



*Steven J. Snyder, Esq.*

*400 Atlantic Avenue  
Boston, MA 02110  
(617) 482 1776  
ssnyder@goulstorrs.com*

*Sumit Nagpal*

*President and CEO  
222 Third Street  
Cambridge, MA 02142  
(617) 621 9775 x311  
sumit@wellogic.com*

The Fourth National  
HIPAA Summit  
April 26, 2002

5:06: Designing Software and  
Medical Devices to Meet Your  
Customer's HIPAA Needs

# Designing Products in a HIPAA World

HIPAA and state privacy laws are here to stay, so you must design your products and services with HIPAA in mind, not only to sell them, but to sell MORE of them.

# Product Design and HIPAA

## *Getting There from Here*

- Assembling the Team
- Understanding HIPAA
- Understanding Your Customer's HIPAA Concerns
- Understanding How Your Product Impacts Your Customer's HIPAA Concerns
- Making Design Decisions
- Promotion and Education

# Assembling the Team

- **Customer Perspective Advisor:** Marketing, Product Management, Physician Advisors
- **Regulatory Advisor:** Wellogic Privacy Officer, Goulston & Storrs
- **User Interface Design:** Wellogic Design Team
- **Application Architecture and Implementation:** Wellogic Engineering Team
- **Management Executive:** CEO

# Internalizing HIPAA

- Tools for learning how to fish
  - Memos
  - Charts
  - Presentations
  - Feedback
- What to do when the rules change

# HIPAA Is

- Administrative Simplification Section of Health Insurance Portability and Accountability Act of 1996
- A series of regulations in draft and final form promulgated by the Department of Health and Human Services
- A potential source of liability for certain “Covered Entities”
- A structure for addressing privacy and security issues

# Scope of HIPAA

Privacy

Transactions

Security

---

Disclosure

Format

Physical

Use Restrictions

Conditions

Electronic

Consent /  
Authorization

Content

Encryption

Audit Rights

Codes

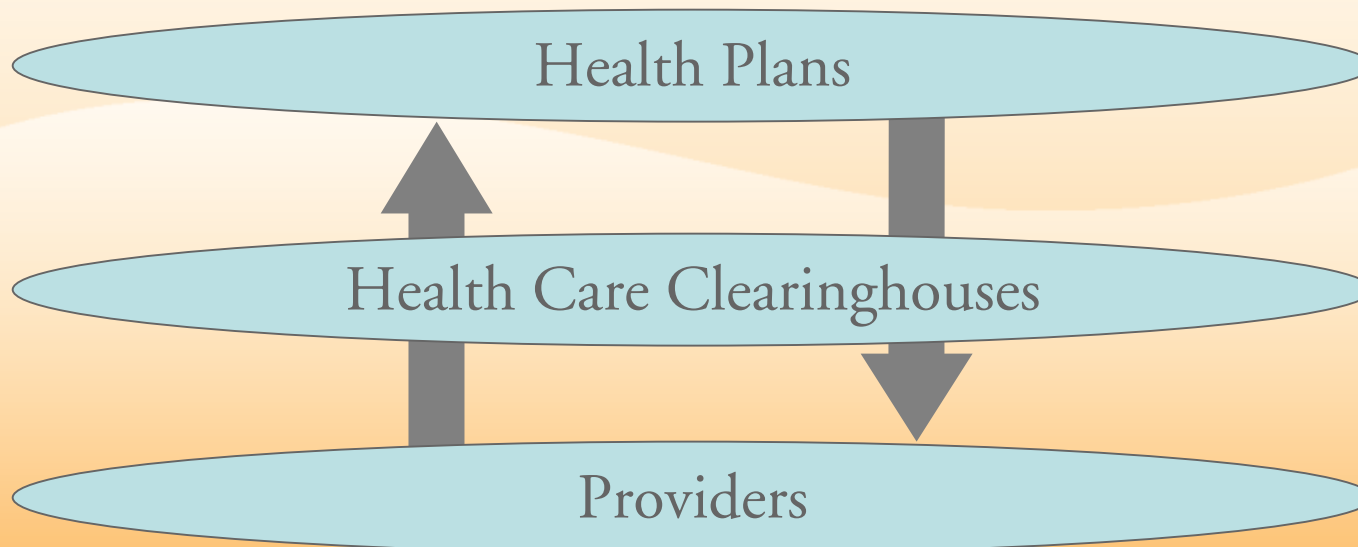
Assessment and  
Planning

# Scope of HIPAA

Privacy

Transactions

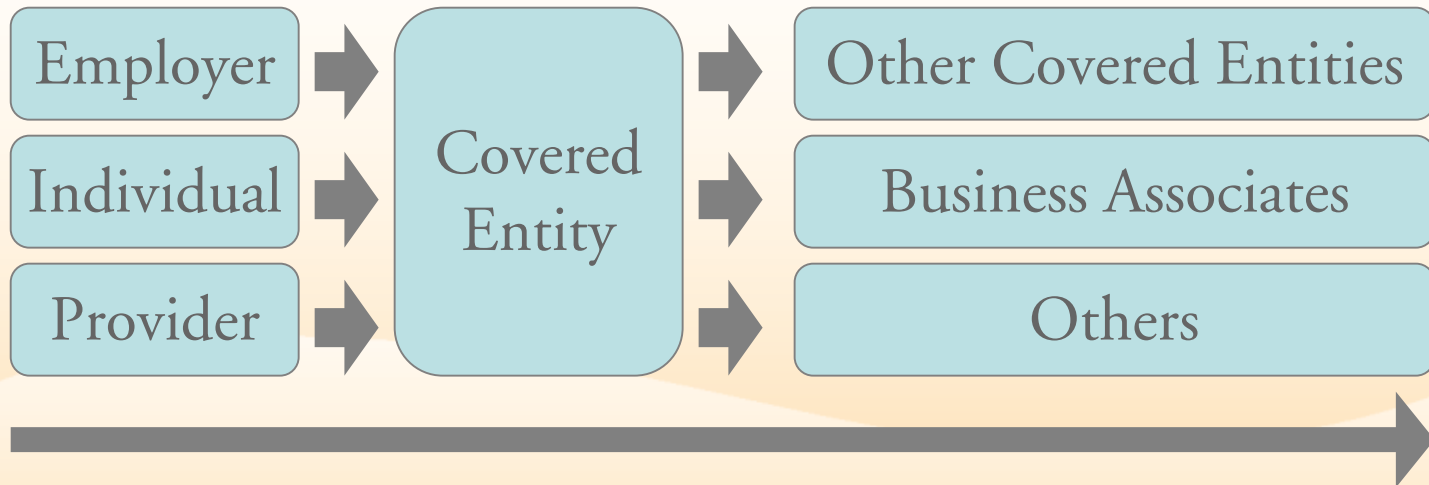
Security





# Covered Entities Under HIPAA

## *Six Things They Need to Worry About*



HIPAA  
Requirements

- Notice
- Permission
- Access
- Security
- Responsibility
- Oversight

# Covered Entities Under HIPAA

## *Six Things They Need to Worry About*



### Notice

- *Permission*
- *Access*
- *Security*
- *Responsibility*
- *Oversight*

### Right to Adequate Notice of Policies and Procedures for Use and Disclosure

- Mandatory content and format
- Delivery: original, when revised and when requested [NPRM]
- Web posting
- Electronic notice
- Document compliance (retaining copies of Notice and record of deliveries and requests)

# Covered Entities Under HIPAA

## *Six Things They Need to Worry About*

- *Notice*
- ➔ **Permission**
- *Access*
- *Security*
- *Responsibility*
- *Oversight*

### No Use or Disclosure Without Appropriate Type of Permission

- Payment, Treatment or Operations: Consent [NPRM]
- Restrictions and Requests
- Authorizations [NPRM]
- Exceptions
- Deidentification
- Minimally Necessary Disclosure [NPRM]
- Document compliance

# Covered Entities Under HIPAA

## *Six Things They Need to Worry About*

- *Notice*
- *Permission*
- ➔ **Access**
- *Security*
- *Responsibility*
- *Oversight*

### Rights to Access, Audit and Amend PHI

- Right to access a copy of most records within 30 days
- Right to amend (action within 60 days)
- Right to an Accounting
- Document compliance

# Covered Entities Under HIPAA

## *Six Things They Need to Worry About*

- *Notice*
- *Permission*
- *Access*
- ➔ **Security**
- *Responsibility*
- *Oversight*

“appropriate administrative, technical and physical safeguards to protect the privacy of protected health information”

# Covered Entities Under HIPAA

## *Six Things They Need to Worry About*

- *Notice*
- *Permission*
- *Access*
- *Security*
- ➔ **Responsibility**
- *Oversight*

- Privacy Official
- Training: workforce and others
- Institutional safeguards and sanctions
- Business Associate Contracts
- Document compliance

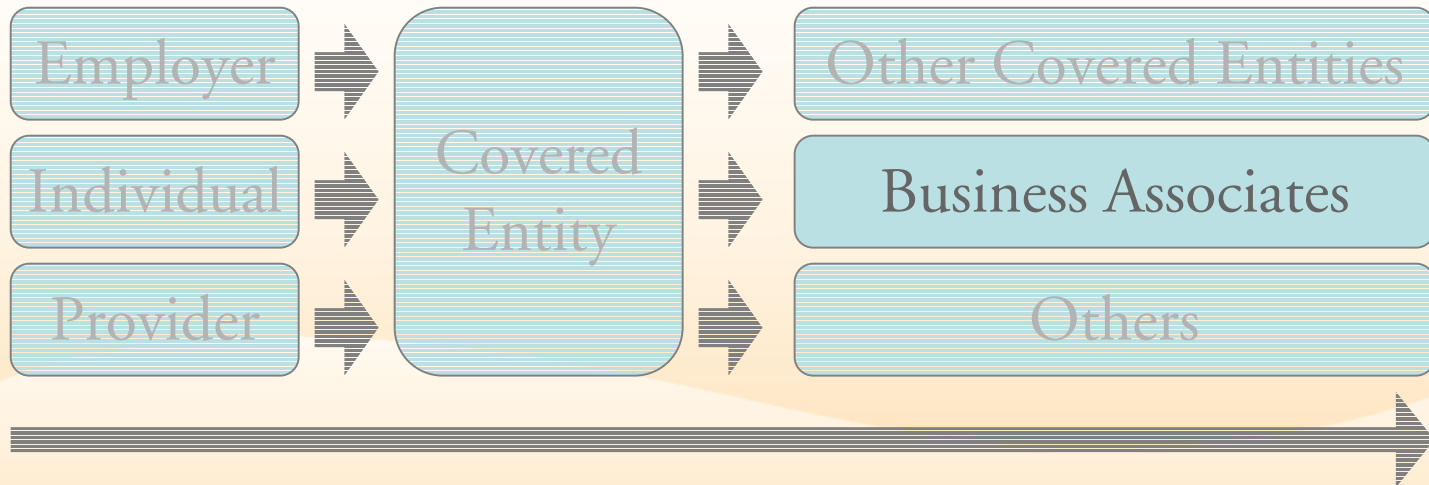
# Covered Entities Under HIPAA

## *Six Things They Need to Worry About*

- *Notice*
- *Permission*
- *Access*
- *Security*
- *Responsibility*
- ➔ **Oversight**

- Documentation
- Evidence of Sanctions
- Demonstration of Technology

# What is a Business Associate?



“person or entity that performs or assists in the performance of a function or activity involving the use or disclosure of PHI”

E.g., third party: legal, actuarial, accounting, JCAHO, claims, pro bono volunteer, software vendor, TPA, PPO



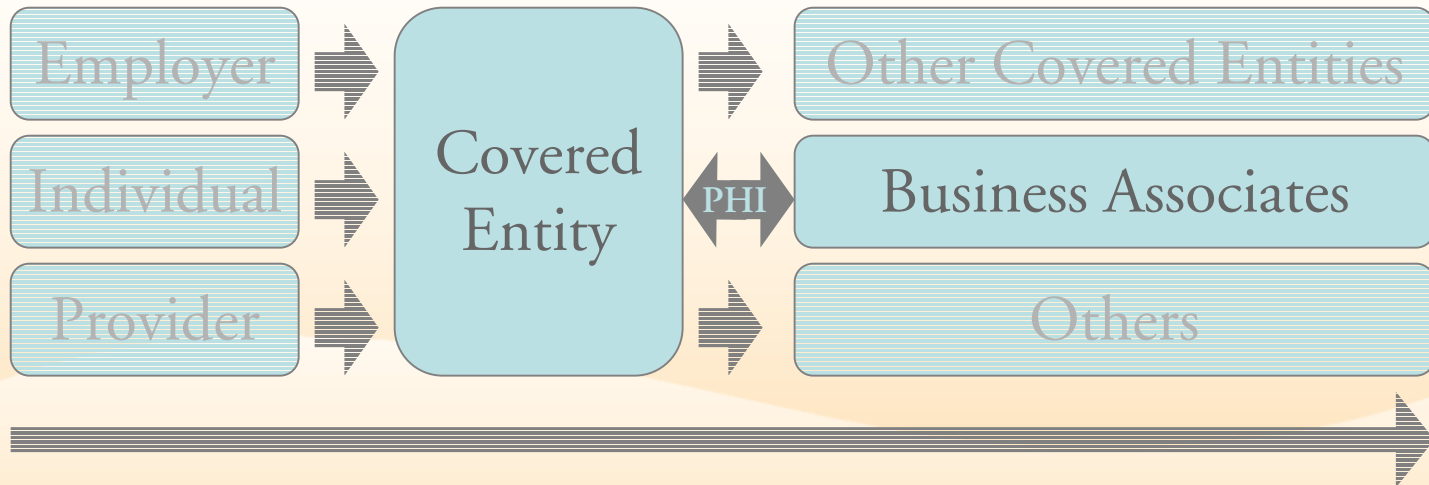
# Business Associates and HIPAA

## *Must They Worry?*

If not itself a Covered Entity, a Business Associate is NOT directly regulated by HIPAA

BUT .....

# Satisfactory Assurances



## Before Using or Disclosing PHI:

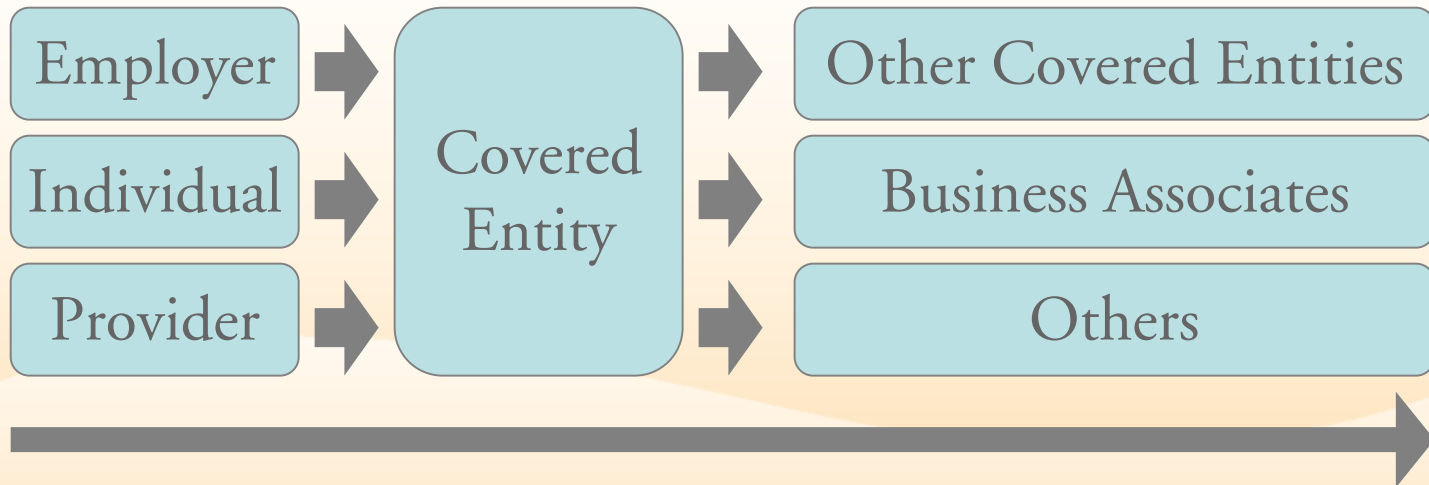
Covered Entity must obtain in writing **satisfactory assurances** that the business associate will properly safeguard the information

# Contractual Provisions

Three categories of provisions:

1. Permitted and required uses and disclosures
2. Specific covenants
3. Termination Provisions

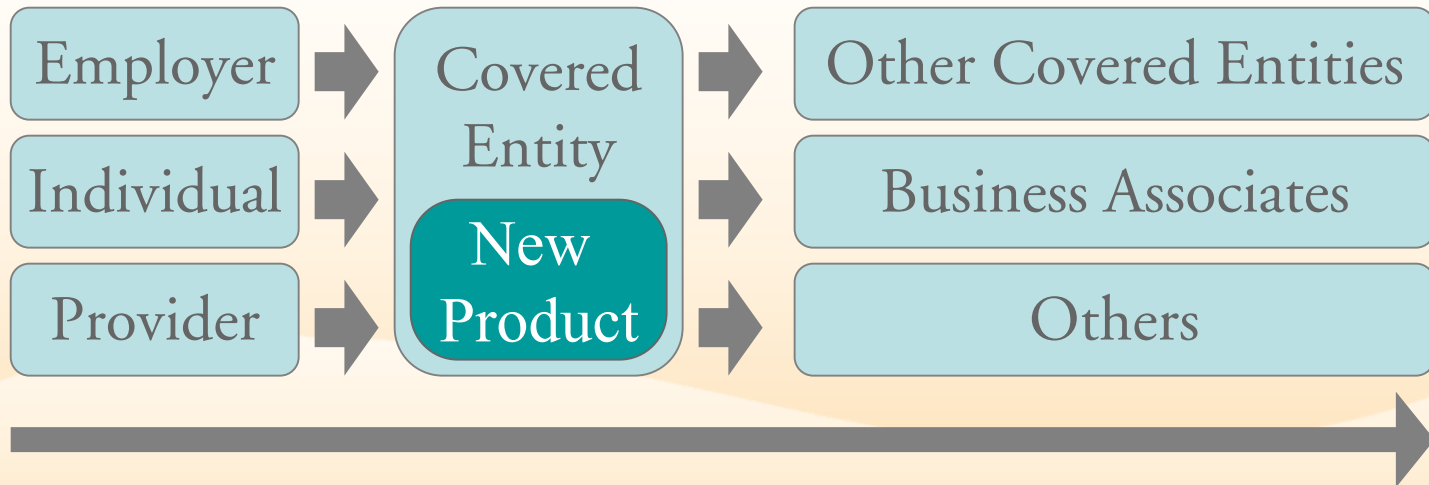
# Your Customer's Understanding of HIPAA Privacy



HIPAA  
Requirements

- Notice
- Permission
- Access
- Security
- Responsibility
- Oversight

# Your Product and Your Customer's HIPAA Concerns



If Covered Entity adds  
New Product ... How does  
it impact / help / harm  
Covered Entity's efforts to  
address the HIPAA issues?

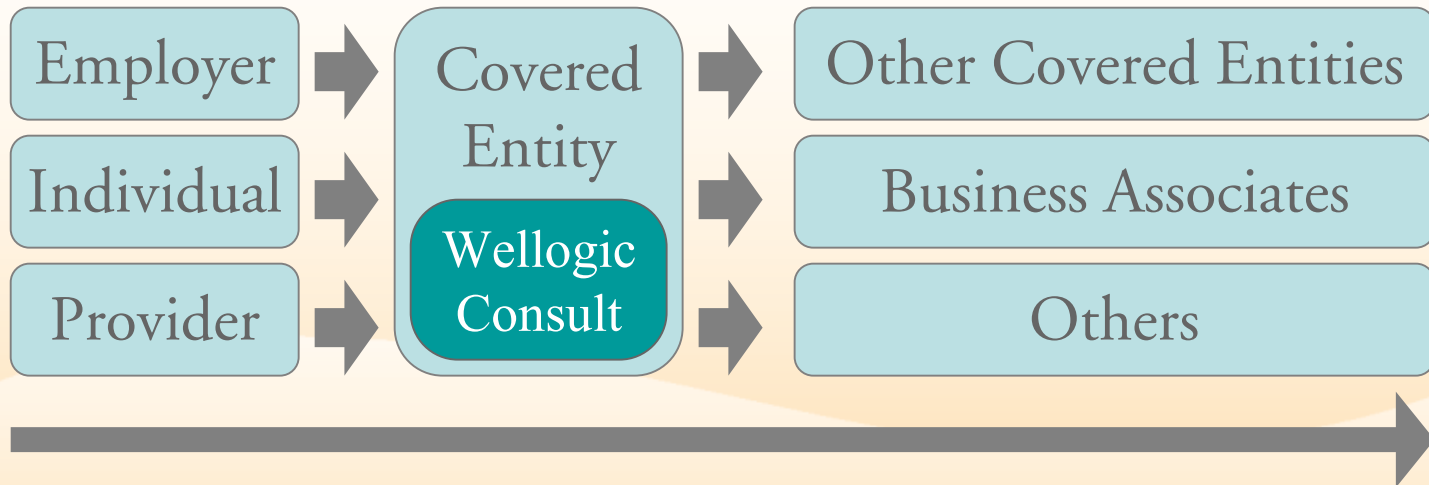
- Notice
- Permission
- Access
- Security
- Responsibility
- Oversight

# A Representative Product: *Wellogic Consult*

## Consult...

- Is a modular clinical applications platform
- Unifies patient information across the continuum.
- Provides clinical decision support at the point of care.
- Enables communication among providers and patients within and between organizations.
- Enhances patient safety, protects patient privacy, improves patient and provider satisfaction and reduces healthcare costs.
- **While supporting HIPAA compliance for your organization.**

# Wellogic Consult



In depth HIPAA  
coverage that also  
solves clinical needs

- Notice
- Permission
- Access
- Security
- Responsibility
- Oversight

Screenshot removed



Screenshot removed

Screenshot removed

# Low Hanging Fruit

- Certain parts of HIPAA are easy to support
  - Notice
  - Access
  - Security
  - Oversight
- Other parts of HIPAA are harder
  - Amendment
  - Permission

# HIPAA: Access

- Consult helps provide access to medical records
  - Allow Patients to See their Record
  - Allow appropriate clinicians to see the record
  - Audit Trail
  - Allow patients to request an amendment to their record
  - Inform appropriate people of an amendment to the record
- As a clinical matter, how does this work?

Screenshot removed

Screenshot removed

Screenshot removed

# HIPAA: Permission

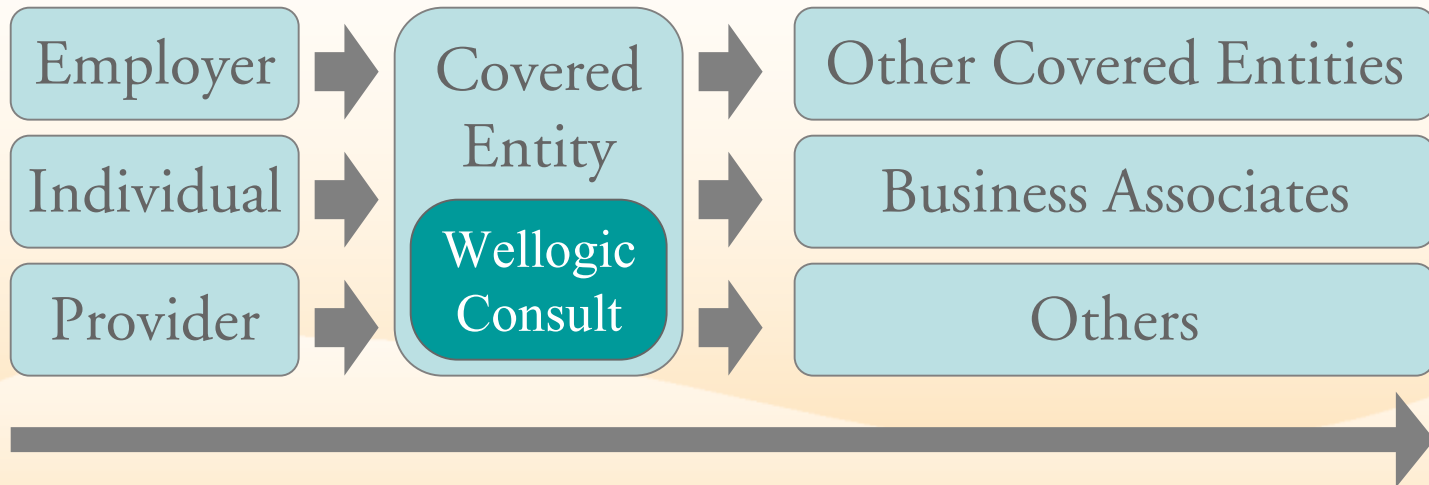
- Consent or Acknowledgement
- Authorization
- Minimally Necessary
- Overrides
- “This Record is Restricted”
- “This Record is Not Complete”



# HIPAA: Security

- State of the art security
- Technical security measures offer safeguards
- Auditing provides a record of security and a means of evaluating success or failure
- Administrative security measures are supported according to each customer's needs

# Wellogic Consult & HIPAA



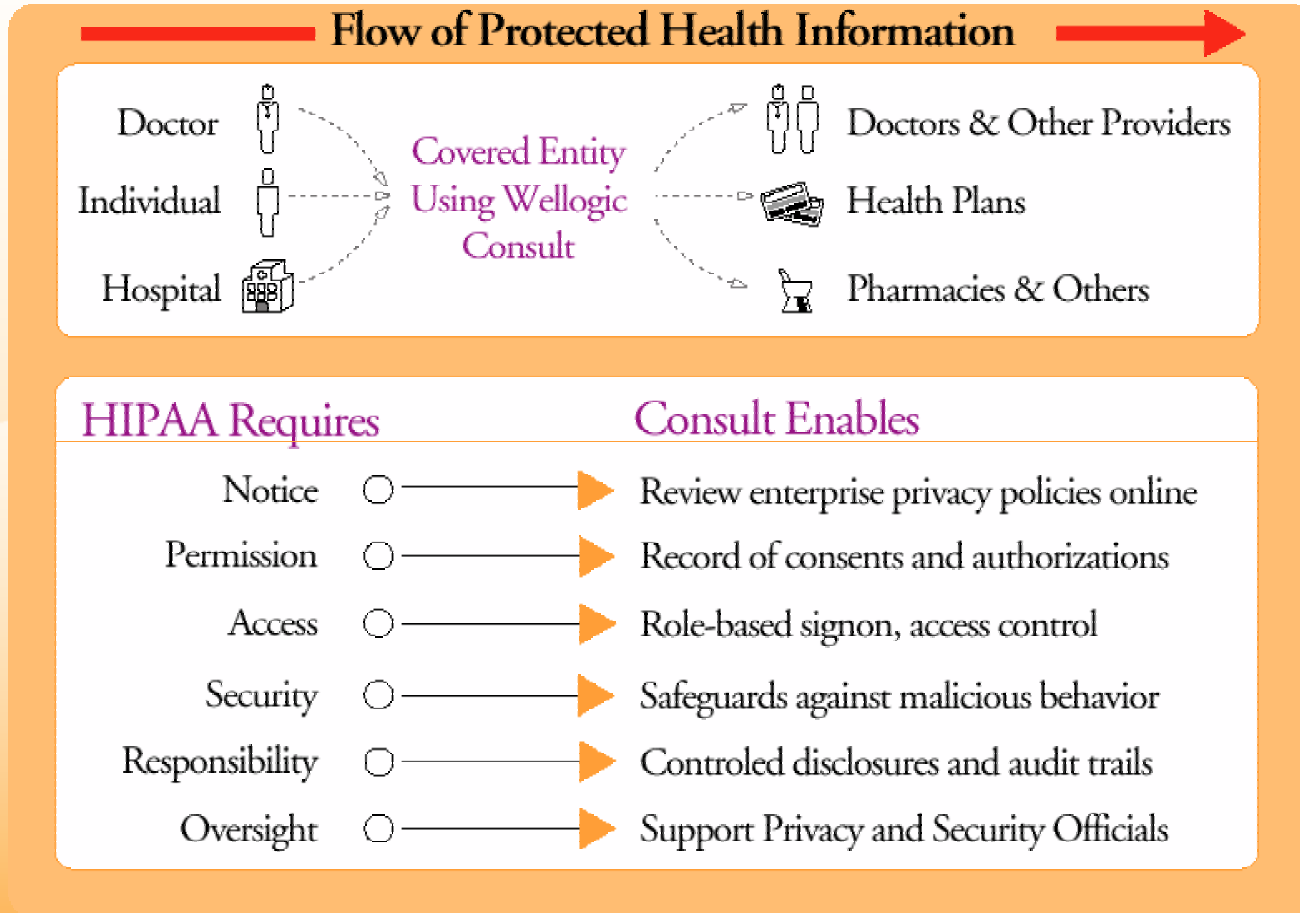
## HIPAA Requires:

- Notice
- Permission
- Access
- Security
- Responsibility
- Oversight

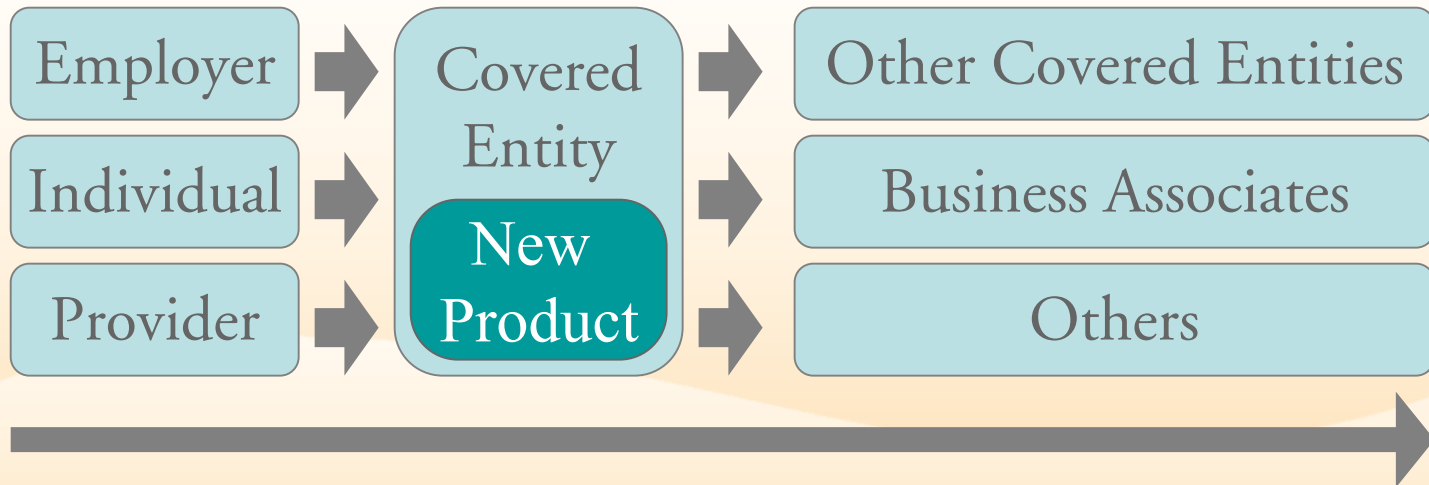
## With Wellogic Consult, you can:

- Access enterprise privacy policies online
- Track consents and authorizations
- Give role-based sign-on and access control
- Prevent hack attack
- Control disclosures and keep audit trails
- Empower privacy and security officials

# Wellogic Consult & Marketing



# Recapping



If Covered Entity adds  
New Product ... How does  
it impact / help / harm  
Covered Entity's efforts to  
address the HIPAA issues?

- Notice
- Permission
- Access
- Security
- Responsibility
- Oversight