Availability of Prescription Information for Secondary Usage – Impact of Outpatient E-prescribing

Summer Institute in Nursing Informatics
July 2008

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Disclosures

Research supported by
- IBM Center for Business of Government Stipend
- American University of Beirut Junior Faculty Research Leave

Author has no commercial funding or research relationships
Objectives

- Awareness of the widespread availability of prescription information
- Understanding of process changes introduced by e-prescribing with respect to the availability of prescription information
- Recognize need for health data stewardship
Topics

- Availability of information – manual prescribing
- State of outpatient e-prescribing
- Process implications of e-prescribing
- Privacy pitfalls
- Health data stewardship
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Manual Prescribing Process

Start

MD selects drug

Optional (standalone)

MD checks formulary

Transfer

MD writes Rx

Patient chooses to fill

Patient takes to pharmacy

End

How to Pay?

Cash

Pharmacy dispenses Rx

3rd Party or Payer records Rx data

3rd Party

Pharmacy checks eligibility

Key Point - Patient has some control over information (not filled or pay cash)
Information Flow in Manual Prescribing

Legend
- Network
- Database
- Secondary Data Mining

PBM/Payer
- Formulary
- Eligibility

AMA

Data Mining

3rd Party Claim Process

Prescriber

Pharmacy
- Pharmacy Mgmt Software

Patient
Individual physicians’ prescribing data sold to pharmaceutical manufacturers.

- IMS Health collects information on about 70% of all prescriptions filled in community pharmacies
  - projects nationally representative data
  - Physician level data for sales force
- Data merged with the Physician Masterfile of the American Medical Association (AMA).
- Growing resistance from physicians - zealous sales agents have confronted physicians with their prescribing histories.

Dr. Adams prescribes Naprezine in 45% of applicable cases. He prescribes Competitor Intralex 50% of the time.

IMS revenue (2007)
$801 million in USA
• Sales force effectiveness (46%)
• Portfolio Optimization (29%)
• Launch, brand, other (25%)

Greene, J. A. Ann Intern Med 2007;146:742-748
Uses of Prescribing Data

- public health agencies,
- studies about drug interactions,
- prescribing trends,
- long-term effects of medication,
- Notifying patients of drug recalls
- Marketing to physicians
- Marketing to patients
- Health insurance denials

Note: Pay for data in most cases - commercial or public usage (Green, 2007)
A Fine Line – Who Benefits?

- Quality improvement programs - warn physicians of adverse drug interactions or underuse of beneficial drugs
- Disease management programs – remind patients to refill prescriptions
- Cost containment initiatives – switching patients to lower-cost equivalent drugs (sometimes with a fee to physician) at behest of a drug manufacturer.

Topics

- Availability of information – manual prescribing
- **State of outpatient e-prescribing**
- Process implications of e-prescribing
- Privacy pitfalls
- Health data stewardship
History of Outpatient E-prescribing

- Mid-1990’s – standalone e-prescribing devices
- RxHub founded in 2001 to provide nationwide, universal electronic information exchange - includes three largest PBMs
- Surescripts formed in 2001 by the two associations that represent the 55,000+ pharmacies in the US:
  - NCPA (independents)
  - NACDS (large chains)
- AHRQ funded pilot studies in 2006
Higher Volumes of Prescriptions…
… not all e-prescribed

Prescription growth in U.S.

- 823 million visits to physician offices in 2000\(^1\)
- 4 out of 5 patients who visit a physician leave with at least one prescription\(^2\)
- 65% of the US population use a prescription medication each year\(^3\)
- Over 3.4 billion prescriptions in 2006\(^4\)
- Number is expected to rise to over 4.1 billion by 2010\(^4\)

E-scripts possible for 40% of prescriptions

(~400 million controlled substances ineligible)

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(4) NACDS estimates.
CMS E-Prescribing Definition

“...the transmission, using electronic media, of prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser”

Note: Adjudication excluded
E-prescribing Benefit per CMS

“... potential to promote efficient and effective drug use by providing up-to-date information regarding drug therapies,” ....
E-prescribing benefit relies upon secondary information

“. . . the improvements enabled by e-prescribing will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers.”
Prescribing Today

- Physicians write a prescription
- Check eligibility
- Determine benefit

Physician

- Patients
- Wait

Pharmacist enforces Quality and Payer Policies

- Call to confirm prescription
- Clarify handwriting
  - Dosage?
  - Drug?
- Request changes if required based on benefits

Pharmacy

- Read script
- Data enter script

PBMs

E-connection From Physician to PBMs

- Eligibility known
- Formulary and preferred drug known at point-of-care
- Patient drug history
- Co-pay minimized
- Clean and legible script when printed
- Physician now payer enforcer
- Only 2/3 of PBMs connected
- High-end decision support needed
- Manage prescription drug benefits

Adopted from Wellpoint, e-Prescribing’s Impact on Cost and Quality: Implications for Pay-for-Performance Initiatives, HIT Summit West (2005)
E-connection From Physician to Pharmacy

- Electronic SCRIPT standard
- Reduced wait time
- Legible script
- Reduced double data entry
- Up to $1 to receive e-script
- Fill in advance for 20-30% scripts not picked up
- Adjudication still required

Adopted from Wellpoint, e-Prescribing’s Impact on Cost and Quality: Implications for Pay-for-Performance Initiatives, HIT Summit West (2005)
E-Prescribing Penetration in Practices

Despite some initial successes, e-Prescribing is not widely used
• only 6% (35,000+) prescribers (physicians and other clinician types) are using e-Prescribing – mostly in large practices
• Less than 2% of the estimated 3.4 billion annual prescriptions ordered are electronic (including fax)

A number of barriers stand in the way of universal adoption in the practice:

- Cost of buying and installing a system
- Time / workflow impact: Initially, increased time compared to paper prescribing
- Time to review warning
- Safety improvements not fully publicized
- Standards/interoperability

Source: eHealth Initiative
Summary of Wellpoint Lessons Learned

- e-Prescribing is not high on most physicians’ radar screens
  - Significant gulf between literature reports and our actual experience

- Office managers do not understand nor value e-Prescribing
  - Reaching the actual physician requires a thoughtful approach

- Free is not cheap enough
  - Significant percent of physicians concerned with price after 1st year

- Significant concerns with a health plan delivering a clinical IT solution exist in the physician community
  - High levels of distrust in physician community that a payer could or would or should be involved with clinical information technology solutions

Wellpoint, e-Prescribing’s Impact on Cost and Quality: Implications for Pay-for-Performance Initiatives, HIT Summit West (2005)
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E-prescribing Process Implications

Impact: Information (can be) recorded in several places – even if medication never received

Start

- MD chooses drug
  - E-link

- MD orders Rx
  - E-link (Transfer)

- Formulary (payer) checks MD
  - Possible

- Payer records Rx data
  - Pharmacy checks eligibility
  - Pharmacy dispenses Rx

End

- Pharmacy hands drugs to patient
- Patient chooses to pay
How does e-prescribing change Privacy?

- E-script recorded by payer (or e-link provider) whether patient chooses to fill or not (or pay cash)
- Record of prescription now exists in a practice database (not just written in a chart)
- MD (prescriber) habits (e.g., first choice of drug) prior to formulary check can be recorded by payer or sold to pharmaceuticals
Information Flow in E-prescribing

Legend
- Network
- Database
- Secondary
- Data Mining

National Patient Health Information Network

Network Database

PBM/Payer
Formulary
Eligibility

Prescriber
E-prescribing Software

NPHIN (RxHub)

PHI E (Surescripts)

3rd Party Claim Process

Pharmacy Health Information Exchange

Pharmacy
Pharmacy Management Software

Secondary Data Mining

1. Formulary
2. Pharmacy Health Information Exchange
3. E-prescribing Software
Topics

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Giving up control of your information …

- Makes it feasible to be combined with the information of others to create evidence-based knowledge that benefits society. [most agree]
- Makes it possible to be reminded to refill your prescription or alerted to a drug recall [some agree]
  - Issue: who should alert? The prescriber or the pharmacy or the manufacturer?
- Makes it possible to be advised (and your physician) of cheaper drug [maybe agree]
Using E-prescribing information

- Presumes prescriber e-script = diagnosis, but ...
  - much of prescribing is trial and error,
  - just-in-case (pain killer after surgery),
  - as-needed,
  - or off-label use

- Presumes dispensed prescription = patient needs it and takes it

- To be useful (patient level) – need medical history and drug usage history – exposing more patient information than in past
Scenario: Prescribed = Taking

- Patient prescribed vicodin for pain relief by dentist
- Patient fills prescription
- How can this dispensing history be interpreted?
  - Patient takes pain killers
  - Patient a prescription drug abuser
- What does data miner see? What if multiple teeth are extracted – one a month for many months?
Scenario: Dispensed = Taking

- Patient susceptible to bronchitis prescribed prednisone in case it is needed
- Take as directed (start immediately and then come in for an appointment)
- Medication expires after one year
- Patient renews every year

How can this dispensing history be interpreted?
- Patient is on steroids every year (chronic)
- Patient following prescribers instructions – steroid never taken (healthy)
- Takes course of antibiotics in two of these years (acute case treated)
Scenario: Take or Not to Take

Who is healthier (same diagnosis)?
- Patient takes medications regularly
- Patient who doesn’t

How can this dispensing history be interpreted?
- Patient taking medications regularly has chronic disease
- Patient not taking medications is healthy

How does patient’s health (medication history) come into play?

From data mining perspective, very hard to make patient decisions on prescription information alone
PERCEPTIONS TOWARDS PRIVACY
How The Public Sees Health Research and Privacy Issues

Dr. Alan F. Westin

Professor of Public Law and Government Emeritus, Columbia University

Director, Health Privacy Program, Privacy Consulting Group

at the IOM Workshop, Washington, D.C., February 28, 2008
September 2007 National Survey

Sponsored by IOM Project on “Health Research, Privacy, and the HIPAA Privacy Rule”

Conducted online by Harris Interactive and Alan Westin, Sept 11-18, 2007; 2,392 respondents 18 or older

Results adjusted to be representative of the total adult U.S. population of 255 million

Three major sets of cross-tabulations: by standard demographics; by various health conditions; and by personal experiences and policy attitudes

Can only present highlights and implications today; my full report available at... afwestin@gmail.com
Respondents asked to agree or disagree with four statements about health privacy issues (random order)

“I generally trust my health care providers -- doctors and hospitals -- to protect the privacy and confidentiality of my personal medical records and health information”

- 83% agree
- 17% disagree

But, 12%, representing 27 million adults, believe that a health care provider has disclosed their personally-identified medical or health information in a way they felt was improper
“Even if nothing that identifies me were ever published or given to an organization making consumer or employee decisions about me, I still worry about a professional health researcher seeing my medical records.”

- Agree…….. 50%
- Disagree … 50%

U.S. public divided right down the middle on this

Reflects discomfort with sensitive health information being disclosed to “unknown third party”
What Harms Seen if PHI Disclosed

77% -- “I would feel violated and my trust in the researchers betrayed”

67% -- “I could be discriminated against in getting health insurance”

56% -- “I could be discriminated against in getting life insurance”

44% -- “I could be discriminated against by an employer”

39% -- “I could be discriminated against in a government program”

33% -- “I could be embarrassed before friends, associates or the public”

Note the close link between privacy and discrimination concerns
Opt-out Ineffective – Case of PDRP

Physician Data Restriction Program of the American Medical Association
- Opt out up to three years

According to AMA (late 2006)
- only 7000 of roughly 650 000 actively prescribing physicians have enrolled in the PDRP to date
- only 25% of surveyed physicians are even aware that the program exists

PITFALLS OF SECONDARY USE OF INFORMATION
<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
<th>Reference</th>
<th>Details</th>
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<tbody>
<tr>
<td>1996</td>
<td>Congress passed HIPAA, and instructed the Dept. of Health and Human Services (HHS) to address the rights of patients to privacy.</td>
<td>“Not later than the date that is 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to [Congress]…detailed recommendations on standards with respect to the privacy of individually identifiable health information.”</td>
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<td>2001</td>
<td>President Bush implemented the original HIPAA “Privacy Rule” recognizing the “right of consent”.</td>
<td>“…a covered health care provider must obtain the individual’s consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations.”</td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>Amendments to the “Privacy Rule” became effective eliminating “right of consent”.</td>
<td>“The consent provisions…are replaced with a new provision…that provides regulatory permission for covered entities to use and disclose protected health information for treatment, payment, healthcare operations.”</td>
<td></td>
</tr>
</tbody>
</table>
It is O.K. per HIPAA for a health related business (or associates) to communicate to you if the advertisement, mailer, brochure, or other communication is:

- About a drug, product or service that is covered by your plan and the communication comes from your insurer
- Related to your illness or treatment
- Involved in the management or coordination of your health care, or recommendations for alternative treatments, therapies, health care providers or settings of care

Electronic Privacy Information Center (www.epic.org)
Examples from EPIC

• A drug manufacturer can pay a doctor or a pharmacy to send refill reminders, information about specific drugs or alternative drugs to all patients that have a certain condition. *The only difference between this kind of marketing and a T.V. commercial is that this advertisement comes directly from someone you trust, your doctor or your pharmacy. Yet it was designed and paid for by a drug company.*

• You could receive marketing of services or products based on your personal health problems such as diabetes or HIV/AIDS. This could happen without your permission. *Why? Because it is classified as case management or coordination of care.*

Electronic Privacy Information Center (www.epic.org)
Denying health insurance …

“Health insurers in California refuse to sell individual coverage to people simply because of their occupations or use of certain medicines”

“Dozens of widely prescribed medications — including Allegra, Celebrex and Prevacid — may lead to rejection, according to the underwriting guidelines that the health plans provide to insurance brokers but not to the public.”

Drugs that can deny you health insurance

Eight of the 20 top-selling prescription drugs, ranked by their 2005 U.S. sales

- Lipitor (cholesterol)
- Zocor (cholesterol)
- Nexium (heartburn, ulcers)
- Prevacid (heartburn, ulcers)
- Advair (asthma)
- Zoloft (depression)
- Singulair (asthma)
- Protonix (heartburn, ulcers)

Other common drugs

- Accutane (acne)
- Allegra (allergies)
- Celebrex (arthritis)
- Concerta (attention deficit)
- Lamisil (fungal infections)
- Parolodel (menstrual disorders)
- Prozac (depression)
- Ritalin (attention deficit)
- Tagamet (heartburn, ulcers)

California SB 1096 (pending)

- Drugstores would be free to share patients' prescription records with companies that specialize in bulk mailings - would help consumers by providing letters reminding people to take their medication or refill a prescription.

- Issue is what else could be done with this information (no restrictions in HIPAA)

“Measure would let drugstores pass prescription information to bulk mailers”
http://www.latimes.com/business/la-fi-lazarus11-2008jun11,0,6320149.column
EMR vendor to share patient data with genetics research firm

Perlegen Sciences, Inc. will have exclusive access to the EMR vendor's database of U.S. records (4 million patients) for the purpose of assessing and selecting patients from whom appropriate genetic samples could be collected to understand the genetic influences important in predicting patient-by-patient responses to drug therapy.

won't have access to patient identities (only de-identified patient records), re-identified only by participating healthcare institutions.

Once re-identified, participating patients and physicians will receive financial compensation for providing samples for further analysis.

Healthcare IT News By Richard Pizzi, Associate Editor 03/20/08
Topics

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- Health data stewardship
“Today, the health industry relies upon the HIPAA construct of covered entities and business associates to protect health data.”

Health Information Technology (HIT) and Health Information Exchange (HIE) increases availability of health data

“The recommendations in this report call for a transformation to enhanced protections for all uses of health data by all users, independent of HIPAA covered entity status.”
NCVHS Recommendation

- NCVHS urges that the term “secondary use” be abandoned in favor of explicit description of each use of health data, such as “report communicable disease to public health,” “use health data for quality improvement” or “keep health information in my personal health record.”

- Move towards health data stewardship

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
Potential Harm from HIT/HIE enabled health data

“Erosion of trust in the healthcare system may occur when there is a divergence between what the individual reasonably expects health data to be used for and uses made for other purposes without the knowledge and permission of the individual.” NCVHS

Consumer analogy: ¼ of population are Privacy Fundamentalists who agrees or strongly agrees with the statement: “Consumers have lost all control over how personal information is collected and used by companies.”

Potential Harm from HIT/HIE enabled health data (continued)

“Compromises to health care may result when individuals fail to seek treatment or choose to withhold information that could impact decisions about their care because either they do not understand or do not trust how their data might be used or their identity protected.”

“Risk for discrimination, personal embarrassment, and group-based harm may be amplified as there is greater ability to compile longitudinal data, re-identify data that have been de-identified, and share data through HIE.”

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
Health Data Stewardship Proposal

“NCVHS proposes that all organizations and individuals with access to personal health data follow attributes of appropriate data stewardship.”

“The American Medical Informatics Association defines health data stewardship as encompassing the responsibilities and accountabilities associated with managing, collecting, viewing, storing, sharing, disclosing, or otherwise making use of personal health information.”
NCVHS Recommendation for appropriate health data stewardship includes, but not limited to: …

- accountability and chain of trust
- transparency
- individual participation
- de-identification
- security safeguards and controls
- data quality and integrity
- oversight of data uses.

Logging and inspection should be added (e.g., health record equivalent of free credit report)
Summary

- Patient prescription information widely available
- E-prescribing reduces control that patient may want over certain kinds of prescription
- E-prescribing increases availability of information
- Increased access to e-prescribing information means
  - Potential for faster results at individual patient level (data already available at population level)
  - Increased risk of mis-interpretation
  - Unsolicited or discriminatory uses of information
Questions?

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Author References


E-prescribing Projects

“Ways to Encourage E-prescribing Implementation” for JAMIA Viewpoint article
- Pharmacy Ex: Inverted transaction fees per location (e-scripts below daily volume of 25% free)
- Physician Ex: Type e-script (not data entry)

“Stakeholder Benefit Dependencies” for Informatics for Health and Social Care (IHSC) Journal

“Role of Social (Prescriber-Pharmacy) Network in E-prescribing Adoption” – ongoing research