

Privacy Programs for the Pharmaceuticals Industry

Health Care Compliance Association Pharmaceutical Summit
Sunday, June 10, 2001

Presented by:

Brent Saunders, JD, MBA
PricewaterhouseCoopers
202-822-4089

Oliver Johnson, II, Esq.
Merk&Co., Inc.

PRICEWATERHOUSECOOPERS 

Today's Agenda

- Impact of HIPAA/privacy on Pharmaceutical and Health Care Product Companies (Brent Saunders)
- How to Build a Privacy Program (Brent Saunders & Oliver Johnson)

Why Be Concerned About Privacy?

- Legal risk
 - New laws mandate compliance
 - Some laws (eg, HIPAA) impose civil and criminal penalties for violations
 - Privacy is a growing area for plaintiff's lawyers
- Relationships with business partners
- Reputational harm in the eyes of the public
- Competitive advantage
- Growing sense that smart privacy policies can be achieved through broader information management practices

Impact on Your Company

HIPAA/privacy will have an impact at key links of the value chain of pharmaceutical and/or health care product companies

- Clinical research
- Product support services
- Post-marketing surveillance and reporting
- Sales and marketing to physicians/providers providers
- Consumer sales and marketing
- HIPAA/privacy will have an impact on most companies as an employer/self insurer

Impact -- Clinical Research

- IHI in the hands of physicians/investigators is covered by HIPAA (ie, no disclosure except pursuant to authorization or to HIPAA's research provisions)
- Research provisions
 - Requires waiver from IRB or privacy board
 - Detailed criteria for waiver and documentation
 - Notice to patients from covered entity

Impact -- Product Support

- Companies may be acting as a “business associate” in the course of product support activities
- Such disclosures would require:
 - Patient authorization or
 - Compliance with “business associate” rules

Impact -- Post-Marketing Surveillance

- Covered entities (and their business associates) may disclose:
 - To a public health authority
 - To a person subject to FDA jurisdiction (for example, to track products, enable product recalls, etc.)
- HIPAA does not permit covered entities to disclose PHI to non-governmental registries unless recipient is subject to FDA jurisdiction and FDA requires collection of information

Impact -- Human Resources

- HIPAA directly covers all employers that sponsor ERISA-covered group health plans
- Such entities will need to abide by HIPAA's
 - use and disclosure restrictions
 - administrative requirements
- Significantly, only the unit within the entity need comply with HIPAA requirements

Building a Privacy Program



A privacy program is a management process comprised of formal notice of practices and risk mitigation systems designed to safeguard and monitor an organization's use and misuse of protected or confidential information and compliance with the law.

Elements of Model Privacy Program Initiatives

1. Designate a privacy official
2. Create a privacy infrastructure
3. Development of privacy policies and procedures
4. Notice of privacy practices
5. Training on privacy
6. Safeguards (administrative, technical, physical)
7. Complaint processes (receipt & disposition)

Elements of Model Privacy Program Initiatives

8. Evaluation and ongoing monitoring of business partners and vendors use of protected information
9. Non-retaliation policy
10. Monitor regulatory landscape
11. Audit and monitor practices for compliance
12. Documentation and retention of P&P, communications, actions, activity or designations
13. Integrate into existing compliance program
14. Integrate into existing security plan