PDR® Network
Safety Communication Compliance™

Health IT and Rapid Adoption of Electronic Health Records in the U.S.

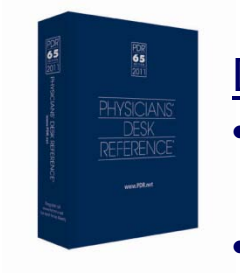
Impacts and Opportunities for Medical Devices

GS1 April 2011

Edward Fotsch, MD
Chief Executive Officer
PDR Network
ed.fotsch@pdr.net

PDR Network: Delivers Non-Advertising Drug Information, Alerts & REMS to U.S. Prescribers

PDR® Network
Safety Communication Compliance™



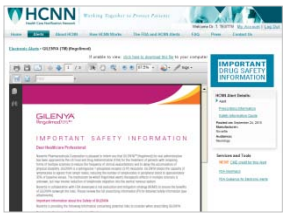
Drug Information Service

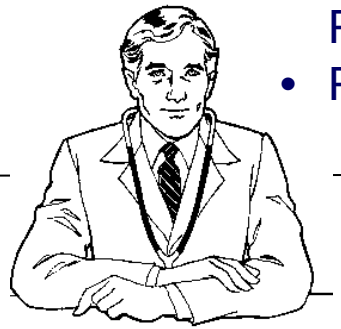
- PDR Main, email, Web and Mobile ~500k MDs
- Daily, weekly, monthly and annual outreach to U.S. prescribers

Drug Alerts/REMS

- Only electronic FDA-approved network
- ~10M Alerts & REMS delivered
- REMS w CME

HCNN
Health Care Notification Network
a service of PDR Network





Mobile PDR

- Full labels
- Med images
- Robust Search
- All mobile platforms

EHR Services

- Labels/Alerts
- EHRevent.org
- RxEvent.org
- eCare Services

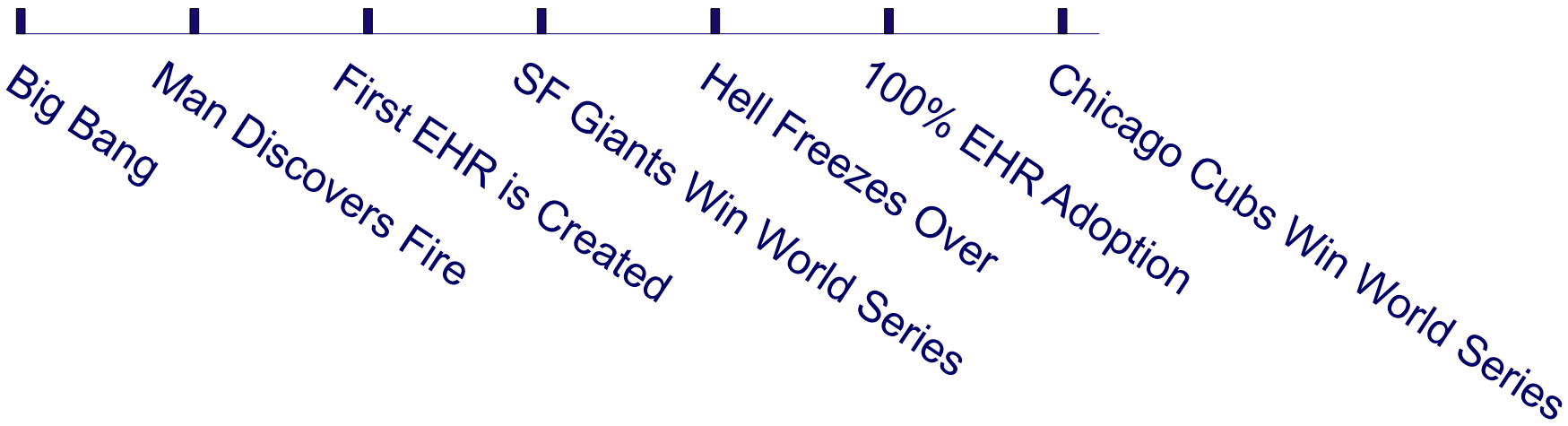
EHR Market Overview

I. EHR Marketplace, Drivers and MD Workflow

II. EHR Relevance to Pharma and Device Manufacturers

III. UDI and EHRs

EHR Adoption Timeline Circa 2008



So What Changed????

$20B+ to MDs for EHR Adoption

- ARRA budget provides for about **$19.2 billion for EHR Adoption**
- The CBO estimates that HCIT spending could be about **$36 billion**
- Physician practices:
  - funds totaling up to **$44,000 per physician** over a 5-year period **if ready** in 2011
- Hospitals:
  - funds totaling up to **$11 million** over a 4-year period **if ready** in 2011

Roberts DW, Halamka J, Leavitt M. Impacts of the American Recovery & Reinvestment Act of 2009 on ONC, NeHC, HITSP, and CCHIT. March 11, 2009; http://www.himss.org/content/files/ARRA_ONCNeHCHITSPCCHIT031109.pdf

After the Carrot Comes the STICK!

In 2015, penalties for hospitals and individual providers **start at 1% of Medicare payments** and **go up to 3%** by 2017.

The definition of **“Meaningful Use”** determines which organizations receive payments versus penalties.

Failure to adopt EHRs within the next 3 years will result in net **losses to MDs measured in hundreds of thousands and hospitals measured in millions**.

What's ARRA Mean to HIT? February 26, 2009. http://enterprise-imaging-radiology-management.advanceWeb.com/editorial/content/editorial.aspx?cc=194800&CP=3. Accessed on May 29, 2009

Beyond $$$ Incentives
There is “Hands-on” Help from HHS

PDR® Network
Safety Communication Compliance™

HealthData Management

Regional Extension Centers Start to Roll

By Joseph Goedert

The HITECH Act of 2009, in addition to establishing Medicare and Medicaid incentive payments for the meaningful use of electronic health records, also appropriated $2 billion in discretionary spending to the HHS Office of the National Coordinator for Health Information Technology for additional initiatives to aid providers in achieving that goal.

The largest initiative, which snagged $677 million of those funds, is the Health Information Technology Regional Extension Centers program.

Under the program, a nationwide network of 62 RECs has been created to provide heavily subsidized help for at least 100,000 small and safety-net primary care providers, as well as critical access and small rural hospitals, to adopt and achieve meaningful use of EHRs.

“Meaningful Use”: A Key Concept

$Billions in incentives for MDs are tied to Meaningful Use of EHRs. Meaningful Use Requires MDs to:

1. Write prescriptions electronically (ePrescribing)
    - ePrescribing applications drive formulary compliance
    - ePrescribing provides an opportunity to display FDA-required product information including drug Alerts and REMS
2. Maintain problem and medication lists electronically
    - MDs will be able to sort patients quickly by meds and conditions
3. Provide electronic connections to patients for PHRs and reminders
    - patient connectivity required by Meaningful Use is available for regulatory messages to go to Patients, not just MDs

Payors Align EHR Incentives

PDR Network
Safety Communication Compliance™

"The Pink Sheet"

August 5, 2010

Private Payers Follow Government Lead In Offering Electronic Health Records Meaningful Use Incentives

At least four private payers are following the lead of the federal government by offering health care providers financial incentives for the "meaningful use" of electronic health records. The programs also piggyback on the meaningful use standards that are set by CMS, so expectations on what providers need to do to demonstrate meaningful use in order to qualify for incentives is consistent between the public and private payer systems.

During an Aug. 5 meeting sponsored by Health Affairs and the Health Industry Forum, representatives from WellPoint, Highmark Blue Cross Blue Shield, Aetna and UnitedHealth Group offered insights on what they are doing to encourage the adoption of electronic health records.

Electronic Health Records (EHR): More EHR Money from Hospitals

PDR Network
Safety Communication Compliance™

THE WALL STREET JOURNAL.
WSJ.com

Hospital System Offers $400 Million to Docs With Online Records

September 28, 2009, 10:01 AM ET

In the push to get doctors to digitize their patient records, one New York hospital system is going to dangle a $400 million carrot. The North Shore-Long Island Jewish Health System is planning to offer doctors who establish electronic medical records up to $40,000 annually for five years, according to the New York Times.

- Hospitals and health plans are piggybacking on Fed incentives to drive EHR adoption

- Physician Use of handheld technology is moving from info and data access to EHR and eRx applications
- "ePocrates launches EHR initiative" Feb. 2010

THE WALL STREET JOURNAL.
WSJ.com

OCTOBER 8, 2009

Smart-Phone Makers Call the Doctor

Apple, Research in Motion See Opportunity in Medical Field as Hospitals Step Up Efficiency Drives

By NIRAJ SHETH and YUKARI IWATANI KANE

The medical waistband is the latest front in the battle among smart-phone makers for the business customer.Last month, Stanford Hospital & Clinics, in Palo Alto, Calif., started a trial with Apple and Epic Systems Corp., a provider of health-care information systems, to test software that will let medical staff access patient charts on Apple's iPhone.

Forces Driving Rapid EHR Adoption and Use by U.S. Providers

PDR® Network
Safety Communication Compliance™

- $20B in federal funding to MDs to adopt EHRs
  - $600M+ in hands-on training to adopt EHRs
- $Bs in federal penalties for non-adoption of EHRs
- $Bs in commercial payer incentives for EHR adoption
- $Bs in EHR underwriting for physicians by hospitals
- Non-cash EHR incentives
  - EHRs are a requirement to recruit new physicians
  - EHRs are a functional requirement to produce the growing volume of quality reporting for payers and board certification ('chart pulls' are prohibitively expensive)
  - Patient demand and expectation for online access to basic records and providers is growing (note Kaiser #1 marketing strategy)
  - Payers are increasingly noting EHR services on provider directories
  - 'All the other guys are doing it'

EHR Adoption is #1 Priority

PDR® Network
Safety Communication Compliance™

Healthcare IT News
PUBLISHED IN PARTNERSHIP WITH HIMSS

Survey: EHRs number one priority for healthcare IT professionals

July 19, 2010 | Molly Merrill, Associate Editor

SAN FRANCIS
existing inform
"adequate" an
according to a

The survey, by
tools and deve
2010 and prim
contacts (deve

According to t
of an EHR project or plan to start one within the next 18 months.

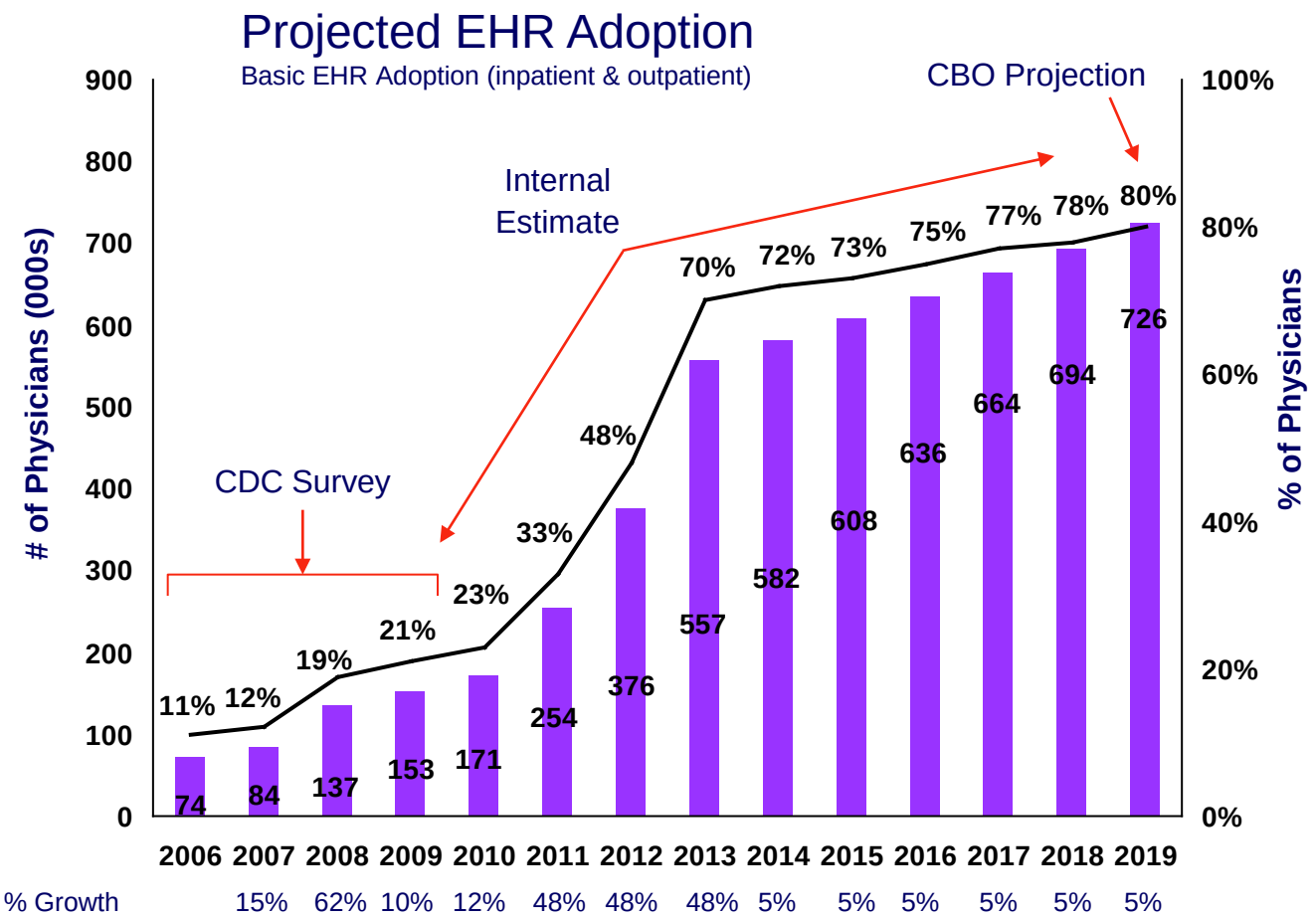
Healthcare IT News

Hospital EMR sales almost doubled from 2008 to 2009

September 21, 2010 | Bernie Monegain, Editor

OREM, UT – The sale of hospital EHR systems nearly doubled in 2009 over 2008, driven by the American Reinvestment and Recovery Act, according to a new report by research firm KLAS. Epic and Cerner captured nearly 70 percent of the new large hospital sales.

EHR Adoption Projections



Trends

- Rapid rate of adoption projected due to Meaningful Use incentives
- Consolidation expected amongst vendors (e.g. Allscripts/Eclipsys merger)
- Move to Web-based products, which allow for speedier integration of new functionality and content

Source: CDC/NCHS, National Ambulatory Medical Care Survey for 2006-2009. CBO projection for 2019
Note: Overall physician base grows from 745,000 in 2010 to 907,000 in 2019 based on BLS projected growth rates.

EHR Adoption Measured by Markets

Cerner Corp. (CERN)- 2 Year Stock Charting

Trends

All EHRs stocks have risen rapidly

- M&A in EHRs is growing
- Heterogeneous nature of medical practice means specialty-specific EHRs rather than a single dominant EHR
- ~100 EHRs qualify for Meaningful use

PDR Network EHR Activity

PDRN EHR Service	Description and Partners	Status
EHRevent.org	Adverse EHR Events routed to EHR vendors and stored in PSO. Developed with FDA, AHRQ, ONC and iHealth Alliance (liability carriers)	Live: National Launch December 2010
Core PDR Drug Service	Full and updated FDA-approved drug labels including drug Alerts and CME for every label- created with iHealth Alliance (liability carriers) and FDA	Live: National Launch January 2011
RxEvent.org	Online reporting of adverse drug and device events integrated into partner Web sites and EHRs. Developed with manufacturers and FDA	Beta: March 2011 National Launch May 2011
PharmEHR National Conference	Only national conference focused on the intersection of pharma and EHR adoption.	April 6/7
PDR eCare Service	Online drug support services from manufacturers added to 1.0 service: samples, patient financial assistance, etc	2011 launch

PDR® Network
Safety Communication Compliance™

I. EHR Marketplace, Drivers and MD Workflow

II. EHR Relevance to Pharma and Device Manufacturers

III. UDI and EHRs

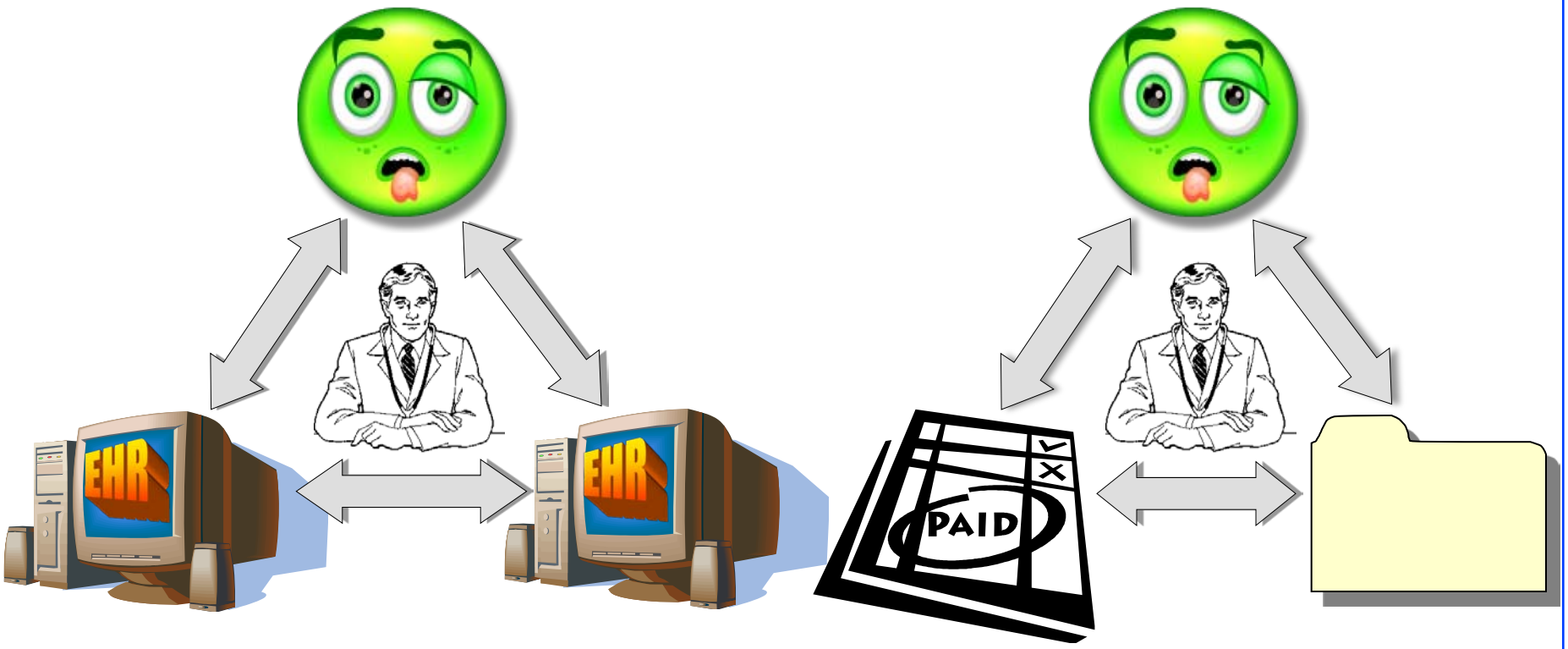
EHR Relevance to Pharma and Device

EHR Adoption:

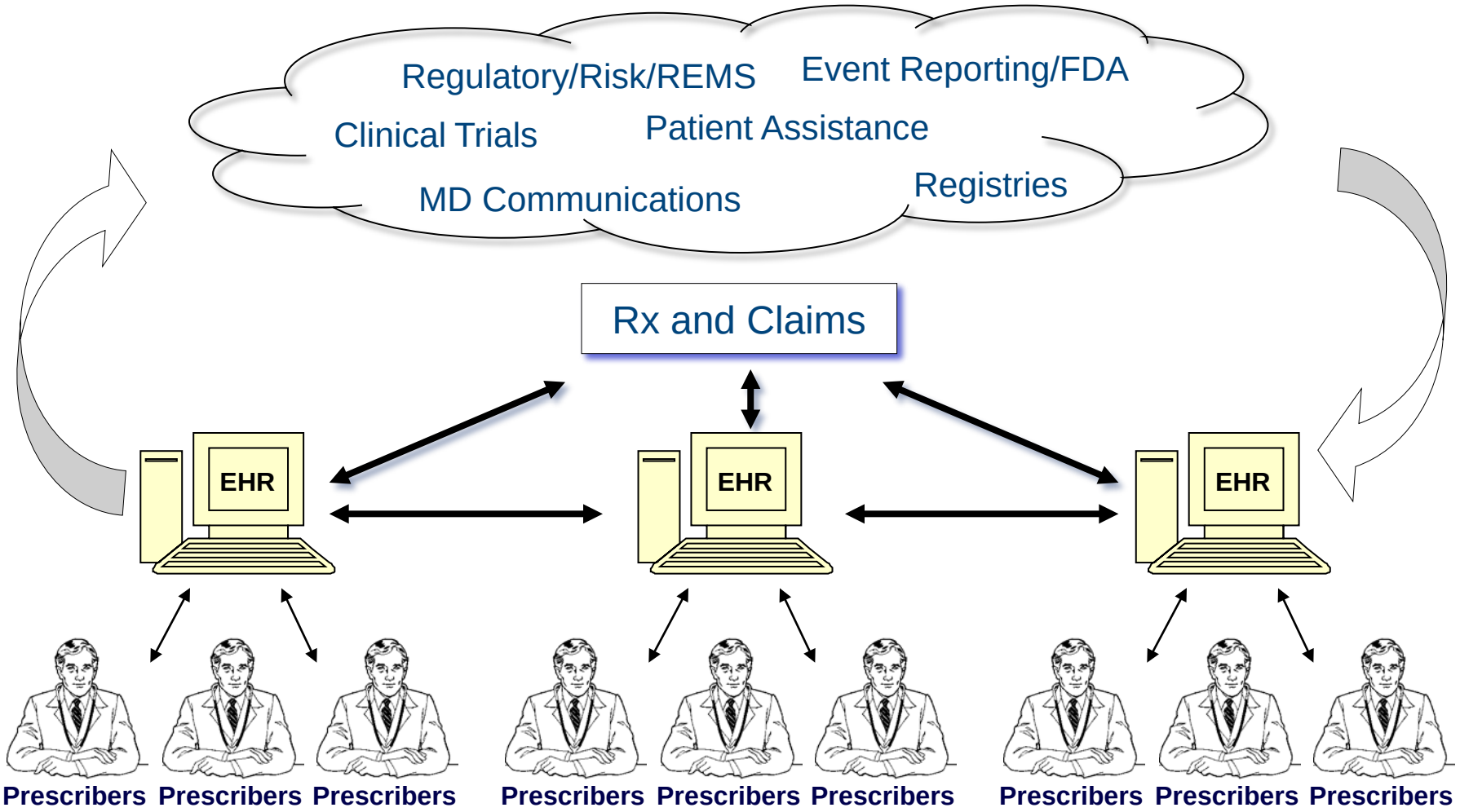
- Changes provider workflow and access
  - electronic connectivity to prescribers / providers
  - JIT information delivery at point of care / prescribing
  - expanded formulary compliance
- Increases data access
  - clinical trials / R&D
  - quality measure reporting
  - registries
- Creates online patient connectivity as a ‘requirement
  - online reminders
  - access to patient’s record
  - direct to patient information, warnings, etc.

EHR Changes to MD Workflow

- MD Revenue = Patient + Chart + Charge
- Prescribing = ePrescribing



EHRs as a Key Communication Platform



EHR Pharma Approach

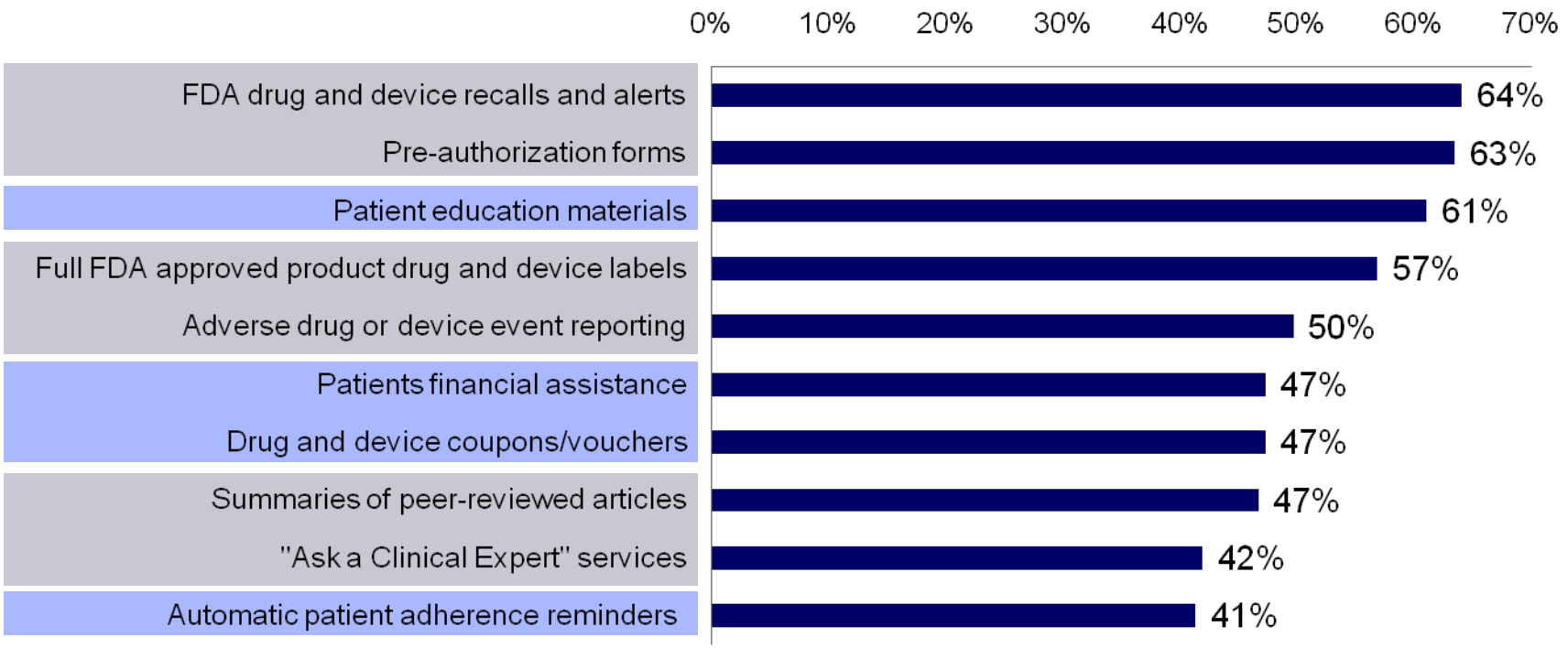
- Understand specialty-specific EHR adoption status and trajectory
- Understand EHR workflow and relevance to brand
  - ePrescribing and formulary compliance, product support, REMS, etc.
- Pose key questions including:
  - can brand goals be accomplished without MD connectivity via EHRs
  - can EHRs become a vehicle to drive traffic to:
    - physician portals and other existing online product support services
    - brand-specific pre-authorization forms
    - samples / patient financial assistance / pre-paid co-pay cards
- Understand patient connectivity required by EHRs and relevance to medication adherence

PDR Network EHR Survey of Physicians

PDR® Network
Safety Communication Compliance™

Please rate the value of the following services if included in your EHR.

% of Physicians rating “Very Valuable” or “Valuable”



Source: 2011 PDR Network EHR Physicians Survey n = 167

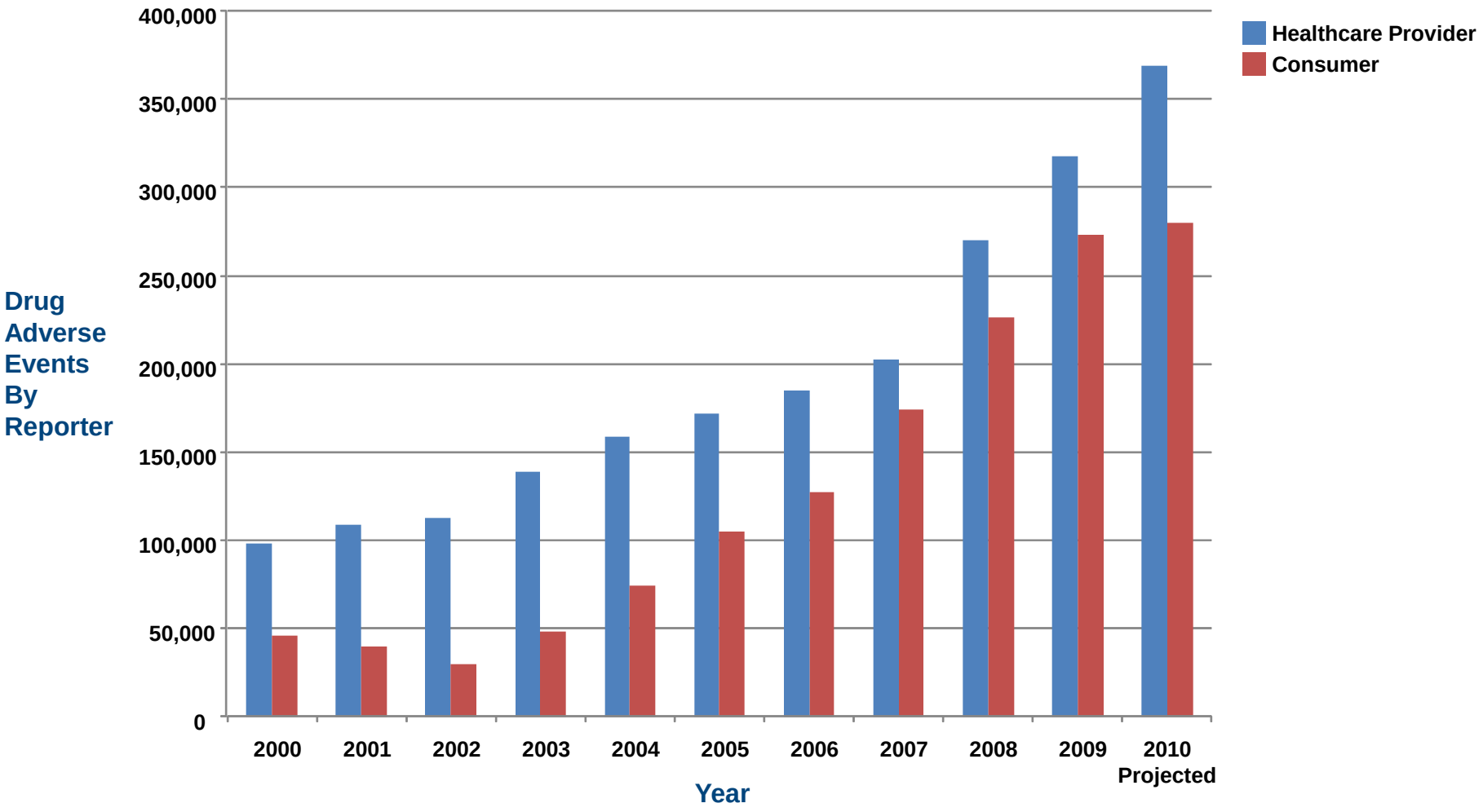
EHRs and Adverse Event Reporting

- ~500,000 Adverse Drug Event (“ADE”) reports annually to FDA – and growing - most from HC Providers
- 95% of ADE reported first to manufacturers (5% reported direct to FDA via MedWatch)
- Only ~10% of ADEs actually reported 1, 2
- ADE reporting is slow and expensive for manufacturers
  - most ADEs reported to manufacturers via 800#
  - Follow-up with providers is difficult, time-consuming and expensive
  - after triage manufacturers report to FDA
- ADE reporting is difficult for providers and discourages reporting
- ADE reporting is challenging and labor-intensive for the FDA

1. Scott HD, Rosenbaum SE, Waters WJ, et al. Rhode Island physicians' recognition and reporting of adverse drug reactions. *R I Med J.* 1987;70:311–16. [PubMed]

2. Rogers AS, Israel E, Smith CR. Physician knowledge, attitudes, and behavior related to reporting adverse drug events. *Arch Intern Med.* 1988;148:1589–92.

Adverse Drug Events Submitted to FDA



Source: FDA AERS database

Adverse Device Events Submitted to FDA

- Medical Device Adverse Reports (top 20 manufacturers)
  - 2009 full year: 221,902
  - 2010 thru 9/10: 257,880
  - 2010 annualized: 343,840 (55% increase!)

Source: FDA MAUDE database

Adverse Event Reporting Summary

PDR® Network
Safety Communication Compliance™

FDANEWS
WASHINGTON DRUG LETTER®

Science Board Finds FDA's Adverse Event Reporting 'Seriously Flawed'

11/29/2010

An FDA advisory board review of the agency's adverse event reporting system (AERS) has found that the system is failing to provide the FDA with the information it needs to detect emerging safety issues. "A very high percentage of these reports lack critical information," said Stephen Spielberg, co-chair of an FDA Science Board subcommittee that conducted a review of AERS, in a presentation last week. For example, the reports received by the agency often lack essential information such as the age and gender of the patient involved, the dose of the drug taken, the company that manufactured the drug and a clinical description of what happened to the patient.

Adverse Event Report EHR Opportunity

PDR® Network
Safety Communication Compliance™

- **Integrate ADEs into EHRs and Online Platforms**
  - major EHR vendors, liability carriers, medical societies, APhA, major pharmacies
- **Improve ADE services for manufacturers**
  - route ADEs in standardized E2B format to manufacturers or FDA
  - reduce cost and hassles of ADEs for manufacturers: according to FDA, paper reports cost ~ $35 per report to process vs. $12 per electronic report
  - customize ADE reporting forms and process on a drug or device-specific basis
  - provide manufacturers with simplified and affordable access to reporting MDs for follow-up
- **Improve ADE service for providers**
  - ADE integrated into workflow (EHRs and partner Web sites)
  - provide online confirmation of receipt or follow up as appropriate
  - customize and/or pre-populate forms so that they make sense for the product (not one-size-fits-all)
- **Improve speed, accuracy and quality of ADE system (ASTER, MEADERS)**
  - Pfizer-sponsored ADE integrated into EHRs showed dramatic benefits

PDR® Network
Safety Communication Compliance™

I. EHR Marketplace, Drivers and MD Workflow

II. EHR Relevance to Pharma and Device Manufacturers

III. UDI and EHRs

UDI / Longitudinal Device Tracking:
Current Status and Challenges

PDR® Network
Safety Communication Compliance™

- **Majority of patients with devices are lost to follow-up**
  - surgeon's relationship with patient is temporary; ends with CPT payment
  - primary care physicians lack device detail
  - key facts are not tracked by any physicians (ambulatory status, etc.)
- **Outcomes and quality tracking not possible**
  - claims data inadequate
- **Longitudinal device tracking and resultant quality improvement is currently unavailable**
  - quality improvement, monitoring and public health suffers

UDI / Longitudinal Device Tracking:
Current Status and Challenges

PDR® Network
Safety Communication Compliance™

THE WALL STREET JOURNAL.

BUSINESS **OCTOBER 13, 2010**

Keeping Tabs on Implants

Registry to Monitor Problems With Hip, Knee Replacements

An effort to track hundreds of thousands of replacement hip and knee surgeries across the U.S. each year will soon start gathering data, with the potential to uncover implant problems more quickly.

That could eventually mean more recalls in a $12 billion industry led by companies including Zimmer Holdings Inc., Johnson & Johnson and Stryker Corp. Still, manufacturers are backing the "American Joint Replacement Registry" and have chipped in start-up funding.

UDIs and EHRs

The UDI / EHR Opportunity:

- Use UDI and EHRs to track and interact with devices longitudinally

Challenge:

Were UDIs to become a standard they would still fall short of providing longitudinal tracking because:

- The UDI would need to get into the patient's record via the surgeon or hospital;
- The patient's record with the surgeon or hospital would need to communicate with the primary care provider (relationship between patient and surgeon/hospital is ephemeral);
- Patients change primary care providers and;
- Primary care providers often lack the information AND the motivation to participate meaningfully in longitudinal outcomes

The Solution:

- EHRs, Meaningful Use and Patient Connectivity Can Help

UDI / Longitudinal Device Tracking: UDI + Meaningful Use + Patient Connectivity

PDR® Network
Safety Communication Compliance™

- **EHR Meaningful Use payments mandate EHR use AND patient connectivity**
  - PHRs, e-Communications and e-Reminders are required for "Meaningful Use" of EHRs
- **Patient connectivity now growing rapidly**
  - largest vendor has >3M actively connected patients
  - 50% U.S. patient connectivity reached in three years
- **Patients actually want provider connectivity and information re: THEIR drugs and devices**
- **FDA can benefit from patient connectivity**
  - to provide patient with credible information
  - to allow access to information on longitudinal tracking of drugs and devices
- **Manufacturers can benefit from patient connectivity**
  - longitudinal data for product design and improvement
  - regulatory compliance- post approval studies, REMS etc.

Online Patient Communications and PHRs are Rapidly Becoming the Standard

PDR® Network
Safety Communication Compliance™

UDI / Longitudinal Device Tracking:
The Opportunity

PDR® Network
Safety Communication Compliance™

- **FDA and Industry can achieve key strategic goals via UDI, EHRs, Patient Connectivity and PHR's**
  - longitudinal patient specific device communications
  - data mining from PHRs; far richer data source than claims data
  - opportunity for direct patient surveys
  - direct connectivity for Alerts, Reminders and Warnings
  - bring FDA Sentinel System to life
  - low cost - most of funding has already come from Feds

- **Patient privacy and HIPPA issues avoided**
  - patients "opt-in" to a service they actually want; customized information Alerts and Warnings specific to **their** device
  - experience-to-date indicates most patients will opt-in to this service

UDI / Longitudinal Device Tracking: **How?**

PDR® Network
Safety Communication Compliance™

- **Unique Device Identifier entered into PHR**
  - activity tied to “Meaningful Use”
- **Patient offered ongoing “device-specific information” via PHR**
  - patients “opts-In” to receive customized warnings/recalls, reminders and information
  - device service is similar to the “reminder service” required under MU
  - service includes possibility for periodic surveys by FDA or device manufacturer
- **Patients receives device-specific messages via PHR**
  - welcome / introductory message (pre and post-surgery device-specific services)
  - periodic updates (suggest semi-annually)
  - Ad-hoc messages (warnings, etc.)
- **Customized disease specific patient surveys**
  - device-specific surveys based upon random patient samples
  - device-specific surveys based upon CCD (Continuity of Care Document) data in PHR
    - i.e., survey only diabetic patients with cardiac wires
- **Patient links to FDA approved relevant consumer information**

PDR® Network
Safety Communication Compliance™

Health IT and Rapid Adoption of Electronic Health Records in the U.S.

Impacts and Opportunities for Medical Devices

GS1 April 2011

Edward Fotsch, MD
Chief Executive Officer
PDR Network
ed.fotsch@pdr.net