



United States Department of  
**Health & Human Services**

*Office of the Secretary*  
Office for Civil Rights (OCR)

# **Federal Update on HIPAA/HITECH Privacy**

Susan McAndrew, J.D.  
Deputy Director for Health Information Privacy  
HHS Office for Civil Rights

*19<sup>th</sup> HIPAA Summit*  
*March 9, 2011*



# OVERVIEW

- Status of Current Activities
  - Other HITECH Rules and Guidance
  - Status of Breach Notifications
  - Status of Enforcement and Compliance
  
- HITECH Privacy & Security Rule NPRM
  - Breach Notification and Enforcement IFR
  - Genetic Information Non-discrimination Act



# Recent OCR HITECH Activities

- Guidance on Unsecured PHI (April 2009)
- Breach Notification Interim Final Rule and Updated Guidance on Unsecured PHI (Aug. 2009)
- HITECH Enforcement Interim Final Rule (Oct. 2009)
  
- Workshop on De-identification (March 2010)
- Accounting for Disclosures RFI (May 2010)
- Security Rule Risk Analysis Guidance (July 2010)
  
- HITECH Proposed Rule (July 2010)



# Breach Notification Statistics

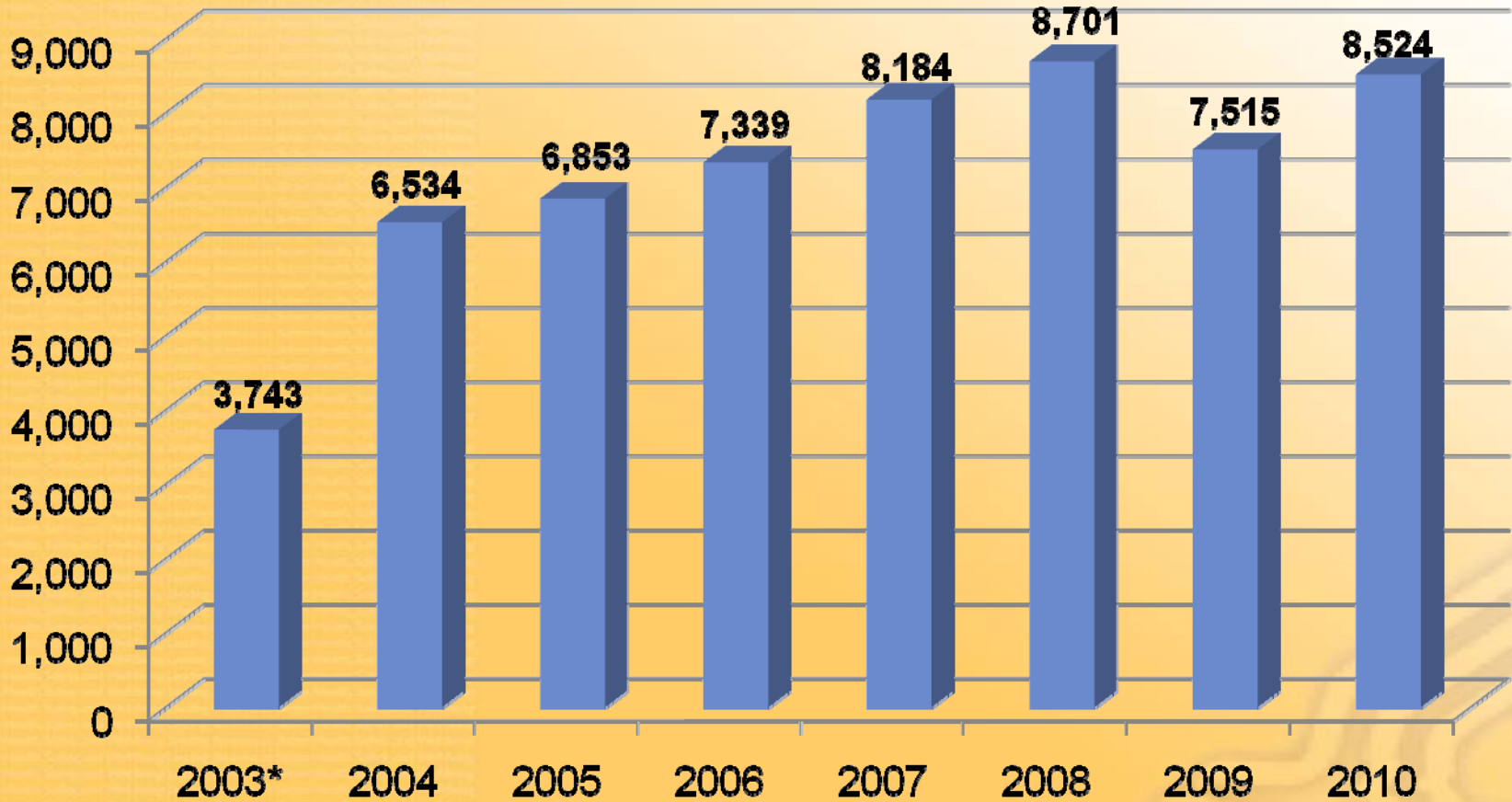
(as of February 28, 2011)

- 241 reports involving over 500 individuals posted
- Over 29,000 reports involving under 500 individuals
- Top causes of large breaches
  - Theft
  - Unauthorized Access
  - Loss
- Top media types for large breaches
  - Laptops
  - Paper records
  - Desktop Computers
  - Portable electronic devices





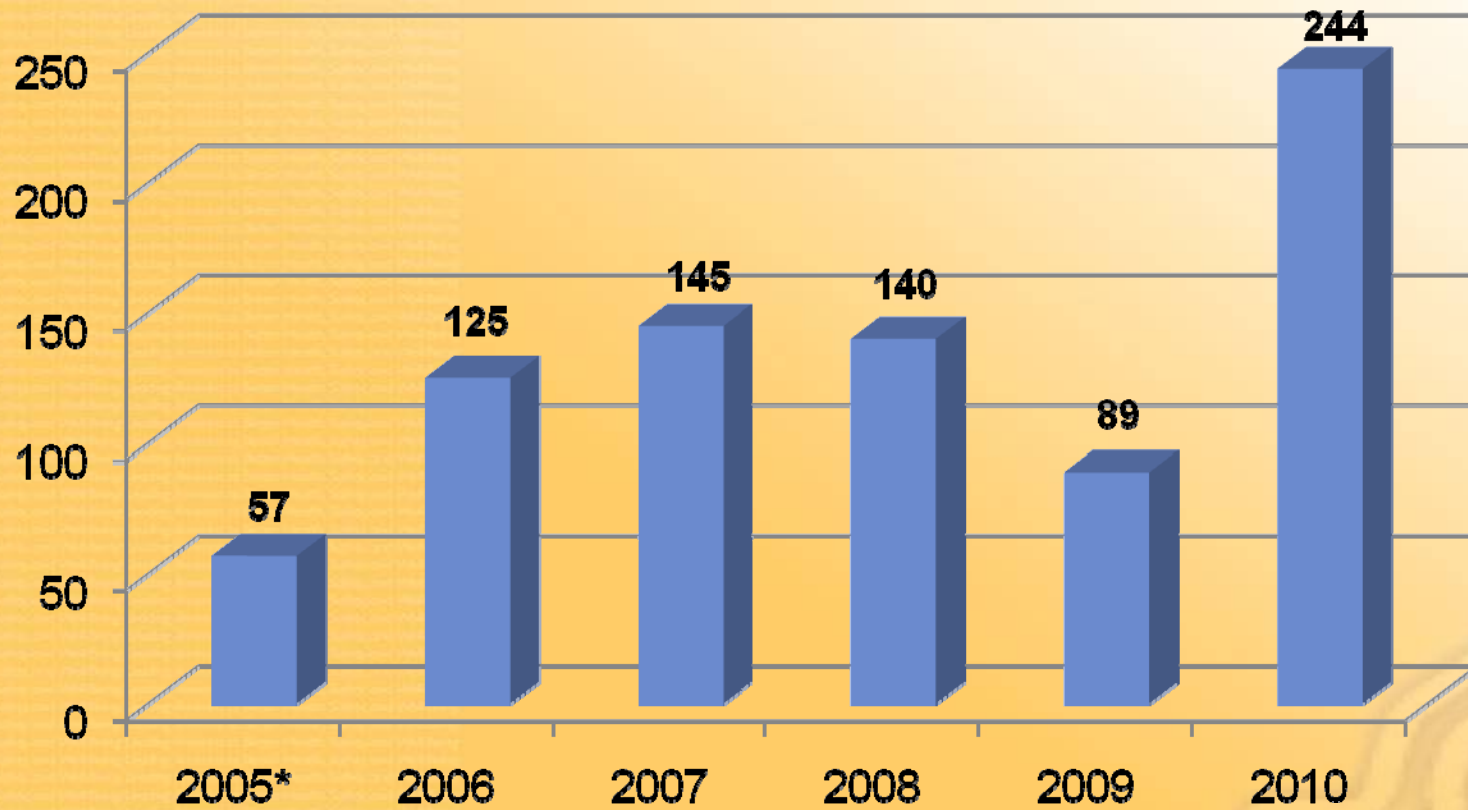
# Privacy Complaints Per Year



\* Partial year



# Security Complaints Per Year



\* Partial year



# All Privacy Complaints

## Status of All Complaints April 14, 2003 - January 31, 2011

Complaints Remaining Open (9%)

5,133

Complaints Resolved (91%)

52,986

**Total Complaints Received 58,119**

\* Referrals to DOJ - 484



# Total Privacy Investigated Resolutions

## Total Investigated Resolutions

April 14, 2003 - January 31, 2011

Corrective Action Obtained  
(Change Achieved) (66%)

12,781

No Violation (34%)

6,679

**Total Complaints Investigated 19,460**





# Enforcement Actions

- Cignet Health/Maryland (February 2011)
  - Civil Money Penalty of \$4.3 Million
  - Failure to provide access; failure to cooperate
- Massachusetts General Hospital (February 2011)
  - Loss of PHI by manager in infectious disease department; lack of safeguards in taking phi off premises
  - 3-year corrective action plan & \$1 million resolution amount
- Management Services Organization /Washington (December 2010)
  - Improper disclosure of e-PHI for marketing purposes
  - 3-year corrective action plan & \$35,000 resolution amount
  - Part of agreement with OIG and DOJ (false claims issues)

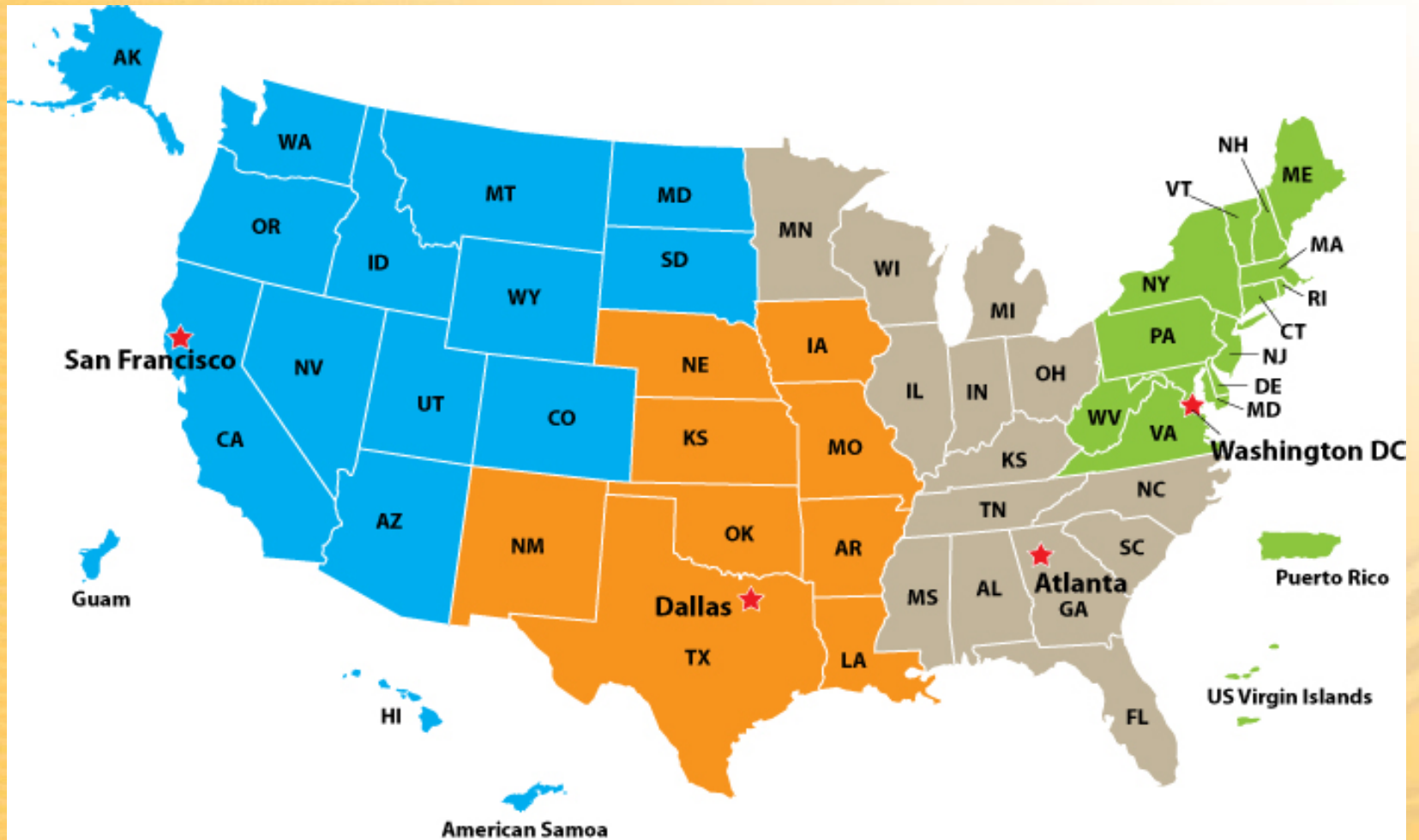


# State Attorneys General Training

- Invitations to 50 State Attorneys General and District, Territories
- 4 In-Person Training sites:
  - Dallas April 4 & 5
  - Atlanta May 9 & 10
  - Washington DC May 19 & 20
  - San Francisco June 13 & 14
- Computer based training will follow



# State Attorneys General Training Sites







# HITECH/HIPAA Proposed Rule

- Published July 14, 2010 (75 Fed. Reg. 40,868)
- Over 300 comments received by September 13, 2010
- Final Rule targeted for 2011
  - Final HITECH content in the NPRM
  - Final Enforcement and Breach Notification IFR
  - Final other HIPAA content in NPRM
  - Final GINA NPRM





# HITECH/HIPAA Proposed Rule

## ■ HITECH Content:

- Business associates
- Enforcement
- Electronic access
- Marketing ,
- Fundraising,
- No sale of PHI
- Right to request restrictions

## ■ Other Content:

- Research authorizations, Student immunization records, Decedent information



# Genetic Information Non-discrimination Act

- NPRM issued October 7, 2009
- Comments due by December 7, 2009
  - Approximately 25 comments were received
- CMS/DOL/IRS issued IFR (Oct. 2009)
  - Title I – nondiscrimination by health plans
- EEOC issued Final Rules (Nov. 2010)
  - Title II – nondiscrimination by employers



# GINA Title I Privacy

- Section 105 regarding privacy and confidentiality amends Part C of Title XI of the Social Security Act by adding section 1180.
- Section 1180 requires revision of the Privacy Rule to:
  - clarify that genetic information is health information; and
  - Prohibit health plans from using or disclosing genetic information for underwriting purposes.



# OCR GINA Final Rule

- Joint Definitions
- Coverage of Health Plans
- New Prohibition





# Accounting for Disclosures

- Request for Information (May 2010)
  - 174 comments received
- ONC Certification Standards
  - IFR issued (January 2010)
  - Final standards (July 2010)
  - Accounting certification criteria made optional for Meaningful Use Stage 1
- Notice of Proposed Rulemaking
  - At OMB (February 2011)



# Want More Information?

- The OCR website is:  
<http://www.hhs.gov/ocr/privacy/>
- My contact is:  
[susan.mcandrew@hhs.gov](mailto:susan.mcandrew@hhs.gov)