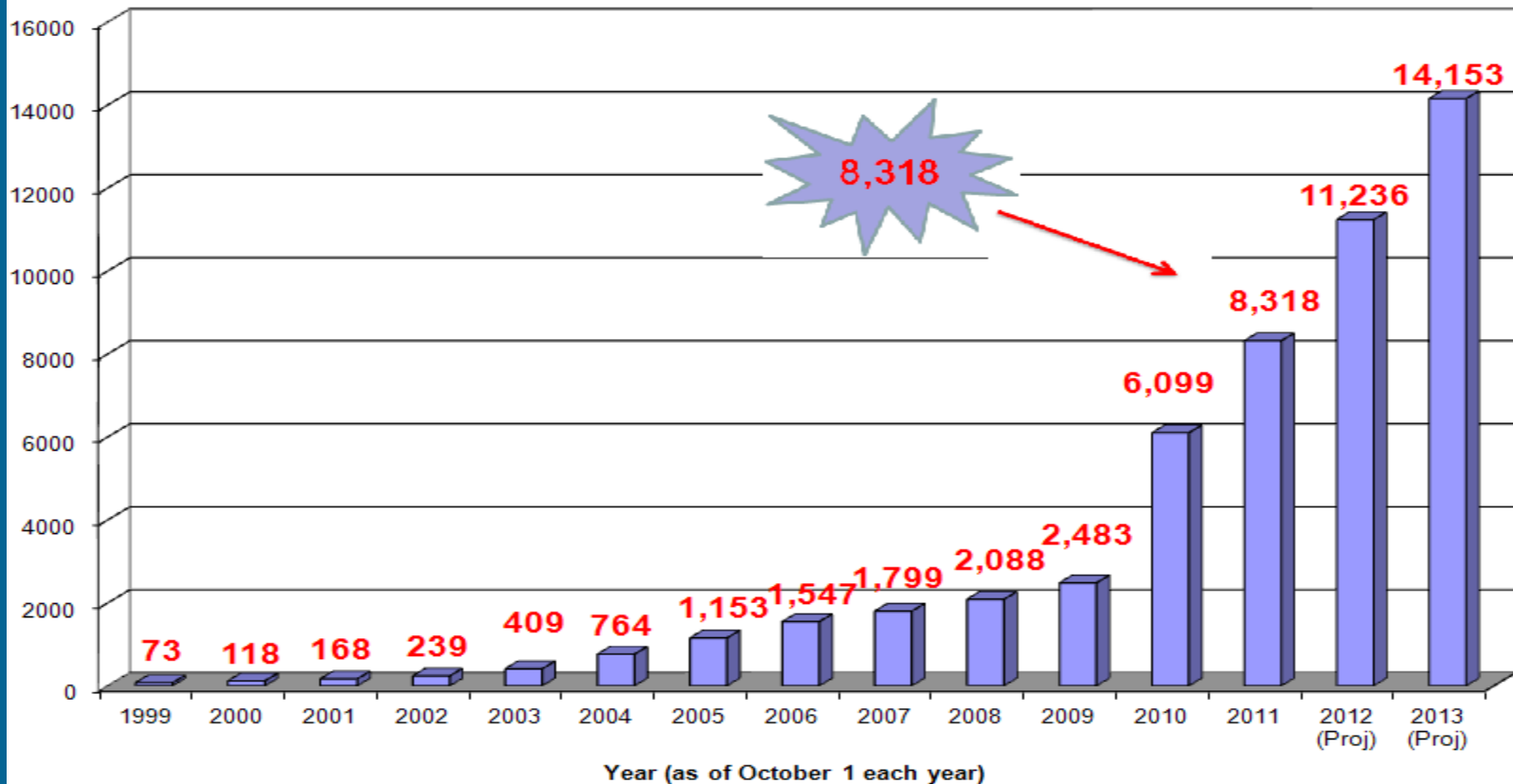
Growth of 340B Covered Entity Sites

Growth of Section 340B Covered Entity Sites



Growth of 340B Contract Pharmacies

Growth in 340B Contract Pharmacy Arrangements



What's Keeping Us Busy?

- Affordable Care Act
 - Section 7101 allowed for the expansion of the program to 5 New Entity Types
 - Section 7102 allowed for greater integrity of the 340B program
 - Annual Recertification for all entities
 - Pricing transparency
 - Civil Monetary Penalties
 - Administrative Dispute Resolution
 - Section 7103 GAO study on improvements

Recent Program Legislation

- Health Care and Education Reconciliation Act
 - Section 2302 Orphan Drug Exclusion for new covered entity types
 - Critical Access Hospitals
 - Free Standing Cancer Hospitals
 - Rural Referral Centers
 - Sole Community Hospitals
- Medicaid and Medicare Extenders Act 2010
 - Children's Hospitals exempt from Orphan Drug Exclusion

GAO Findings

- The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services.
- Covered entities interviewed reported using it for these purposes.
- Distribution of drugs at 340B prices generally did not affect providers' access to drugs.

GAO Findings cont.

- Oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements.
- 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater.

Recent OIG Study

- State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs
 - June 2011
- OIG recommendations :
 - CMS direct States to create written 340B policies
 - CMS inform States about tools they can use to identify claims for 340B-purchased drugs
 - HRSA share 340B ceiling prices with States. (HRSA will need to seek legislative authority to implement)
 - HRSA, in conjunction with CMS, improve the accuracy of the Medicaid Exclusion File

Program Integrity – Other activities

- Non-discrimination policy
- Audits
 - Authority
 - Guidelines
 - Plans

Program Integrity and Recertification

- Current:
 - FQHC grant eligibility quarterly
 - DSH percentage quarterly
 - Ownership status quarterly
- Began phased implementation of annual recertification starting 8/1/2011
 - Ryan White Programs completed October 2011
 - STD/TB-currently in process
 - IHS/Family Planning -January 2012
 - Continue with other entities as online systems are developed

Patient Safety and Clinical Pharmacy Services Collaborative (PSPC)

- Quality Improvement Collaborative aimed at improving health outcomes and patient safety for high-risk patients
- Enhance care coordination
- Foster multidisciplinary, team based care
- Strengthen patient centered medical home
- Integrate medication management

Who is involved in the PSPC?

Community based teams across the country

- Organizations include safety net provider and hospitals, public health departments, and HIV clinics
- Partners include colleges of pharmacy, primary care associations, and Quality Improvement Organizations,
- Multidisciplinary care teams delivering patient centered services to improve medication safety and health outcomes

PSPC Aim

“Patient-centered, integrated care teams, armed with cost-effective clinical pharmacy services to improve the health outcomes and safety for high medication risk patient populations in alignment with national quality standards .”

PSPC's vision:

By 2015 – 3,000 communities have an integrated delivery system that assure optimal health outcomes and patient safety

How to get involved in PSPC 4.0

1. Step 1 – Read PSPC Info Packet
2. Step 2 – Complete PSPC Participation Package (online)
 - Share contact information for team/partners
3. Step 3 – HRSA will review information and send a “welcome” email to the team lead

Website: <http://www.hrsa.gov/patientsafety>

Contact Information

Office of Pharmacy Affairs (OPA)

Web: www.hrsa.gov/opa
www.hrsa.gov/patientsafety

Pharmacy Services Support Center (PSSC)

Phone: 1-800-628-6297
Web: <http://pssc.aphanet.org>

340B Prime Vendor Program (PVP)

Phone: 1-888-340-2787
Web: <http://www.340bpvp.com>