Legal Strategies in HIPAA Privacy Regulation and Compliance

Bruce Merlin Fried, Esq.

The Health Colloquium at Harvard

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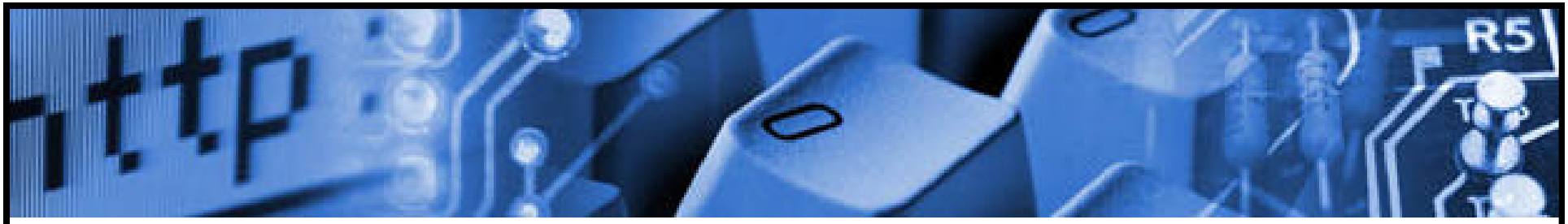
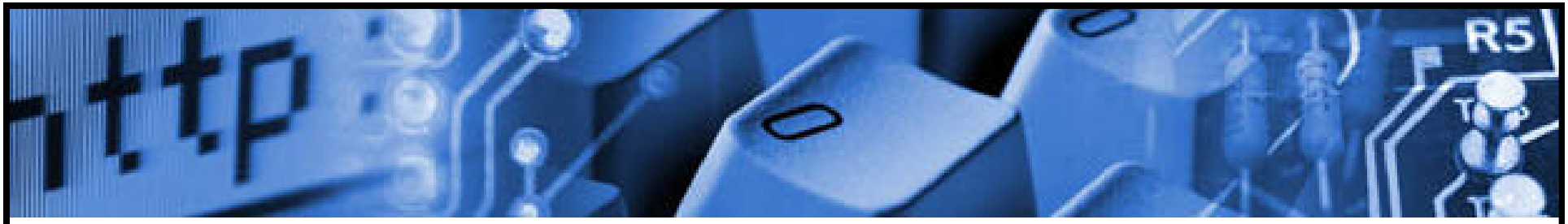
ShawPittman LLP



Where to Start?

At the Beginning…

- Who and What Are You?
  - Covered Entity
    - Plan, Provider, Clearinghouse
  - Business Associate
- Who Are Your Customers?
- The Answers Will Implicate Various HIPAA Provisions

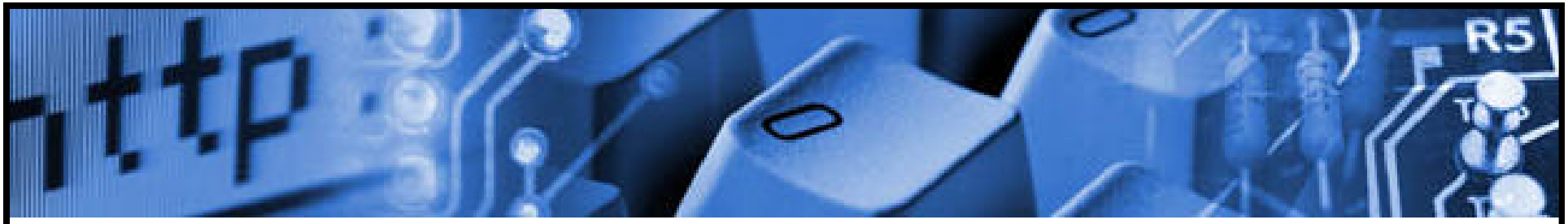


The Beginning…

Navigating the Corporate Culture

Privacy as A Business Objective

- Attitude and Culture make the difference between opportunity and obligation
- Opportunity encourages success
- Obligation encourages resistance
- Education is key!



Assessing Your Entity…

Where Are You? Where Do You Need To Be?

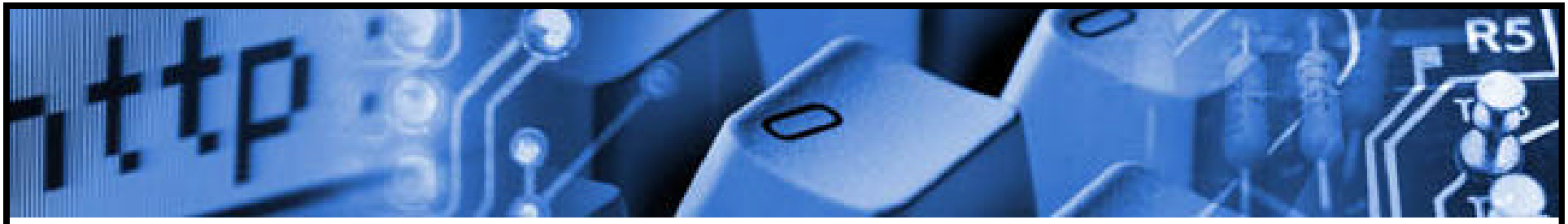
1. Is Your Data Protected?

– Is it individually identifiable health information? If so, its PHI

2. Where does PHI Flow in Your Organization?

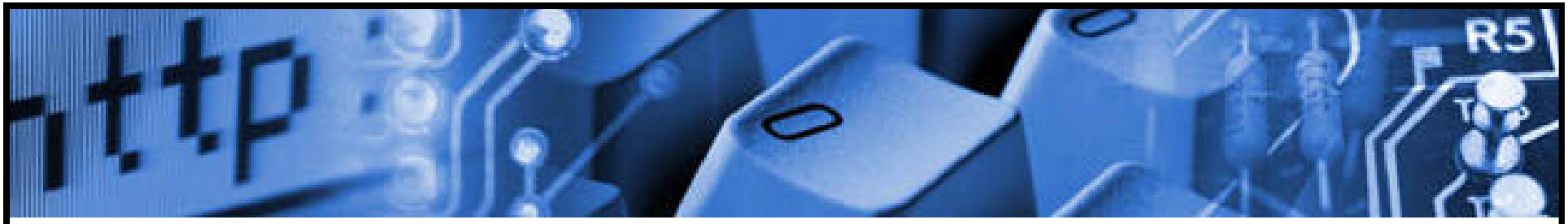
– Who sees it? Who uses it? Who discloses it? For what purpose? To Whom?

3. Are Your Policies, Procedures and Documents HIPAA Compliant?



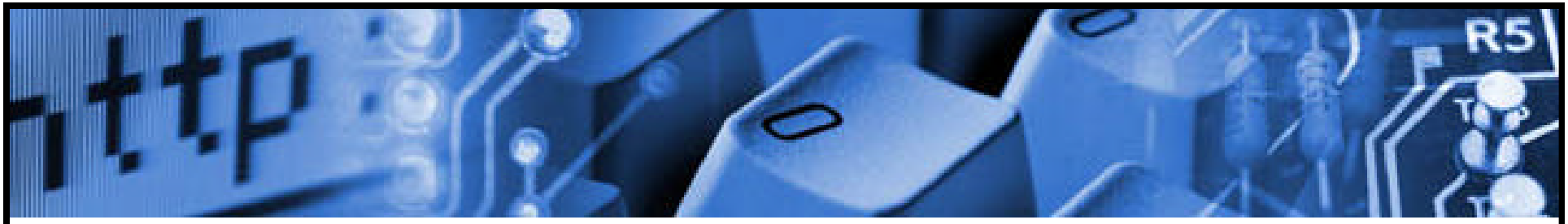
Assessing Your Entity…

4. Who Are Your Business Associates?
5. What About the Administrative Requirements? Training? Privacy Officer?
6. Are You Protecting An Individual's Right to Privacy?
7. Will Your Information Systems Meet the Challenge?



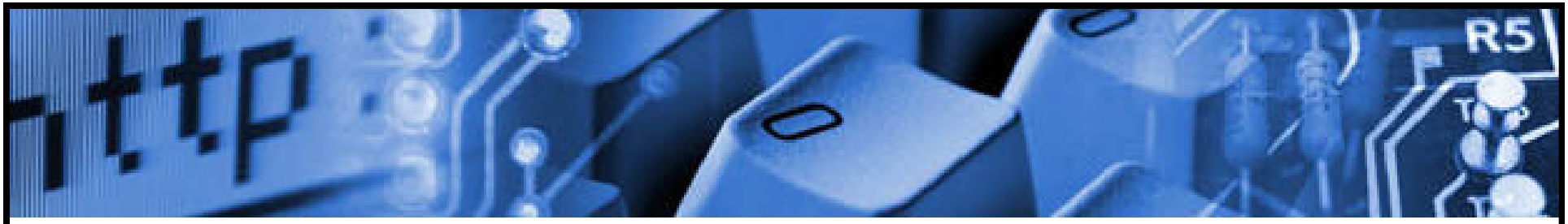
Documents

- Privacy Policy
- Notices to Patients
- Consents
- Authorizations
- Business Associate Contracts



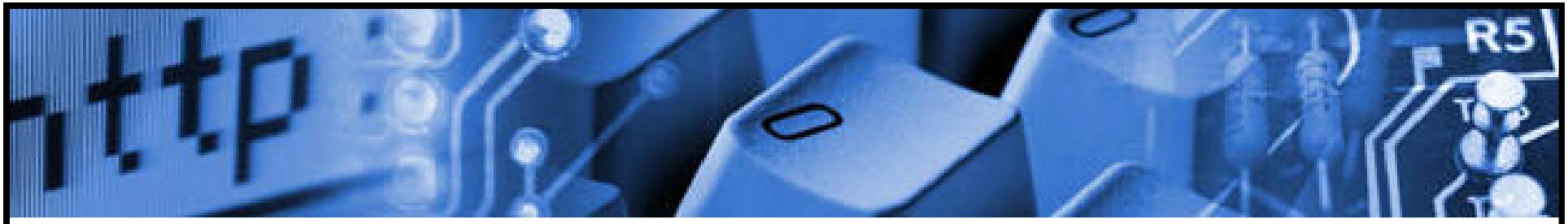
Business Associate Arrangements

- Review Existing Contracts
- Include HIPAA Business Associate Language in Agreements
  - Compliance with HIPAA, no improper use or disclosure
- Include Non-HIPAA Protections:
  - Indemnification
  - Maintenace of Insurance Coverage
  - Covered Entity Exclusive Owner of PHI



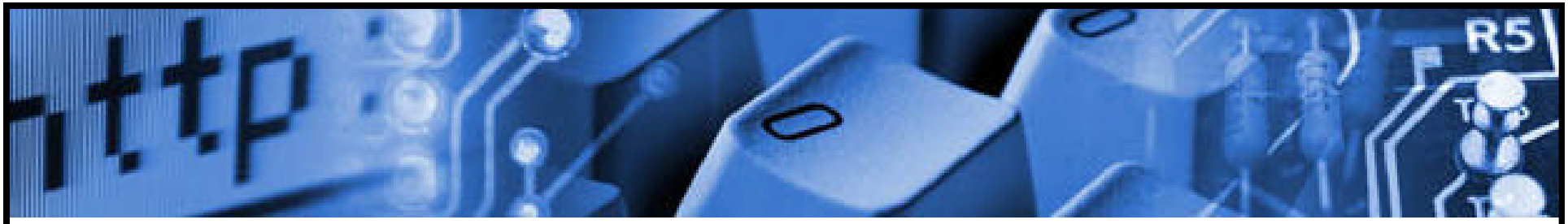
Privacy Officers/Training

- Someone Must "Own" Privacy
  - Authority to Assure Compliance
  - Point of Contact for Patients, CEs, BAs, Enforcement Officials
- Existing Staff or New Hire
- Assuring Necessary Knowledge At All Levels
  - Executives
  - Managers
  - Staff



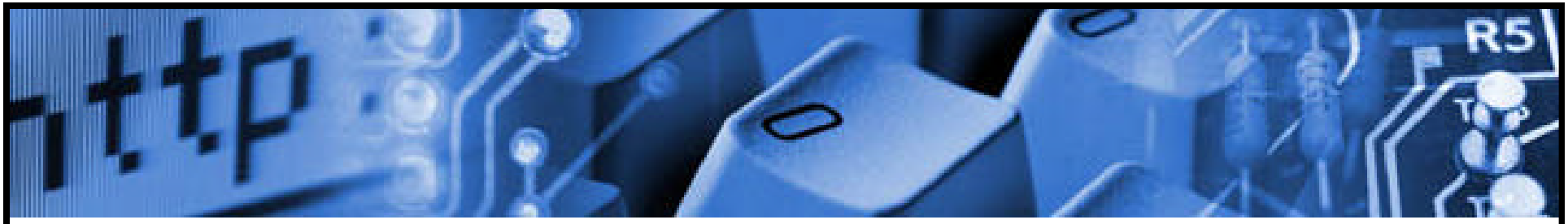
Ensuring Individual Rights

- Notice
- Confidential Communications
- Patient Access to Records
- Patient Request for Amendments
- Patient Restriction on Use/Disclosure
- Accounting for Disclosures



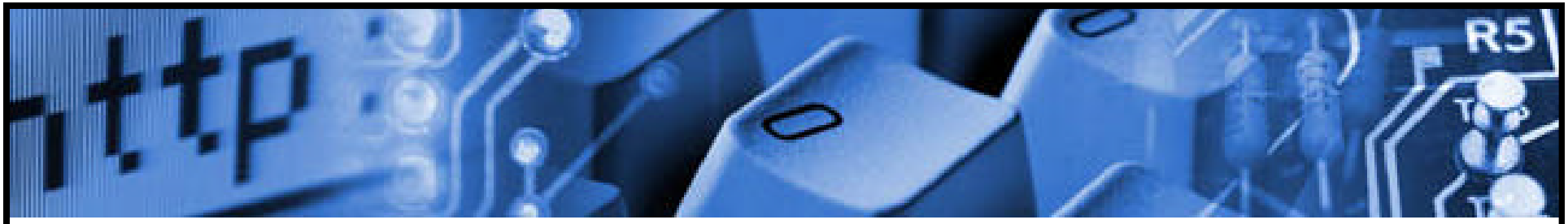
Information Systems

- Privacy Information Management
- Designated Record Sets and Document Retention
- Sunsetting of Systems



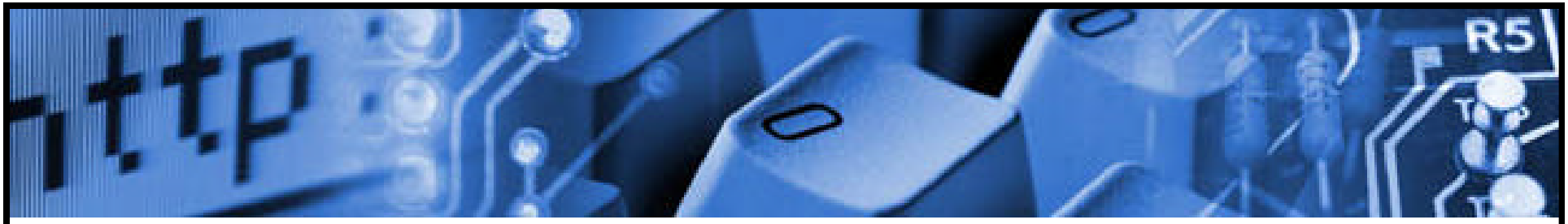
What Law Applies?

- Preemption Analysis
  - Within one state
  - Among various states
- Conflict of Laws



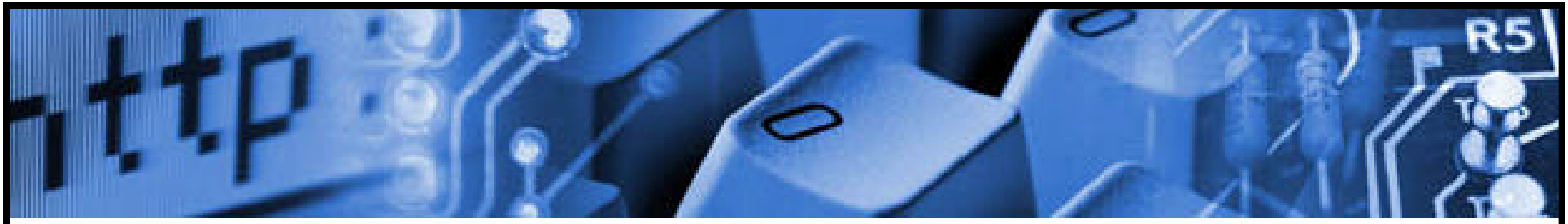
Disclosing What Is Minimally Necessary

- A “reasonable” standard
- Does each staff person need access all PHI
- Roles determines access

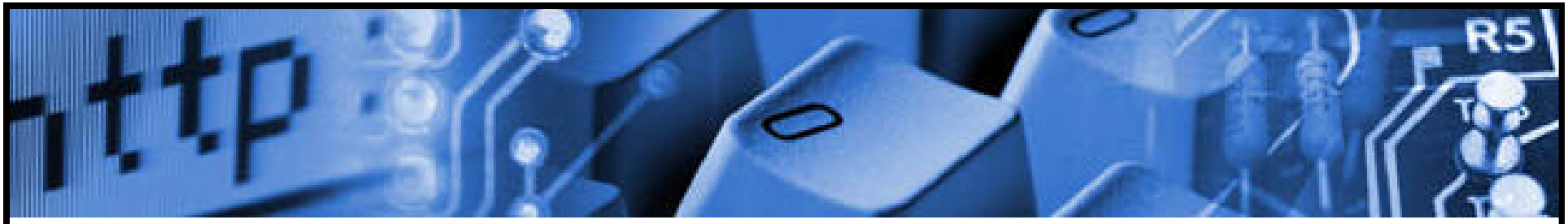


How is HIPAA Like Fraud and Abuse?

- It is more complicated than you think
- Competent Counsel is Your Best Friend

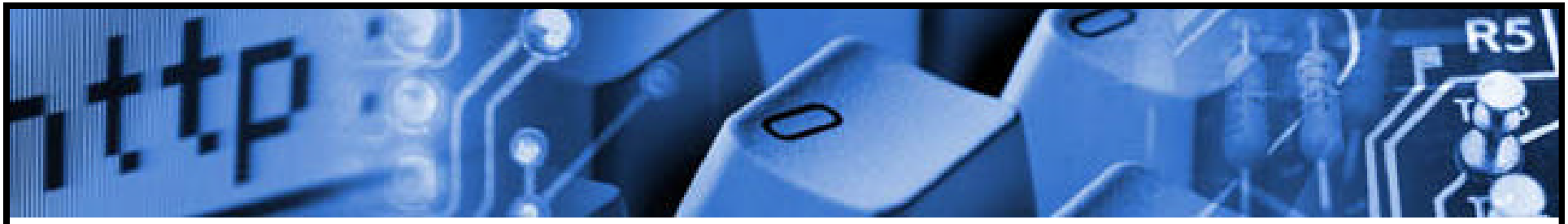


As the Rolling Stones Told Us...



As the Rolling Stones Told Us...

You Can’t Always Get What You Want ….



ShawPittman

Where Law, Business &Technology Converge

Bruce.Fried@ShawPittman.com

2300 N Street, NW
Washington, D.C. 20037

Washington Northern Virginia New York
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