



Positioning You Better™

“Marketing Minefield: How to Successfully Market Healthcare under Evolving Privacy Regulations”

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Agenda

Marketing impact from...

- Federal Health Information Technology (HITECH)
- Health Insurance Portability and Accountability Act (HIPAA)
- HHS/FDA medical privacy protections and enforcement actions
- Review House and Senate Consumer Privacy bills currently before Congress
- Explore how Federal measures impact Florida

Federal Medical Privacy Regulatory Update

HITECH Privacy Final Regulations

- Original due date: February 17, 2010
- Proposed Regs issued: July 14, 2010
- Comments due by September 13, 2010
- Final Regs expected March, September, December....and we wait
- New HHS Office of Civil Rights Director
- Administration HOLD on HHS regs???



Federal Medical Privacy Regulatory Update

- Breach Notification Regulation
- Security Rule
- Electronic Medical Records
- Accounting Disclosure Rule
- Privacy Rule



HIPAA Recent Enforcement Actions

Cignet Health

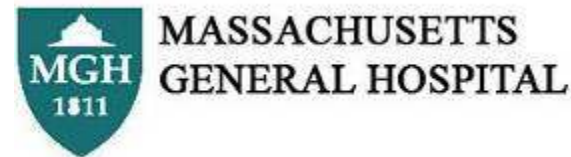
- February 22, 2011
- \$4.3 million fine



- October 5, 2011
- 20,000 ER patients

UCLA Health System

- July 11, 2011
- \$865,000 fine



- February 24, 2011
- \$1 million fine +
corrective action plan

DDMAC to Office of Prescription Drug Promotion (OPDP)

- Name change – elevation within FDA
- Division to Office
- Same strict enforcement
- Director Tom Abrams
- FDA studying DTC print, web, social media advertising



Health Care & Marketing

- The original 2000 HIPAA regulations included three exemptions to allow for marketing:
 1. health care operations
 2. treatment
 3. face-to-face communications
- The **2009 HIT** section of the America Reinvestment & Recovery Act (ARRA) **ONLY amends marketing definition for “healthcare operations”**
- Broad group generally engaged in quality assessments, legal or underwriting services, fund raising, customer service, etc.
- In general, the “business side” of healthcare

Health Care & Marketing

- New restrictions on the use of patient information for these companies effective when HITECH Privacy Regulation finalized
- Not all companies fall into this group
- Providers of treatment are expressly exempt
- Providers who engaged in face-to-face communication with patients also exempt (a separate, but sometimes overlapping exemption)

Health Care & Marketing

HIPAA communications:

1) Treatment

- *“the provision, coordination, or management of healthcare and related services by one or more healthcare providers.”*
- *“...includes such “disease management” functions as pharmacists’ provision of customized prescription drug information and advice about the prescription drug being dispensed.”*
- Current legislation does not affect any program offered by CHR within the pharmacy based on this exemption

2) Face-to-Face Communications

- Face-to-face exemption includes printed material distributed within settings where care is provided:
- Physician’s office
- Exam and waiting rooms
- Pharmacies – including written communication

Consumer Privacy/Data Breach Focus in Congress

- “BIG DATA” as “bad” as “Big Pharma” & “Big Banks”
 - NY hospital major data breach example
 - House passed data breach bill – Rep. Mary Bono Mack
- On September 22, the Senate Judiciary Committee passed three separate data breach/security measures (10-8 vote margin):
 1. Personal Data Privacy and Security Act of 2011 (S.1151), introduced by Judiciary Chair Senator Patrick Leahy (D-VT)
 2. Data Breach Notification Act (S.1408), introduced by Senator Dianne Feinstein (D-CA);
 3. Personal Data Protection and Breach Accountability Act of 2011 (S. 1535), introduced by Senator Richard Blumenthal (D-CT).
- Republicans voted against the measures on the grounds that provisions in the bills will stifle innovation, harm economic growth and job creation.
- DO NOT TRACK REGISTRY – focus is “online cookie tracking” but would include health care websites

Consumer Privacy/Data Breach Focus in Congress

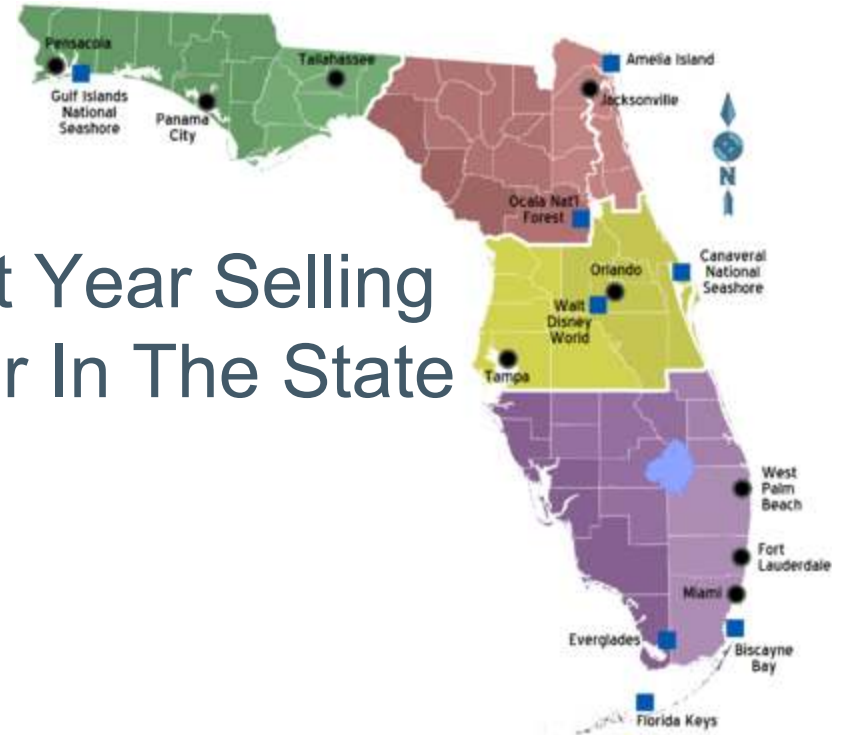
HOUSE		
Representative(s)	Bill Title	Status of Bill
Mary Bono Mack (R-CA)	The Secure and Fortify Electronic (SAFE) Data Act (H.R. 2577)	Passed Subcommittee on July 20
Jason Chaffetz (R-UT)	Geolocational Privacy and Surveillance (GPS) Act (H.R. 2168)	Introduced on June 15
Cliff Stearns (R-FL) Jim Matheson (D-UT)	Data Accountability and Trust Act of 2011, (H.R. 1841)	Introduced on May 11
Joe Barton (R-TX) Ed Markey (D-MA)	Do Not Track Kids Act of 2011 (H.R. 1895)	Discussion draft released May 6
Bobby Rush (D-IL)	Data Accountability and Trust Act (DATA) (H.R. 1707)	Introduced on May 4
Cliff Stearns (R-FL)	Consumer Privacy Protection Act of 2011 (H.R. 1528)	Introduced on April 13
Jackie Speier (D- CA)	Do Not Track Me Online Act of 2011 (H.R. 654)	Introduced on February 11
Jackie Speier (D- CA)	Financial Information Privacy Act of 2011 (H.R. 653)	Introduced on February 11
Bobby Rush (D-IL)	Online Privacy Bill, The BEST PRACTICES Act (H.R. 611)	Introduced on February 9

Consumer Privacy/Data Breach Focus in Congress

SENATE		
Senator(s)	Bill Title	Status of Bill
Richard Blumenthal (D-CT)	The Personal Data Protection and Breach Accountability Act (S. 1535)	Introduced on Sept. 8, approved by Judiciary Committee on Sept. 22
Tom Carper (D-DE) Roy Blunt (R-MO)	Data Security Act of 2011	Introduced on July 28
Dianne Feinstein (D-CA)	Data Breach Notification Act of 2011 (S. 1408)	Introduced on June 28, approved by Judiciary Committee on Sept. 22
Al Franken (D-MN) Richard Blumenthal (D-CT)	The Location Privacy Protection Act of 2011 (S. 1223)	Introduced on June 15
Mark Pryor (D-AR) Jay Rockefeller (D-WV)	The Data Security and Breach Notification Act (S. 1207)	Introduced on June 15
Ron Wyden (D-OR)	Geolocational Privacy and Surveillance (GPS) Act	Currently in draft format
Patrick Leahy (D-VT)	Personal Data Privacy and Security Act of 2011 (S.1151)	Introduced on June 7, approved by Judiciary Committee on Sept. 22
Patrick Leahy (D-VT)	Electronic Communications Privacy Act Amendments Act (S. 1011)	Introduced on May 17
Jay Rockefeller (D-WV)	Do-Not-Track Online Act of 2011	Introduced on May 9
John Kerry (D-MA) John McCain (R-AZ)	2011 Commercial Privacy Bill of Rights Act (S. 799)	Introduced on April 12

View from Florida

- Florida Made \$63 Million Last Year Selling Personal Info On Every Driver In The State - (July 21, 2011)
- Florida Board of Pharmacy
- Florida Medical Privacy Protections track HIPAA



Key Takeaways

- 1) 15 years after HIPAA enacted, Privacy enforcement remains a priority for federal regulators and legislators
- 2) HITECH Proposed Privacy Regulation does not impact the “treatment” & “face-to-face” marketing exemptions in HIPAA
- 3) Big Data/Consumer Privacy next target