
Managing Privacy Risk in Your Commercial Practices

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Overcoming Misperceptions

- “Since HIPAA doesn’t directly cover pharmaceutical companies, there’s not much need to be concerned”
 - Many pharma activities, and activities of pharma business partners, are affected by HIPAA
 - HIPAA is only one of many laws impacting privacy
 - States are passing laws/regulations that directly cover pharma activities
- “Privacy is the latest flash-in-the-pan. Now that the HIPAA compliance deadline has passed, interest will wane”
 - The trend is in the opposite direction. HIPAA may have only heightened privacy sensitivities

Why Privacy Matters

- Customers are demanding it
- Health data is extremely sensitive
- Access to data is critical to pharma business
 - Clinical research
 - Targeted marketing
 - Pharmacovigilance
- Mistakes and lack of safeguards can lead to:
 - Adverse media attention
 - Loss of trust
 - Litigation
 - Increased regulation
- Need to understand how privacy laws/regulations will affect customers/healthcare providers

Why Privacy Is a Challenge

- Requires understanding how personal data is used within the corporation
 - Pharma companies communicate with consumers through a variety of media and for a variety of purposes. Uses and disclosures of personal information vary by program
- Requires understanding and keeping up-to-date with myriad of privacy regulations and guidance
 - US federal privacy laws
 - HIPAA
 - COPPA
 - Consumer protection laws
 - FTC
 - State AGs
 - Emerging state privacy laws
 - Texas
 - California
 - Foreign laws
 - EU Data Protection Directive
 - Canada PIPEDA

Why Privacy Is a Challenge

- Need to balance company's interest in promoting products with public's demand for privacy
 - need to consider not only legal obligations but what's "the right thing to do"
 - best practice approach to privacy may in fact be in company's best interests
- Requires development of coherent privacy program, including effective training tools

Commercial Activities with Privacy Implications

- Sales and marketing
 - Field access
 - Direct marketing
 - Web sites
 - Physician prescriber data
 - Preceptorships
 - Market research
- Sponsorship of third-party programs
 - Adherence
 - Product awareness
 - Disease awareness
- Patient assistance programs

Roadmap to Development of a Verifiable Privacy Program

Need for Verifiable Privacy Program

- Issues will arise, inadvertent mistakes may be made
- Privacy program elements:
 - Individual Responsible (Appoint Chief Privacy Officer)
 - Policies/Procedures
 - Notice / Choice / Access / Amendment
 - Data collection and retention
 - Security
 - Consideration of vendors
 - Training/Education
 - Reporting/Communication
 - Audit/Monitoring
 - Disciplinary Model
 - Incident Mitigation and Response

Privacy Program Development

Begin By

- Understanding customer concerns and perceptions
- Planning for multi-regulatory environment
 - Privacy regulation is not just HIPAA...
- Creating a cross-functional task group to evaluate and propose a comprehensive privacy initiative for the organization

Obtain Corporate Support

- Make management aware of privacy risks and accountable on a function-by-function basis
 - Communicate business case for privacy
 - Unified corporate response is required
- Obtain resources for establishment of privacy office

Privacy Program Development

Get Started

- Inventory your company's identifiable information and understand where, when and how it is collected, used, stored, and shared with third parties
- Analyze business practices and compare with legal requirements and corporate policies

Get Organized Internally

- Incorporate privacy policies into infrastructure
- Develop comprehensive privacy program, including policies, SOPs, training, monitoring and auditing

Privacy Program Development

Don't Put Form Over Substance

- Confirm that written policies and procedures accurately reflect actual practices and system capabilities

Communicate!

- Maintain privacy awareness and accountability amongst management, employees, affiliates and business partners

Finally,

- Continue to consider best privacy practices

Questions?