

# Compliance and Enforcement of the Privacy Rule





#### **Compliance Date**

- April 14, 2003 Compliance for all but small health plans
- One year extension for small health plans
- No statutory extension available in Privacy Rule, unlike extension available for Transaction Rule through 10/16/03



#### Office for Civil Rights

- Enforces Civil Rights laws and the Privacy Rule
- With respect to the Privacy Rule:
  - Promote voluntary compliance
  - Investigation and Resolution of Complaints
  - Exception Determinations



# Why Voluntary Compliance?

- Promoted by HIPAA statute and Privacy Rule
  - Education, Cooperation, Technical Assistance
  - Permitted even after investigation commences
  - Can help mitigate CMPs
- Most efficient way to promote privacy



#### **Technical Assistance**

- Integrated Rule and Preambles to Dec. 2000, Aug. 2002 Final Rules
- Covered Entity decision tool
- December 4, 2002
  Guidance
- Targeted Technical Assistance materials under development

- Fact sheet on August 2002 modifications
- Sample Business
  Associate Contract
- FAQs on our website
- http://www.hhs.gov/ocr/hip aa/



#### December 4, 2002 Guidance

- General Overview
- Incidental Uses and Disclosures
- Minimum Necessary
- Personal Representatives
- Business Associates
- Uses and Disclosures for Treatment, Payment and Health Care Operations

- Marketing
- Public Health
- Research
- Workers' Compensation Laws
- Notice
- Government Access
- Miscellaneous FAQs



## Investigations & Compliance Reviews

- OCR may investigate complaints
- OCR may conduct compliance reviews to determine whether Covered Entities are in compliance



#### Filing Complaints

- Any person or organization may file complaint with OCR by mail or electronically
  - Only for possible violations occurring after compliance date
  - Complaints should be filed within 180 days of when the complainant knew or should have known that the act or omission occurred
- Individuals may also file complaints with Covered Entity



#### **Complaint Process**

- Informal review may resolve issue fully without formal investigation
  - Many complaints will be resolved at this stage
- If not, begin investigation
  - Voluntary resolution yet possible
- Technical Assistance



## Civil Monetary Penalties (CMPs)

- CMPs can be imposed by OCR:
  - \$100 per violation
  - Capped at \$25,000 for each calendar year for each identical requirement or prohibition that is violated
    - Covered Entity has a right to notice and a hearing before a CMP becomes final

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#### No CMPs if:

- Person did not know and by exercising reasonable diligence would not have known - of the violation
- If failure to comply is due to reasonable cause and not willful neglect and entity corrects within 30 day cure period
- Offense is punishable by criminal sanction



#### **CMP Flexibility Summary**

- Exceptions
- Potential extension of the 30 day cure period
- CMP reduction possible if:
  - Amount excessive relative to violation
  - Due to reasonable cause/not willful neglect



# **Criminal Penalties for Wrongful Disclosures**

- For knowingly obtaining or disclosing identifiable health information relating to an individual in violation of the Rule:
  - Up to \$50,000 & 1 year imprisonment
  - Up to \$100,000 & 5 years if done under false pretenses
  - Up to \$250,000 & 10 years if intent to sell, transfer, or use for commercial advantage, personal gain or malicious harm
- Enforced by DOJ



#### **Additional Information**

#### www.hhs.gov/ocr/hipaa/

OCR Privacy Toll Free Number: (866) 627-7748

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