

Organizational Developments and FDA Office of Partnerships' Activities for Pharma and Medical Devices – Current and Future

Barbara Cassens
Acting Assistant Commissioner for Partnerships and Policy
FDA/Office of Regulatory Affairs
AFDO Annual Conference
Houston, TX
June 20, 2017

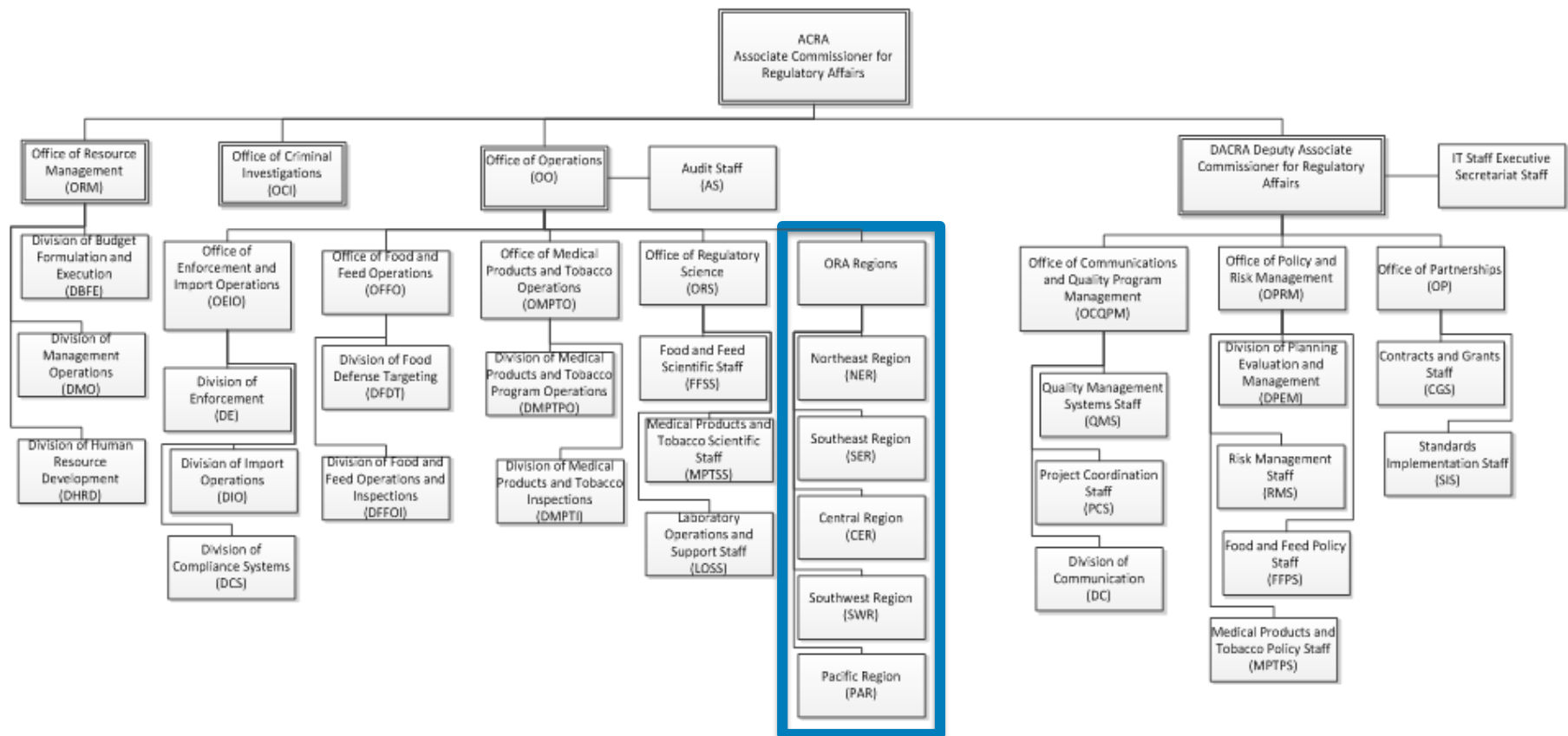
Topics Covered

- Geographically and Program Aligned Org Charts
- OP Organization, Pre and Post Program Alignment
- 2017 MQSA Contract Program
- 2017 Medical Device Contract Program
- Potential OP Future Activities for Pharma and Medical Devices
- Questions

OLD

FDA

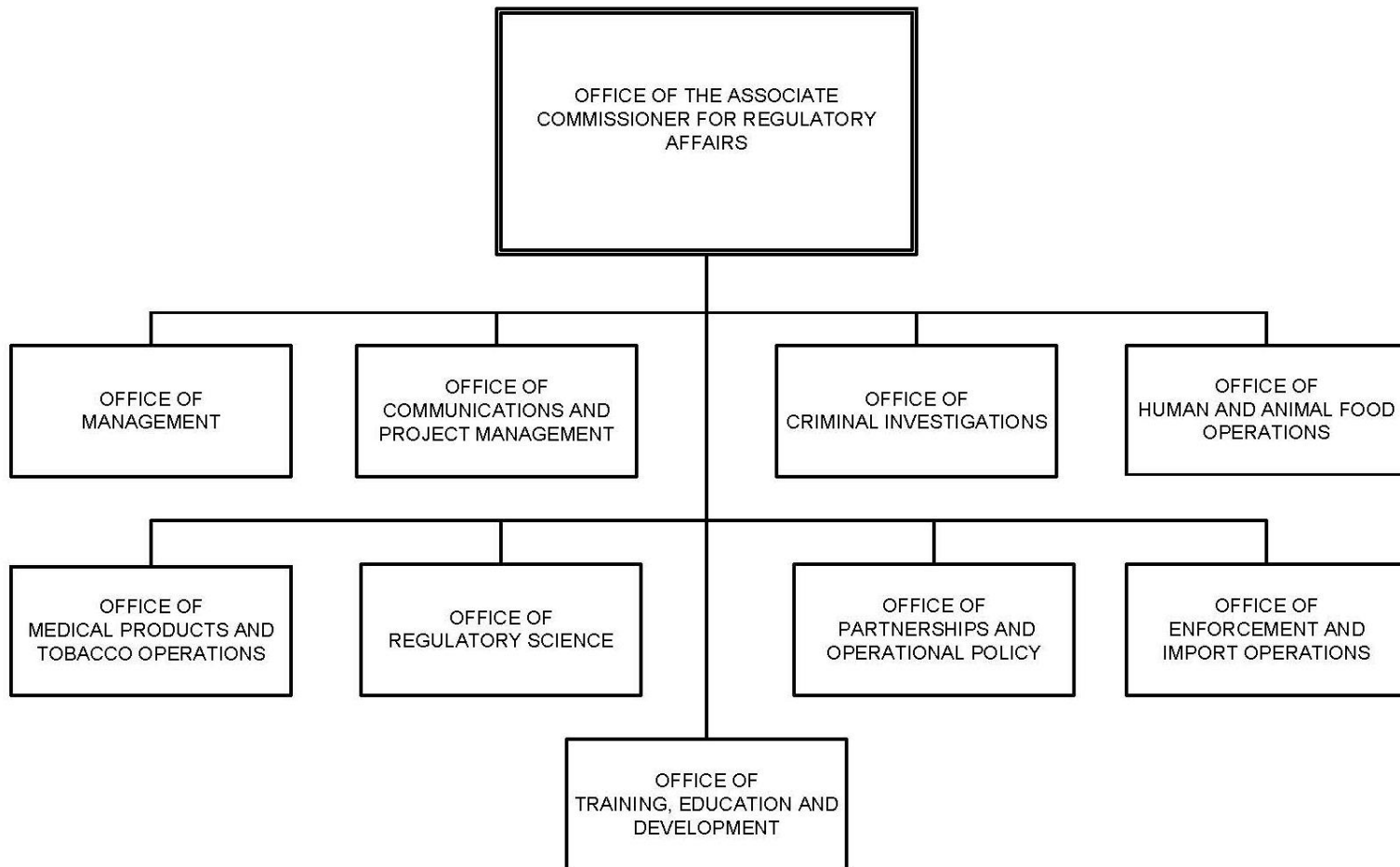
Geographically Aligned Organizational Model



New

FDA

Program Aligned Organizational Model



Office of Medical Products and Tobacco Operations



Ellen Morrison
Assistant Commissioner
Office of Medical Products and
Tobacco Operations

**Director
Tobacco Staff
[vacant]**



**Ginette
Michaud, MD**
Director, Office
of Biological
Products
Operations



**Chrissy
Cochran, PhD**
Director, Office
of Bioresearch
Monitoring
Operations

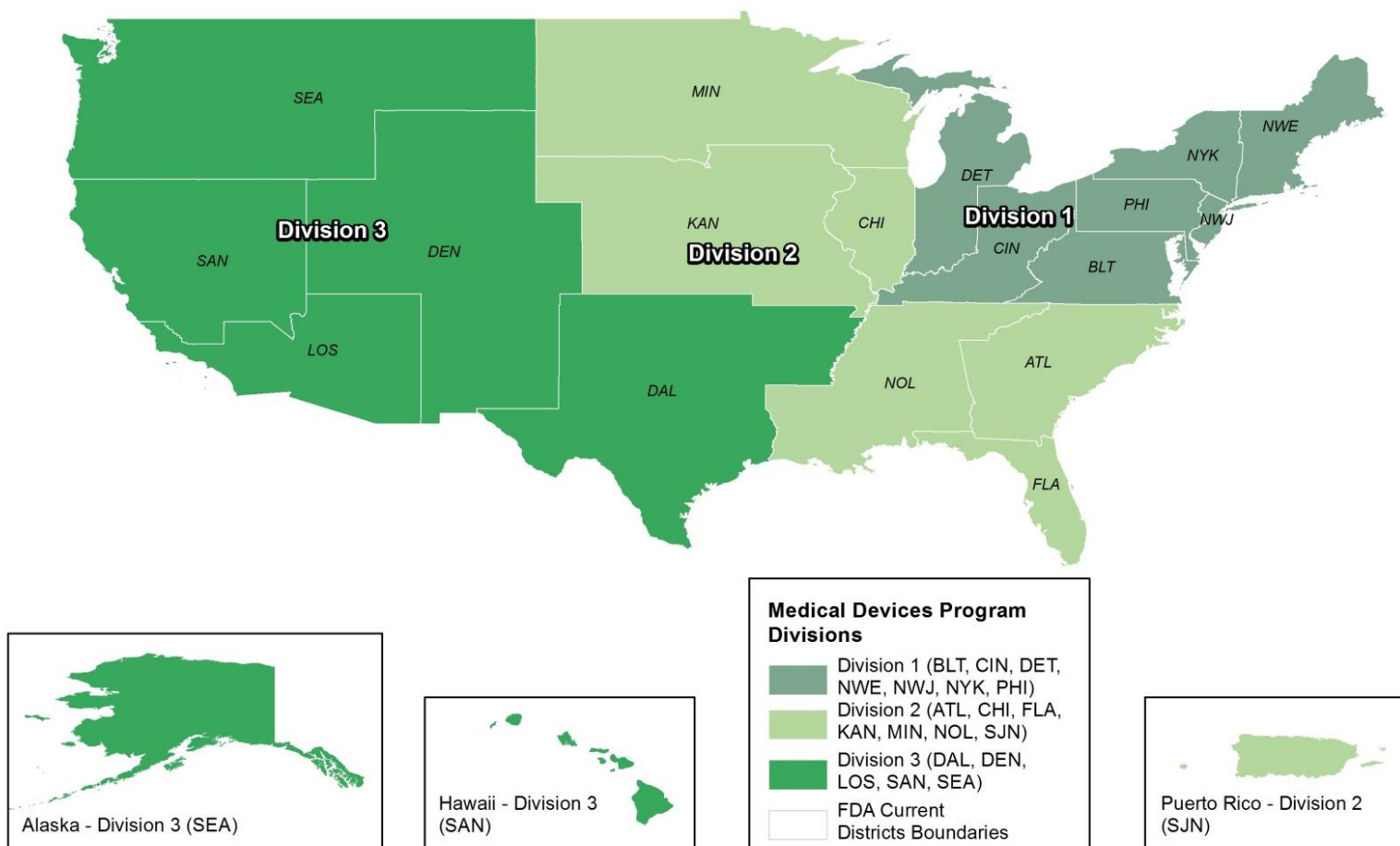


Jan Welch
Director, Office
of Medical
Device and
Radiological
Health
Operations

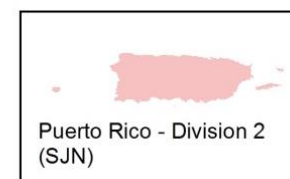
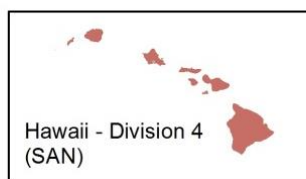
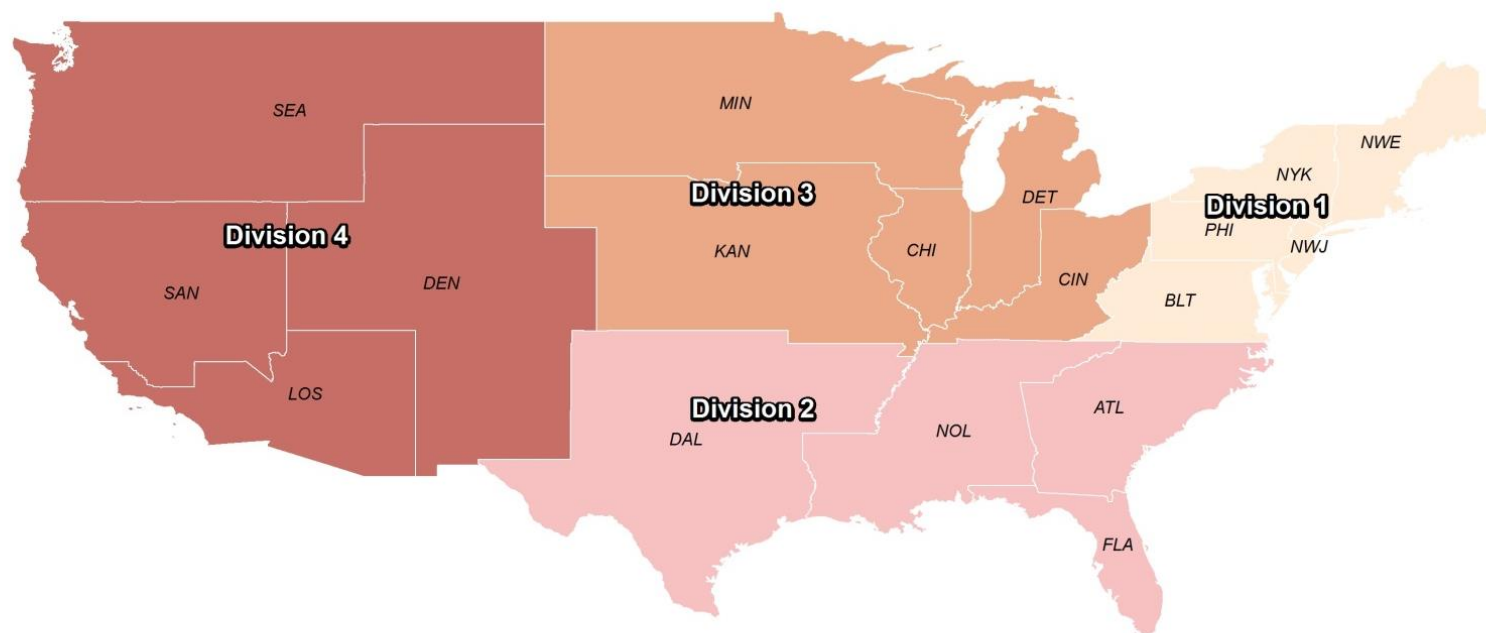


Alonza Cruse
Director,
Office of
Pharmaceutical
Quality
Operations

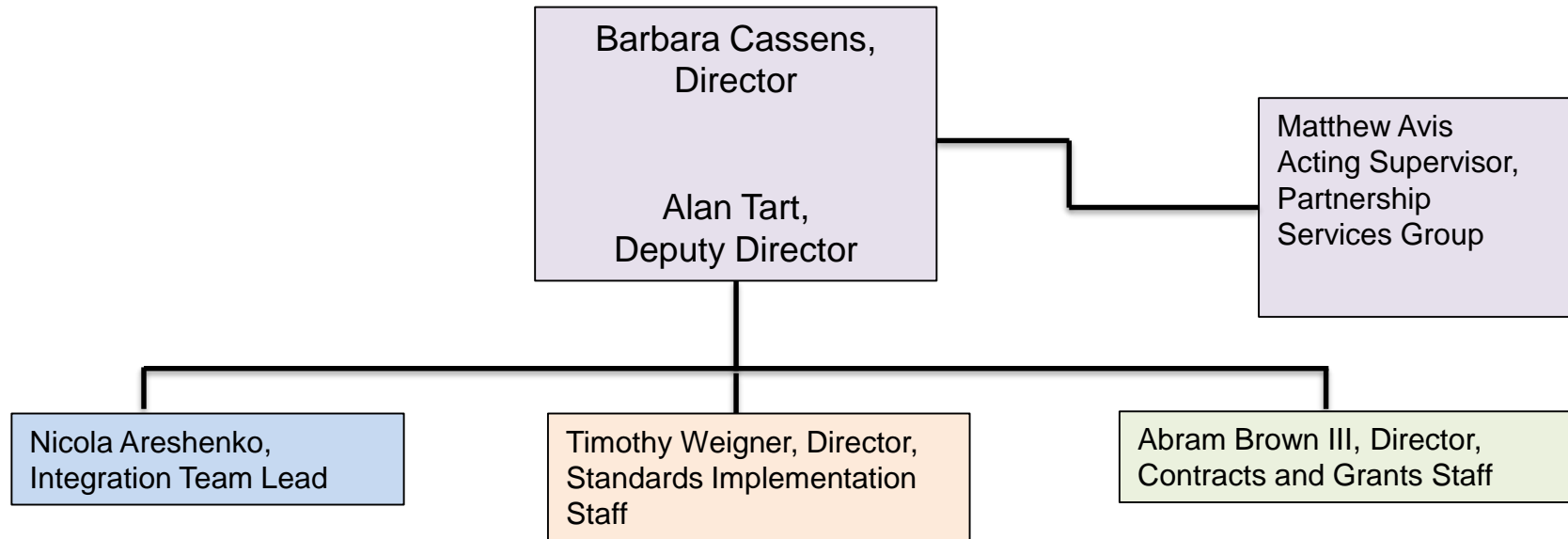
Office of Medical Device and Radiological Health Operations



Office of Pharmaceutical Quality Operations



Office of Partnerships Organizational Chart (Pre- Program Alignment)



OFFICE OF PARTNERSHIPS AND OPERATIONAL POLICY

OFFICE OF PARTNERSHIPS



Barbara Cassens
Director , Office of Partnerships

Alan Tart,
Deputy Director

DIVISION OF INTEGRATION,
Bruce Ross,
Acting Director

**DIVISION OF STANDARDS
IMPLEMENTATION,**
Timothy Weigner,
Acting Director

**DIVISION OF PARTNERSHIP
INVESTMENTS AND
AGREEMENTS,**
Abram Brown III,
Acting Director

Integration
Group, CDR
Nicola
Areshenko,
Acting
Supervisor

International
and Federal
Engagement
Group, Bruce
Ross, Supervisor

Animal Feed
Standards Group,
Dr. Jennifer
Godwin, Acting
Supervisor

Manufactured
Food
Standards
Group,
Michelle
Motsinger,
Acting
Supervisor

Human
and Animal
Food
Branch,
Wendy
Campbell,
Acting
Chief

Produce
Group,
Alicia
Schroder,
Acting
Supervisor

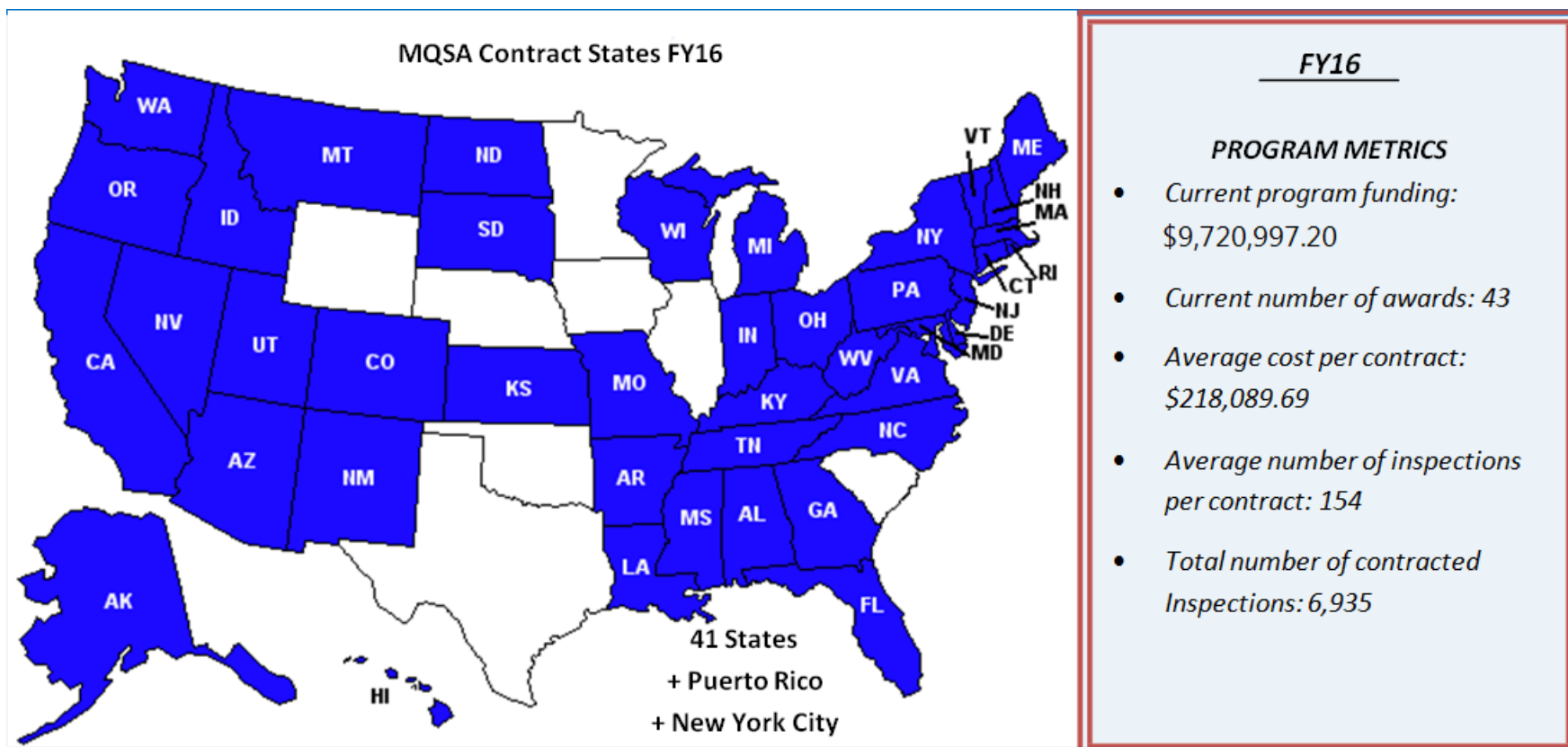
Lab,
Medical
Products,
and
Innovation
Branch,
Erin
Woodom-
Coleman,
Acting
Chief

Partnership Services
Group
Matthew Avis,
Acting Supervisor

MQSA Contract Program

- Congress mandated there be annual reporting of adverse actions taken against mammography facilities; Mammography Quality Standards Act (MQSA, Oct. 1992)
- Reports must include information that is useful in evaluating the performance of mammography facilities nationwide
- The Act requires the establishment of a federal certification and inspection program for mammography facilities
- The contract program is intended to assist state and local authorities in the inspection of certified non-federal mammography facilities

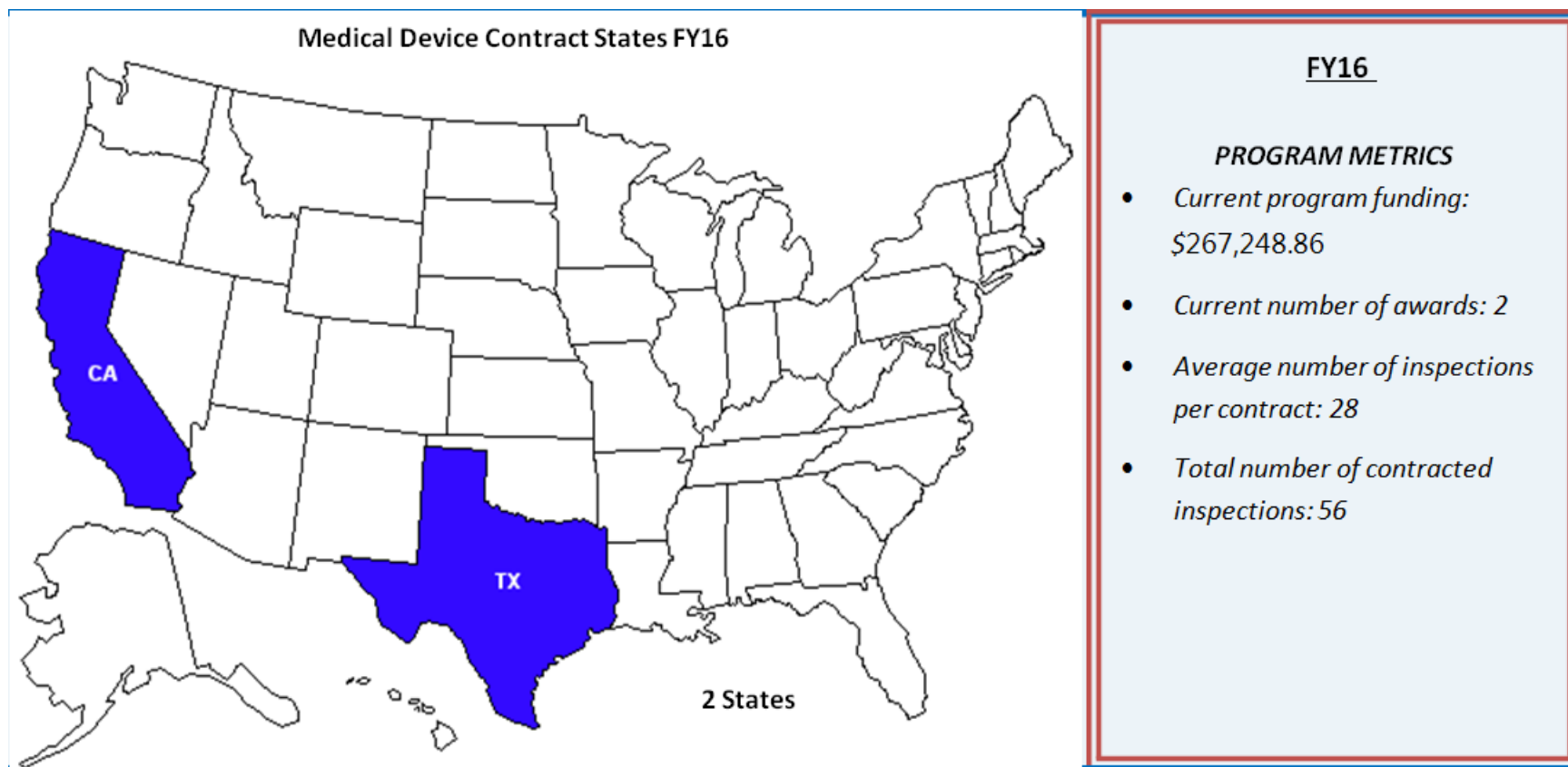
MQSA Contract Program (Continued)



Medical Device Contract Program

- This funding program provides state assistance in the inspection of Class I and Class II medical device manufacturers
- Inspections determine if facilities management has ensured that an adequate and effective quality system has been established (defined, documented, and implemented at the firm)
- By entering into these contracts, district workload can be converted from an inspectional role to a minority role

Medical Device Contract Program (Continued)



Potential OP Future Activities for Medical Devices

- Development and execution of a global medical device program workplan based on enhanced risk criteria evaluation
- Development, execution, and strategic planning for a national mammography program
- Establishment of the inspectorate capability to support a business case for annual work planning
- Development of curriculum within the program that supports sub specialty development and expertise
- Establishing training vehicles and options that complement OTED programs while advancing the sub specialization development for investigators and compliance officers

Potential OP Future Activities for Pharma?

Questions?

Feedback

- OP welcomes your feedback on this presentation and any services provided by OP
- Any feedback provided to this address will be reviewed by the Director of Office of Partnerships

OP.Feedback@fda.hhs.gov

