

Privacy Officers' Perspective In the Pharmaceutical Industry

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HIPAA Audio-conferences

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PHARMACIA

Privacy Issues Healthcare PIHI

- e-Mail: Prozac Persistency Program
- Persistent Cookies
- Hacking MR Washington Hospital
- CVS Case

Right of Privacy

- The claim of individuals to determine for themselves when, how and to what extent information about them is communicated.

1. What kind of Information
2. How we use it
3. Who we are sharing it with

PII, III

PIHI, PHI, IIHI

- **Personal identifiable information (PII)** means any confidential or sensitive information that can be related back to an individual.
- **Personal identifiable health information (PIHI)** means information about an individual's health.

Identifiers

Final Standards for Privacy of Individually Identifiable Health Information

- a. Names;
- b. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and equivalent geocodes, except for the initial three digits of a zip code, if, according to current census data, (i) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (ii) the initial three digits of a zip code for all geographic units containing 20,000 or fewer people is changed to 000;
- c. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- d. Telephone numbers;
- e. Fax numbers;
- f. Electronic mail addresses;
- g. Social security numbers
- h. Medical record numbers;
- i. Health plan beneficiary numbers;
- j. Account numbers;
- k. Certificate/license numbers;
- l. Vehicle identifiers and serial numbers, including license plate numbers;
- m. Device identifiers and serial numbers;
- n. Web Universal Resource Locator (URL);
- o. Internet Protocol (IP) address number;
- p. Biometric identifiers, including finger or voice prints;
- q. Full face photographic images and any comparable images; and
- r. Any other unique identifying number, characteristic or code.

Regulatory/Legal environment Privacy & Security

- **Federal Regulations and Investigations**
- **State laws**
- **Attorney General's actions**
- **Litigation**
- **EU Safe Harbor**
- **Canada.....**

Federal Laws

- HIPAA
- Federal Trade Commission Act
- Children's Online Protection Rule ["COPPA"]
- Privacy Act of 1974
- Gramm-Leach Bliley Act
- Electronic Communications Act of 1986
- Others
- 12 Proposed Statutes

HIPAA

(Health Insurance Portability and Accountability Act)

- **Requires (DHHS) to develop standards and requirements for maintenance and transmission of health information that identifies individual patients.**
- **Protect the security and confidentiality of electronic and other health information.**

For The Pharmaceutical Industry The Rule May Affect:

- HR**
- Sales**
- Marketing and Market research**
- Patient refill, reminder, persistency programs**
- Product-feedback**
- Epidemiology**

For The Pharmaceutical Industry The Rule May Affect:

- R&D**
- Clinical trials**
- Biostatistical analysis**
- Outcomes or economics studies**
- Disease management programs**
- Pharmacy benefits programs**
- Drug safety monitoring**

Privacy Data within

| | <u>External Activities</u> | <u>Internal Activities</u> |
|---------------|----------------------------------|----------------------------|
| Global Supply | • Distribution | • Order processing |
| R&D | • Clinical trials and enrollment | • R&D Databases |
| Sales | • Detailing | • Targeting information |
| Marketing | • Targeting | • Opinion Leader program |
| HR | • Recruitment | • Global Talent Pool |

Mapping

Identification of Regulations and Legal Pitfalls and Tracking of Information Flow:

- **Regions**
- **Customers**
- **Channels**
- **Technology**

Mapping Regions/MCs

- **USA: Federal + States**
- **EU: EC + separate countries**
- **Asia/Pacific**
- **S. America**

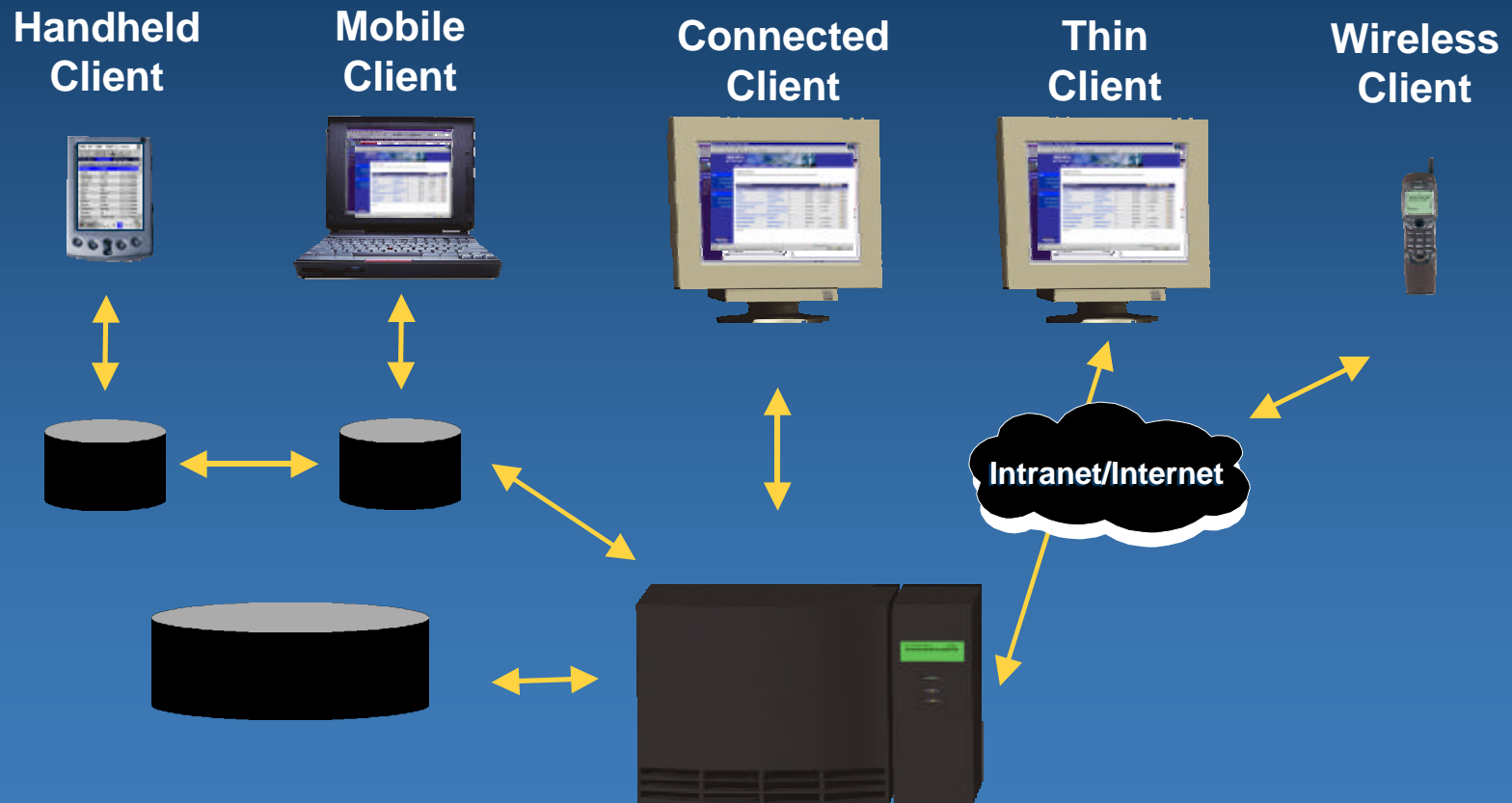
Mapping 'Customers'

- Patients (adult/children...)
- Healthcare professionals (nurses/physicians...)
- Wholesalers/Pharmacies
- Managed care
- 3rd party payers
- Employees

Mapping Channels

- R&D
- Marketing
- Managed Markets
- HR
- Sales

Mapping Technology (e-)

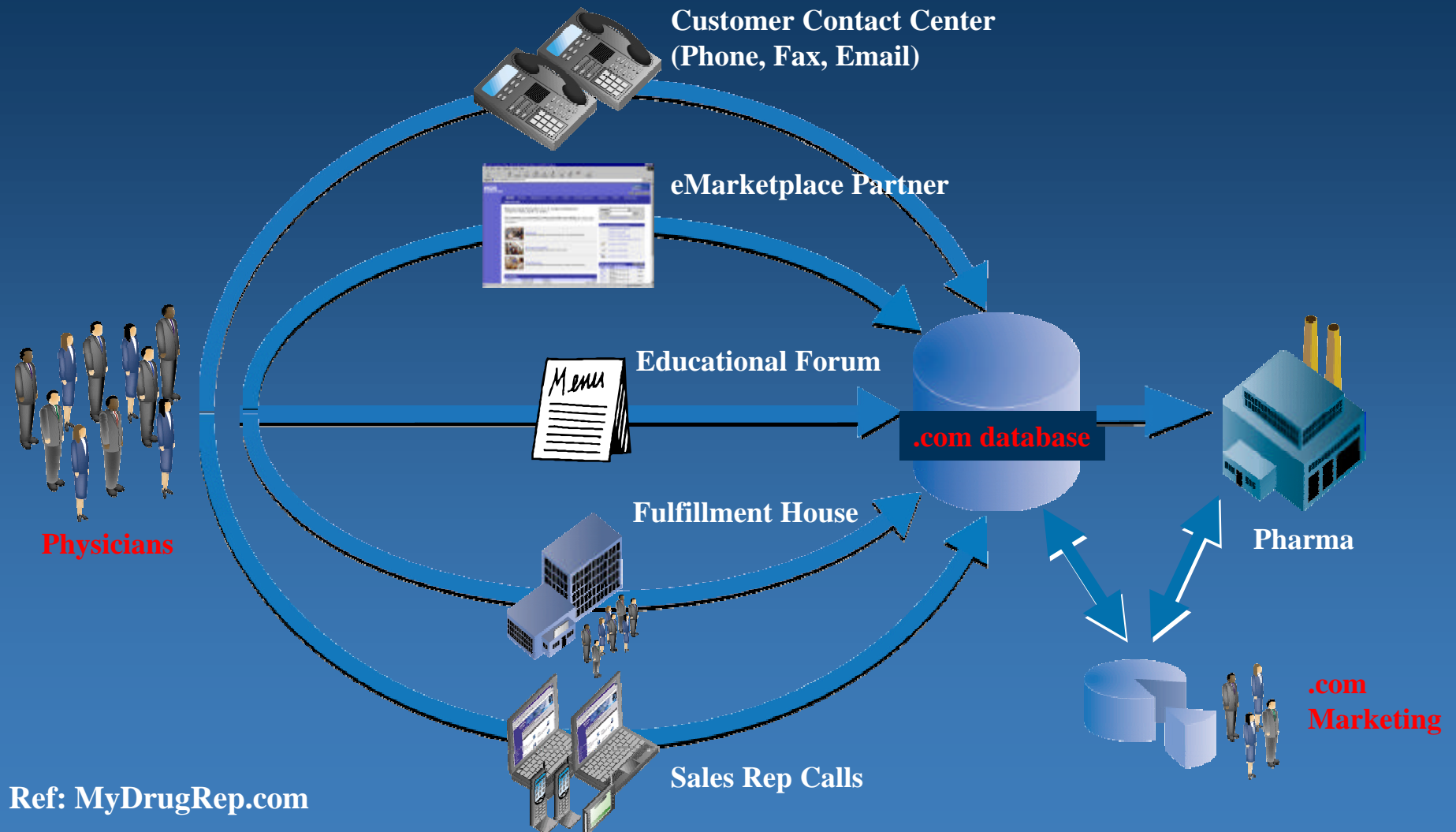


Ref: MyDrugRep.com

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Data Privacy Agreement



Points of Access

- **Pharmaceutical Company Employees**
- **Third Party Developers/Contractors**
- **Third Party Hosting Company**
- **Subcontractors of Third Party Hosting Company**
- **Third Party Transmission Company**
- **Third Party Service Provider**
- **Other Points of Access or Links**

5. Privacy Officer

“The PO has the responsibility for the *creation, implementation and maintenance* of the company’s *privacy* compliance related activities”