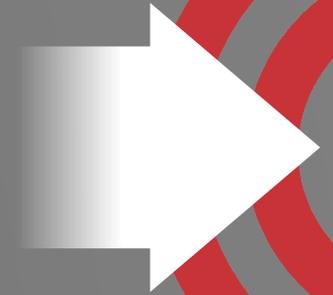


Specialty Pharmacy Concerns and Data Quality Issues in ePrescribing



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October 21, 2011

Conflict of Interest Disclosure Statement



- ▶ **Mihir Patel, PharmD** and **Connie Sinclair, BS Pharmacy**, declare no conflict of interest or financial interest with any pharmaceutical manufacturers, medical device companies, or in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.



➔ **A Brief History of ePrescribing**

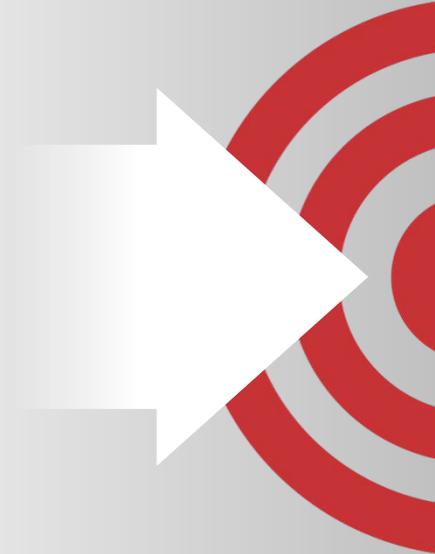
- We've come a long way baby!
- Change of focus

➔ **Current Challenges and Gaps**

- Specialty pharmacy
- Data latency
- Alert Fatigue
- eFormulary data quality

➔ **The Future of ePrescribing**

ePrescribing: A Brief History



ePrescribing: A Slow and Painful Birth



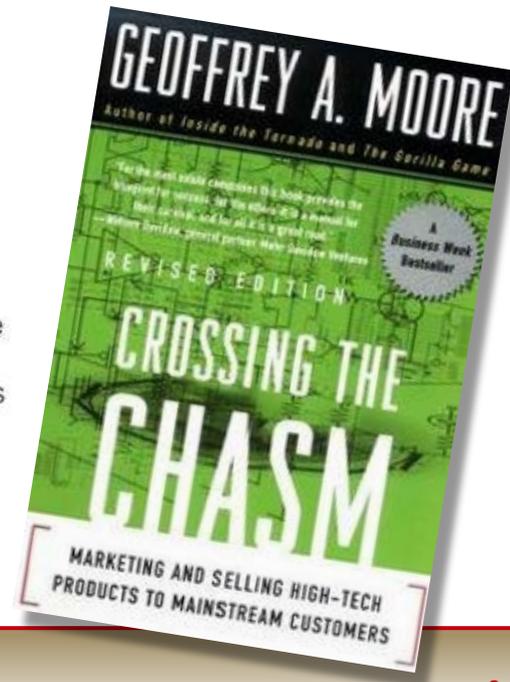
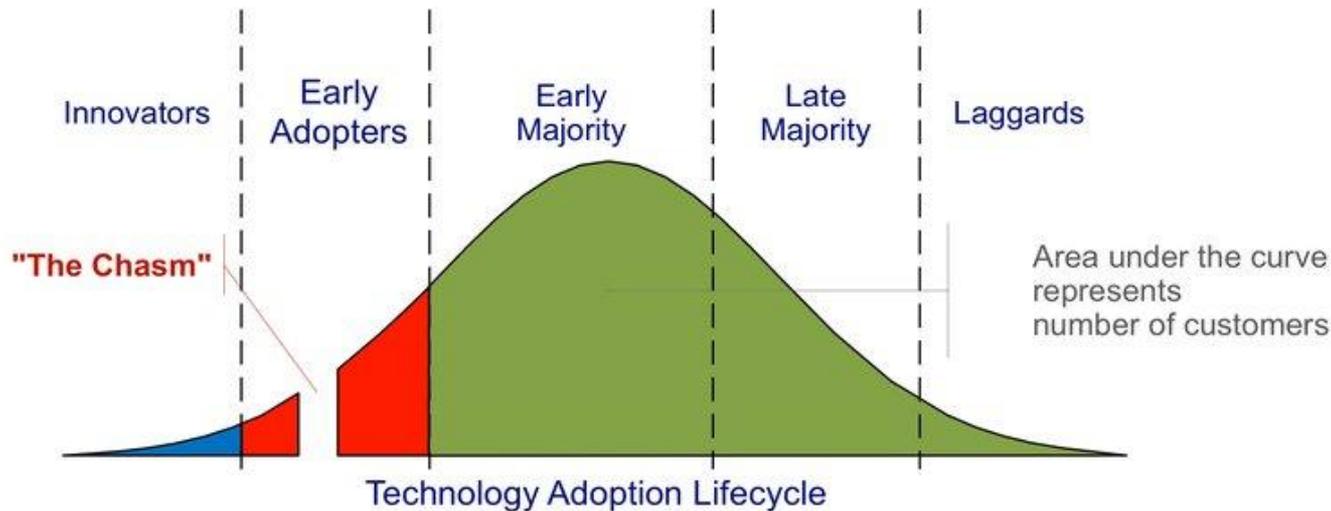
- ▶ For **20 plus years** the industry has known that ePrescribing was inevitable, yet has struggled with getting it off the ground
 - Struggle to finalize standards
 - Challenges with availability of broadband
 - A plethora of vendors have come and gone (remember ePhysican, iScribe, Pocketscript?)
 - Evolution of transaction clearinghouses (Proxymed, Envoy/Emdeon/eRxNetwork, RxHub, SureScripts)
 - Issues of critical mass
 - prescribers with no pharmacies and vice versa



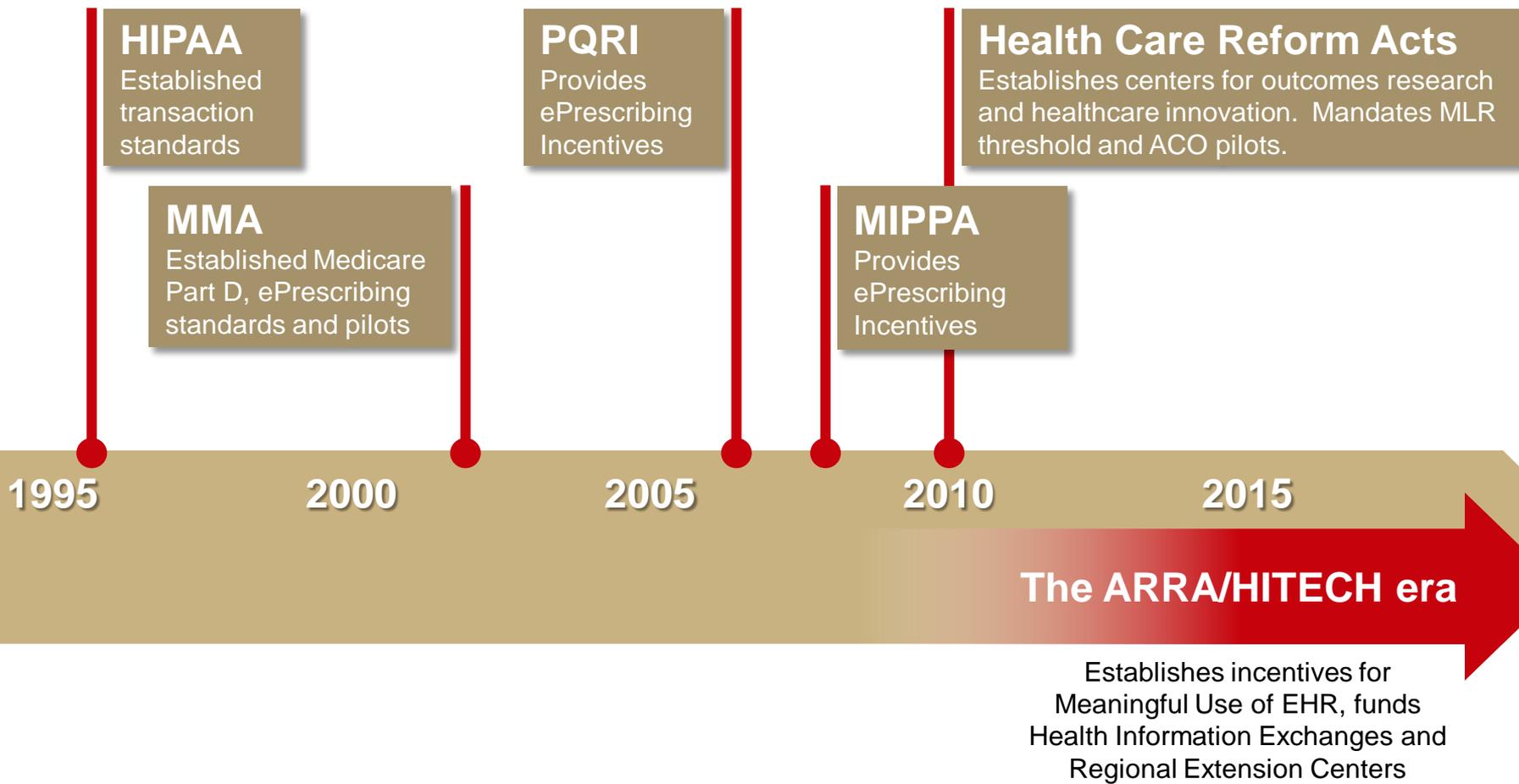
Adoption and Utilization



- ▶ We've been hyper-focused on prescriber adoption and utilization
 - Whatever it took to get the prescriber to use it
 - Remember “Crossing the Chasm”?
 - Reduce keystrokes and clicks, speed rules
 - “Our tool can write prescriptions in just 3 clicks!”
 - Experimentation with business models (eg., “Is free cheap enough?”)
 - Experimentations with devices (Palm, Blackberry, iPhone, Tablets, Laptops)
 - Stand-alone ePrescribing tools helped drive adoption



Government Influence Has Been a Key Driver

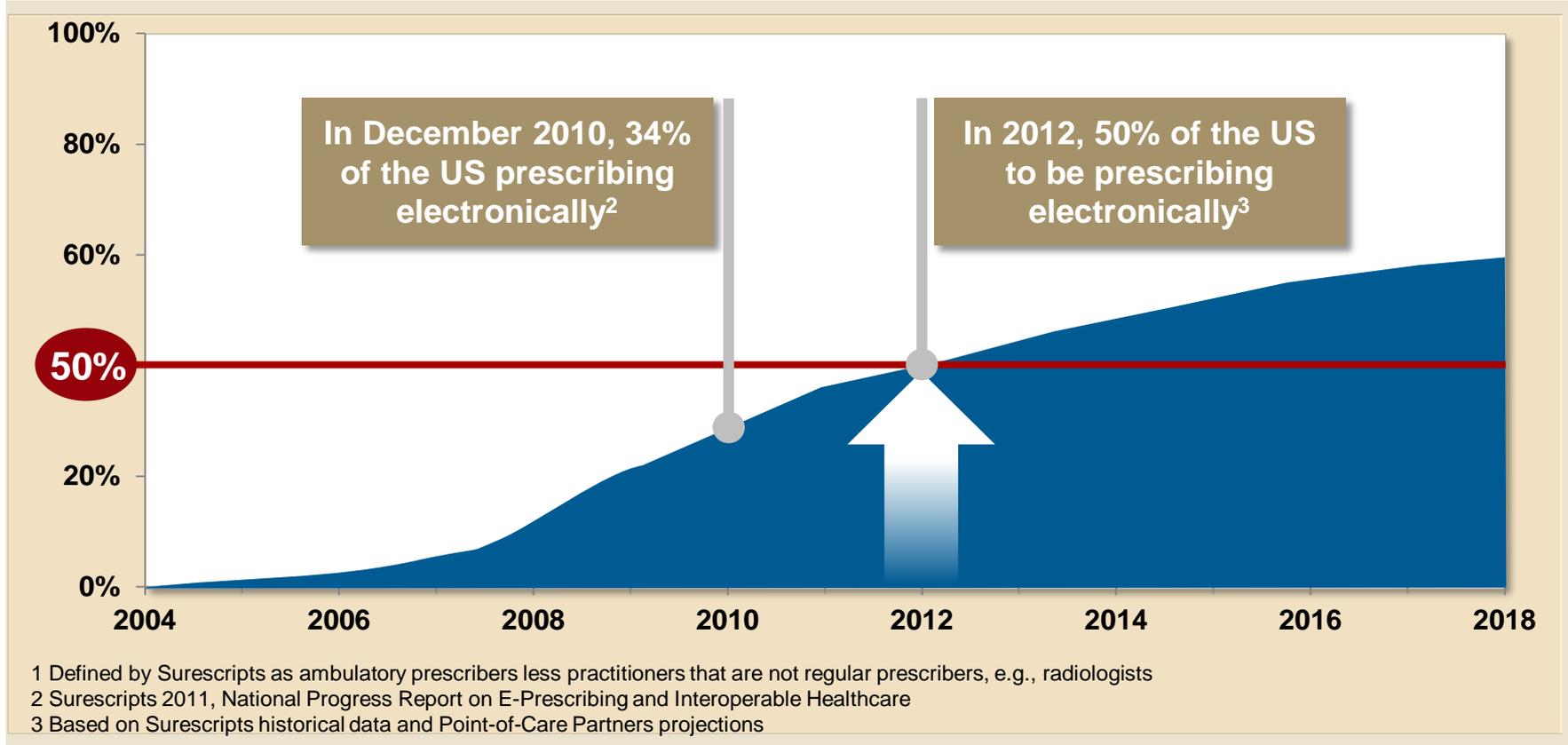


The Chasm Has Been Crossed!

50% of prescribers¹ will soon be prescribing electronically



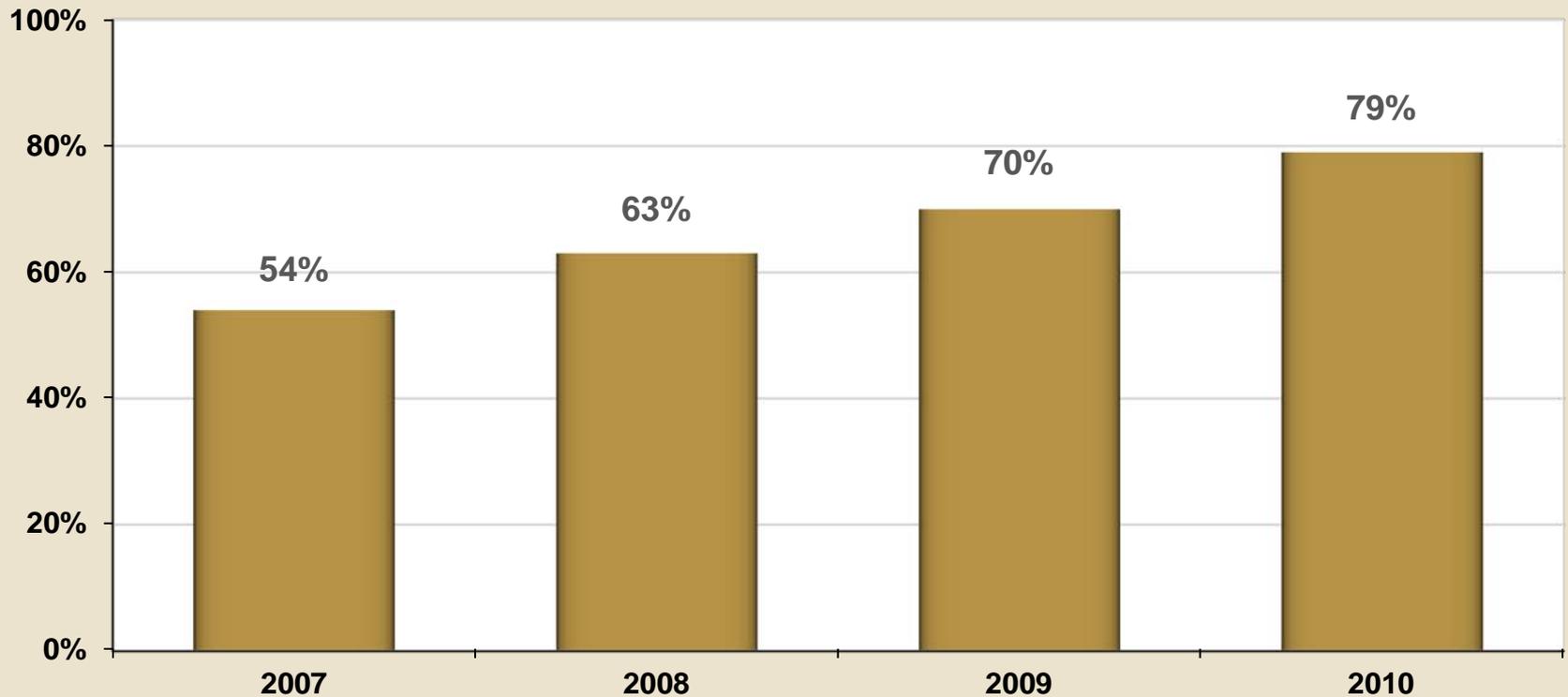
ePrescribers as a Percentage of Total Ambulatory Prescribers



Most ePrescriptions are Generated by EHRs



EHR Prescriptions as a Percentage of Total ePrescribing Volume



Source: Surescripts National Progress Report on ePrescribing 2009, 2010

We've Come a Long Way Baby! Are We Done?



- ▶ **Steady uptake** in both adoption and utilization
 - Critical mass of connected prescribers and pharmacies and plans
 - Growing pool of **experienced users**
 - Accepted standard of care
- ▶ Are the solutions of today ready for what's coming?
- ▶ Most ePrescribing solutions are built on drug database structures that are over 20 years old
- ▶ Many reports of data quality problems
- ▶ What about specialty meds?
- ▶ Issues of **quality** and **usability** taking on more prominence

ePrescribing: Challenges and Gaps

Specialty Pharmacy in Ambulatory Setting



Huge Growth of Specialty Drugs



- ▶ Specialty drugs continue to drive increase in overall drug spend
- ▶ Medco reports specialty trend growth of 17.4% in 2010, the fastest pace since 2004¹
- ▶ “Utilization of specialty drugs grew almost 3 times faster than overall utilization”¹
- ▶ However, EMRs do not yet automate the complex process of ordering specialty medications

“ I decide what I am going to order, then hand it off to my staff to do the paperwork... If anyone was going to this electronically, it would be me. ”

Gastroenterologist and Chief Medical Officer, HIT company,
regarding ordering HepC meds

¹ Medco Health Solution's 2011 Drug Trend Report

Ordering is a Paper-Intensive Process



**CVS
CAREMARK**

Fax Referral To: 800-323-2445
Phone: 800-237-2767

Ship to: Patient Office

Hepatitis C & Hepatitis B Enrollment Form

Date:

Phone:
Fax:

Chronic Hepatitis
Enrollment Form

PRESCRIPTION

INTRON
Weight (lbs)

REDIPEN VIAL
Strength (Dose) Volume to inject
50mcg/0.5ml 0.5ml SQ/QW
0.5ml SQ/QW

RIBAVIRIN®/RIBAPAK
Weight (lbs)

103-131
 132-162
 >162

800mg PO Daily; 400mg QAM
1000mg PO Daily; 600mg QAM
1200mg PO Daily; 600mg QAM
Months



HEPATITIS ASSIST®

HEPATITIS B/C Patient Enrollment Form

Refill x Moun...

PHYSICIAN CONTACT INFORMATION & AUTHORIZATION

Address
City/State/Zip

Date Medication Needed

Ordering and Prescribing Specialty Therapies



- A very **complex**, bureaucratic process
- Manufacturer may limit distribution channel to **specialty pharmacies**
- Plans require dispensing by a **designated** specialty pharmacy
- Most therapies require **prior authorization**
- Each specialty pharmacy has a unique **intake/order form**
 - Nonspecialty products may be bundled in
- Drug product **delivered** to prescriber office, specialty clinic, or patient's home.
- Typically handled as “orders” rather than “prescriptions”
- Pharma or health plan may sponsor a “Hot Line” or “Hub” to assist with the ordering process



State of Automation for Specialty Drug Orders



- ▶ Most specialty pharmacies have the ability to accept electronic SCRIPT transactions
 - Not typically used
 - SCRIPT doesn't accommodate all necessary data
- ▶ Electronic prescribing systems do not support the concept of **restricting** the **routing of certain drugs** to limited list of pharmacies
- ▶ Prior Authorizations are not yet automated
- ▶ Orders are typically documented in the 'Notes' section of EMR
 - May or may not be added to "Medications List"
 - May not run through full Drug-Drug Interaction checks
- ▶ May not appear on the Medication History list since outside the typical prescription flow

Electronic prescribing systems and standards have not evolved to handle the complexities of specialty pharmacy orders.

Medication Management Tools MUST Evolve



- ▶ As specialty trend increases, percentage of drugs that are “ePrescribable” with today’s EMR systems will decrease
- ▶ Trend is towards more aggressive management, more control, more red tape
 - Increased formulary tiers
 - Step therapies
 - Prior authorizations
 - Specialty pharmacies
- ▶ Medication management tools and decision support need to evolve to properly address these requirements
- ▶ Transaction standards need to become more robust
 - Accommodate more data elements

If tools do not evolve, we risk losing the gains for which we have worked so hard!

ePrescribing: Challenges and Gaps

Data Latency in Electronic Prescribing



Data Latency – A Growing Concern



- ▶ Distribution of integrated drug database products is primarily through the ePrescribing or EMR vendor
 - ePrescribing physician chooses the drug from a drug list provided by the compendia vendor
- ▶ Various stakeholders are becoming aware of **significant data latency** problems with this model
- ▶ The complex, multi-step process of data distribution is fraught with delays





▶ Drug Information

- Recently launched drug products unavailable to ePrescribers
- Latest alerts and black box warnings unavailable to ePrescribers

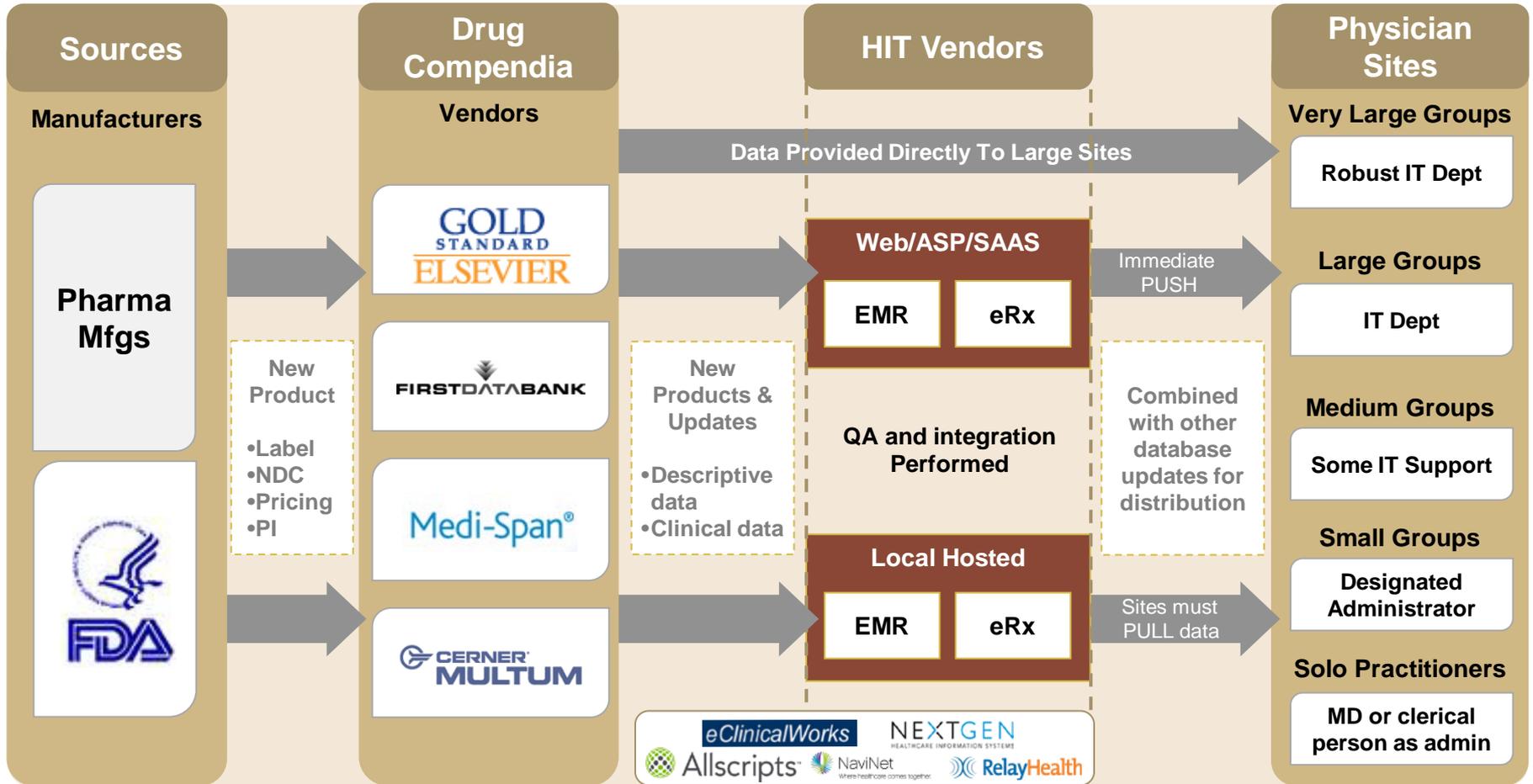
▶ Formularies

- Inaccurate formularies
- Prescribers don't trust the data
- Healthplans and pharma not getting the desired impact from carefully constructed formulary positioning

▶ Pharmacies

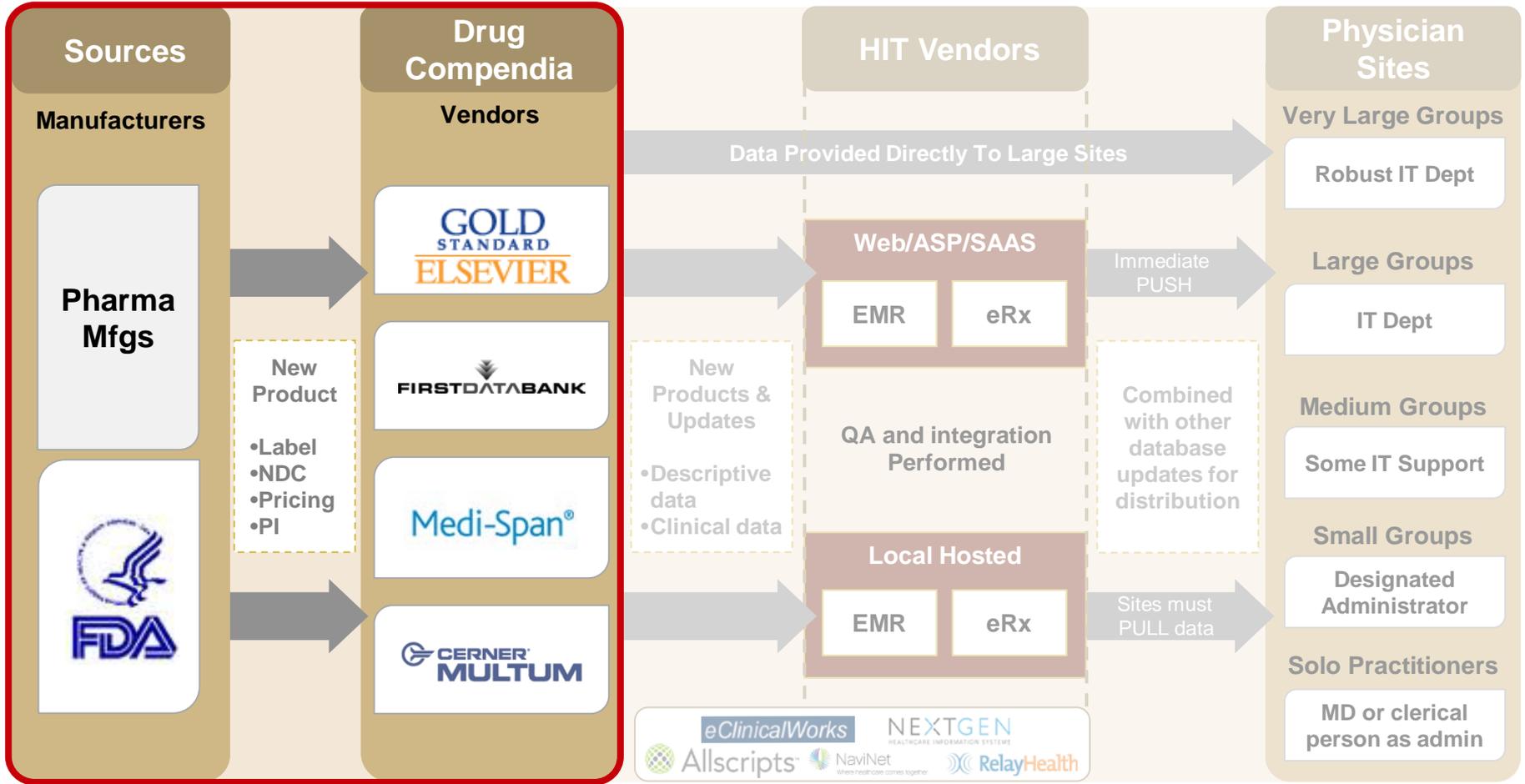
- New pharmacies are opening up every day
- Inconvenient to prescriber & patient if unable to choose desired store

Drug Information Data Flow



The following slides will walk through each step of this flow

Drug Compendia



Drug Compendia Vendors

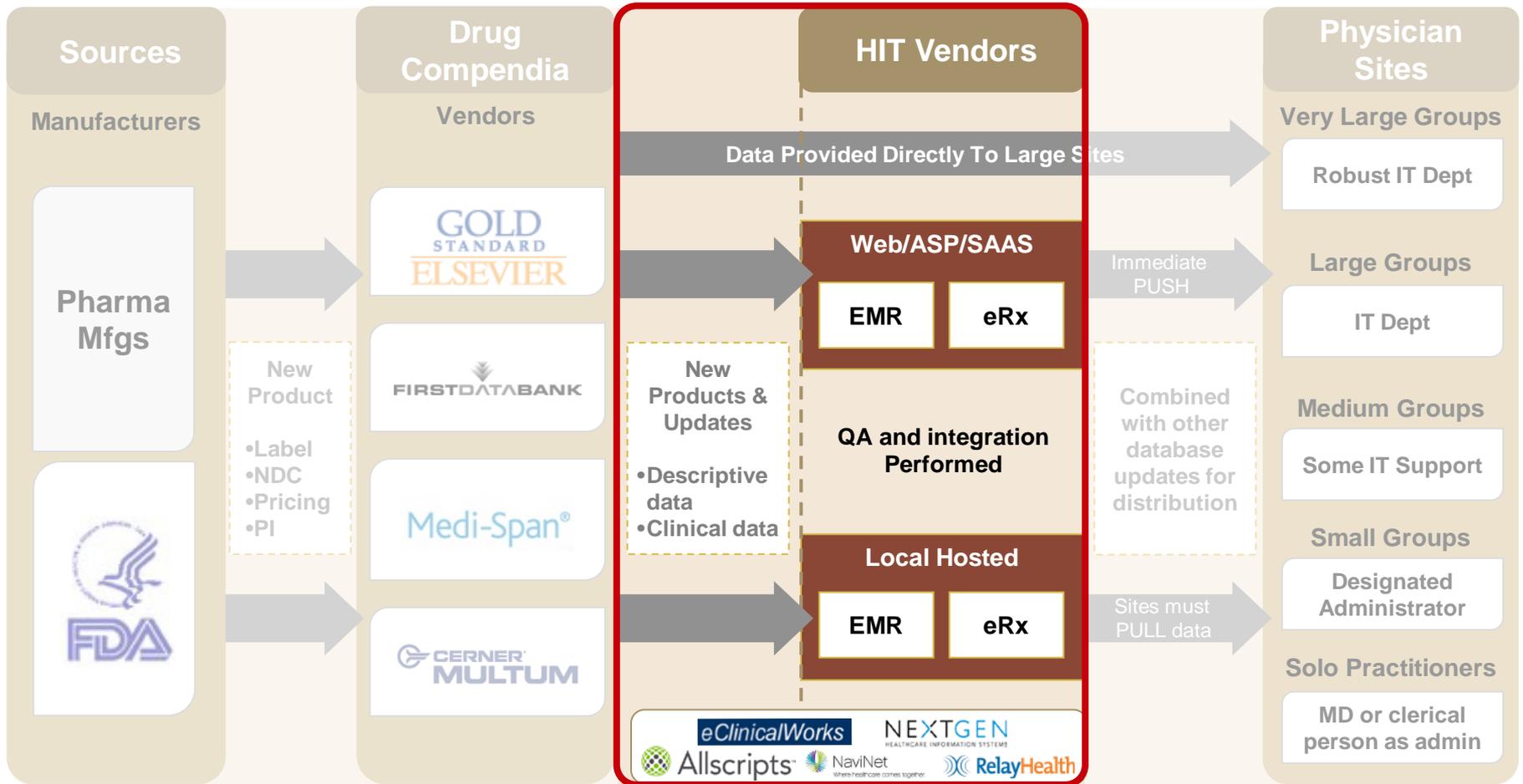


- ▶ Compendia vendors monitor government websites and sources for new product info
- ▶ Highly motivated for timely updating of clinical information and making new product available

Timelines for releasing updates to EMR clients

	Shortest	Typical	Longest
New entity products from receipt of minimum data to release in database	2 hrs	1-2 days	4-8 weeks (will not release without full clinical monographs)

HIT Vendors: EMRs and ePrescribing Systems





- ▶ EMR and ePrescribing vendors take their drug compendia updates weekly, monthly or quarterly
- ▶ Most conduct their own QA and combine with other data updates (e.g., pharmacies, formularies) then make available to client sites.
- ▶ Method of delivery to prescriber client sites
 - Some **push** the **updates** into prescribers system **behind the scenes**, immediately after QA is done (PUSH)
 - Drugs are then immediately available for prescribing
 - Most are posting to a shared site where client staff must take the initiative to **download** and process the update (PULL)

HIT Vendor Timing

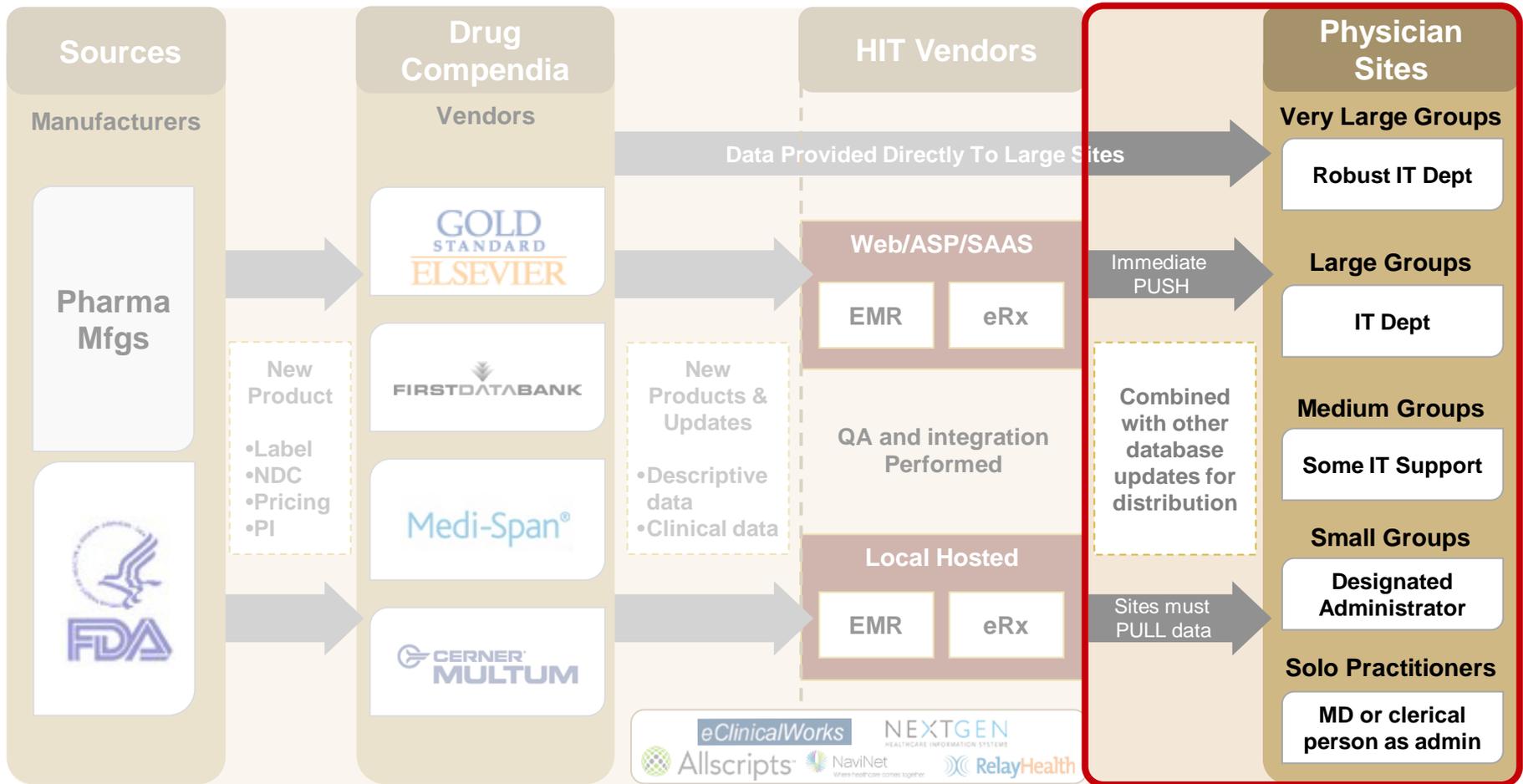


- ▶ EMR and ePrescribing vendors hold onto the update releases for 2-7 business days before making it available to physician sites
- ▶ For vendors that can PUSH the data into prescriber systems, the story ends here as prescribers receive the data immediately

	Shortest	Typical	Longest
Receiving updates from compendia	Weekly	Weekly/Monthly	Quarterly
Vendor QA/processing time*	2 days	5-7 business days	7 business days

* Time lapsed from receipt of updated release from compendia to distribution to clients

HIT Vendors: EMRs and ePrescribing Systems



How Updates are Loaded into Prescriber Systems



- ▶ Most leading HIT vendors require the provider system staff to **do something** to process and load updates
 - The legacy vendors with the most market share are not architected to support PUSH methods
 - Someone on site must download the data
 - Data files can be very large and include drug info, formulary and pharmacy data files
 - HIT vendors are unable to monitor if clients sites are current with processing updates
- ▶ This is the **reason** for the **most significant** delays resulting in out of date drug information



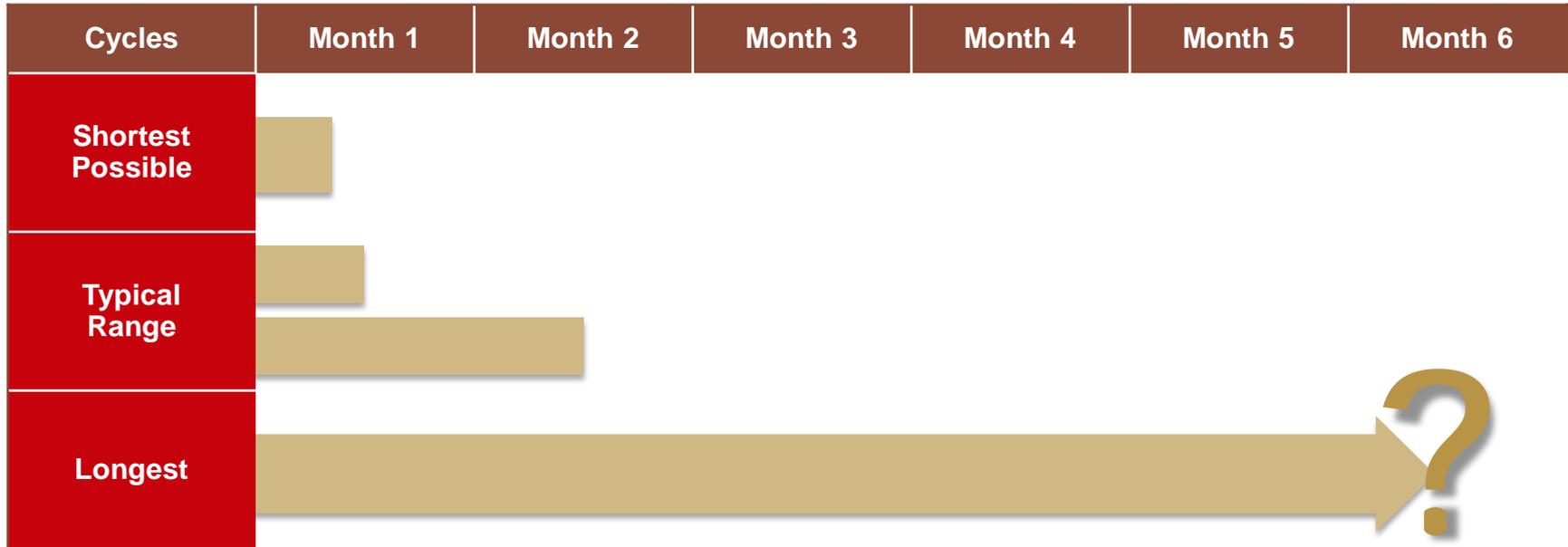
Observations

- ▶ Most groups have someone in IT who manages updates
- ▶ Small groups have someone in the practice designated to load updates
- ▶ Some groups use an external consultant to manage system updates
- ▶ **Prescribers** assume their alert data is current, and are generally **unaware** of **latency** issues

Points of Failure or Risks

- ▶ Anecdotal evidence that many sites ***don't understand the correlation between*** processing the updates and having ***new drugs and alerts available***
- ▶ ***Staff turnover in IT support*** organizations maybe high and impacts quality and frequency of update processing
- ▶ Updates can be time-consuming and **cumbersome** to process
- ▶ Update processing may not be a high priority

Timelines for Product Availability in ePrescribing



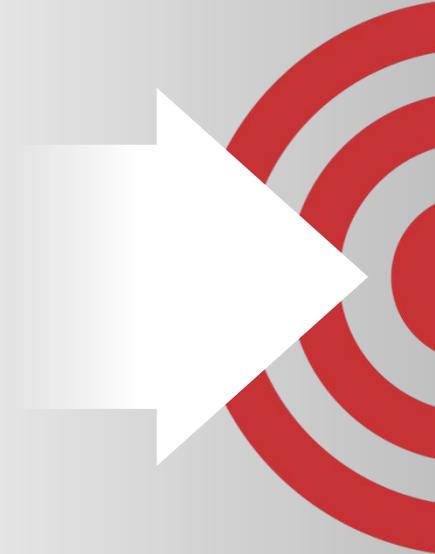
- ▶ Depicts time for new drug product information to reach physician system via compendia releases



- ▶ HIT Vendors should be updating data at least on a monthly basis
 - Weekly is ideal
- ▶ EMR vendors should develop solutions to automate the update process for their clients
 - Takes responsibility off the shoulders of physician practice
 - Most SaaS vendors are easily able to do this
 - Some legacy client/server vendors have done this
 - Client sites should be monitored to assure that updates are occurring in a timely manner
- ▶ Increase awareness of the data latency problem
 - Motivate practices to keep systems updated
 - Drive the industry to develop better solutions

ePrescribing: Challenges and Gaps

Alert Fatigue



Medication CDS Alert Fatigue

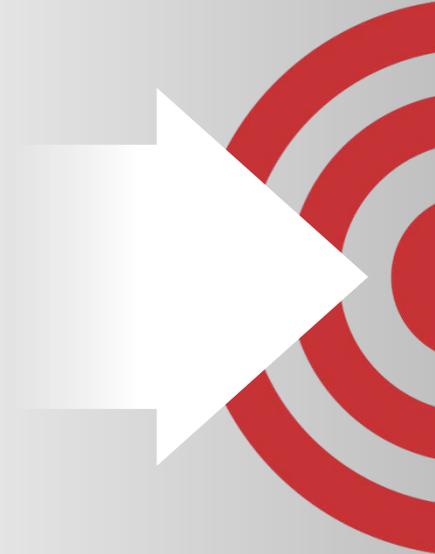


- ▶ Shotgun approach to drug-drug interactions, dosing and duplicate therapy alerts
 - Everybody sees everything
 - Limited by a few basic severity parameters
 - Even “Severe” categories have far too many alerts
 - 89.4% of most severe category are overridden ¹
 - Prescribers tend to “blow through” alerts, don’t believe they are relevant
- ▶ Refinements needed
 - Better classification of drug-drug interactions
 - Better implementations of the data (e.g., screening for route of administration)
 - Customized solutions by provider specialty or practice setting
 - Patient context sensitive alerts (e.g., diagnosis, age, lab values)

¹Weingart SN et al. Arch Intern Med.2004;163;2625-31.

ePrescribing: Challenges and Gaps

eFormulary Concerns



Formulary is part of the ePrescribing process



Address: <https://erx.allscripts.com/AHSWeb/> Go Links SnagIt

Clinician Hide VTB Tools ? Help Lock Logoff

Chart Daily Task List Print Queue Demographics SnapShot Meds New Rx

Chart Site Reports

Bell, Douglas MRN: AHS060727162853730 Sex: Douglas AKA: Douglas Directives: Security: No Restricted Data FYI: FYI
OTHER: SSN: Age: 35 Years DOB: 07/01/1971 Phone: Unknown Allergy: Unknown

Select Patient

Rx Benefit: CIGNA HealthCare for Seniors-Platinum Plan [Edit](#) [Personalize](#)

New Rx

Problems Active All Pending Prescriptions Linked Problems

No entries in list

[New Problem](#) [Details](#) [Resolve](#) [Assess](#) [Rx Detail](#) [Update Link](#) [Remove](#)

Problem-based My Favorites Search Master

Medication	SIG	Days	Qty	Ref	daw
Amoxicillin 250 MG Capsule					
Increlex 40 MG/4ML Solution					
Percocet 10-325 MG Tablet					
Percocet 2.5-325 MG Tablet					
Viagra 100 MG Tablet					

[erX Test Pharmacy](#) 123 N.Chicago test, 670089 60000 P:(847)557-8676 6779

Formulary Alternative: Yes [Save](#) [Cancel](#)



Confirm Prescription Despite Warning

The medication(s) you have prescribed may not be appropriate given this patient's information.

FORMULARY ALERT! This patient's insurance coverage, CareFirst BlueCross BlueShield, excludes the drug you have just prescribed, **Aciphex (rabeprazole sodium)**.

- This drug is non-formulary. Please prescribe an alternative. See [Plan Notes](#) for more information.

Drugs in the same categories (Peptic Ulcer - Proton Pump Inhibitors) that have no limitations include:

-Select One-

-Select One-

Prevacid (lansoprazole) Capsule, Delayed Release(E.C.) 15 mg

Prevacid (lansoprazole) Capsule, Delayed Release(E.C.) 30 mg

Prevacid (lansoprazole) Packet 15 mg

Prevacid (lansoprazole) Packet 30 mg

Prevacid (lansoprazole) Tablet,Lingual Delayed Release 15 mg

Prevacid (lansoprazole) Tablet,Lingual Delayed Release 30 mg

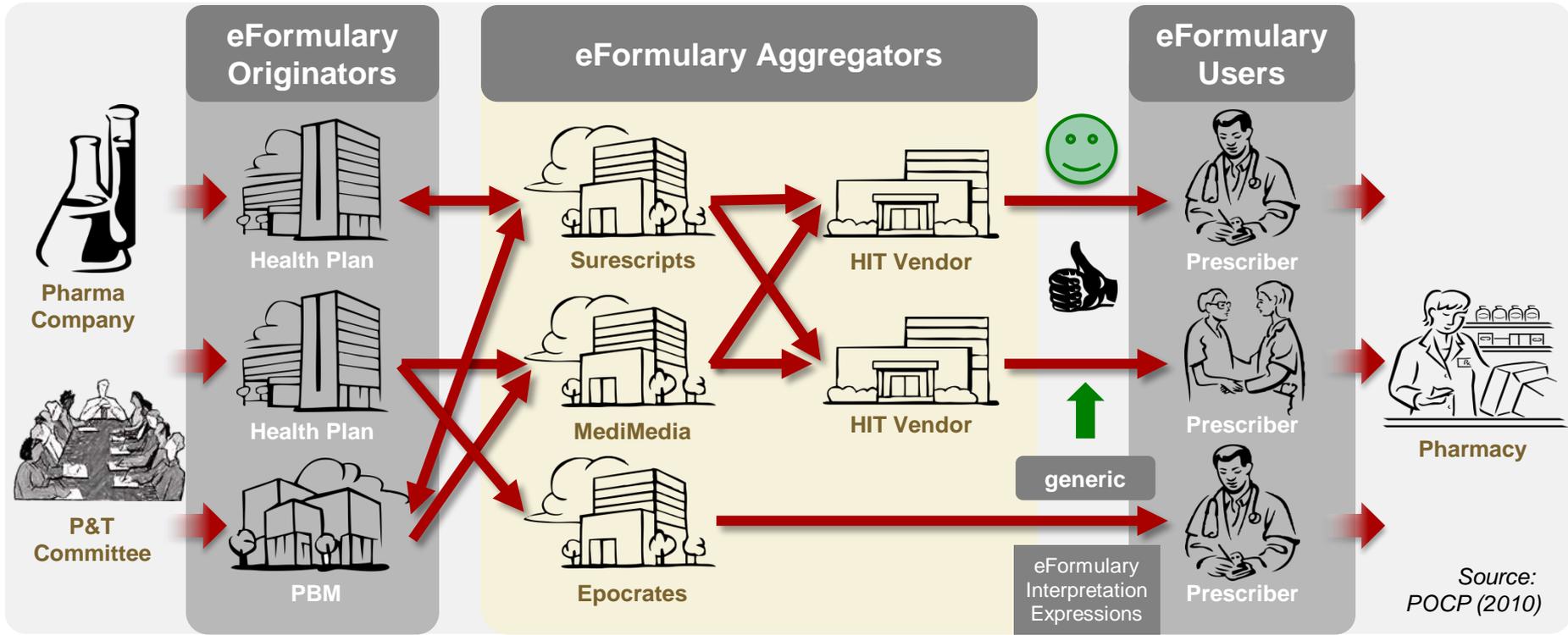
Prilosec (omeprazole magnesium) Tablet, Delayed Release (E.C.) 20 mg

Protonix (pantoprazole sodium) Tablet, Delayed Release (E.C.) 20 mg

Protonix (pantoprazole sodium) Tablet, Delayed Release (E.C.) 40 mg

g the warning.

The eFormulary Process is Complex - Many hand-offs create potential for errors



Source: POCP (2010)



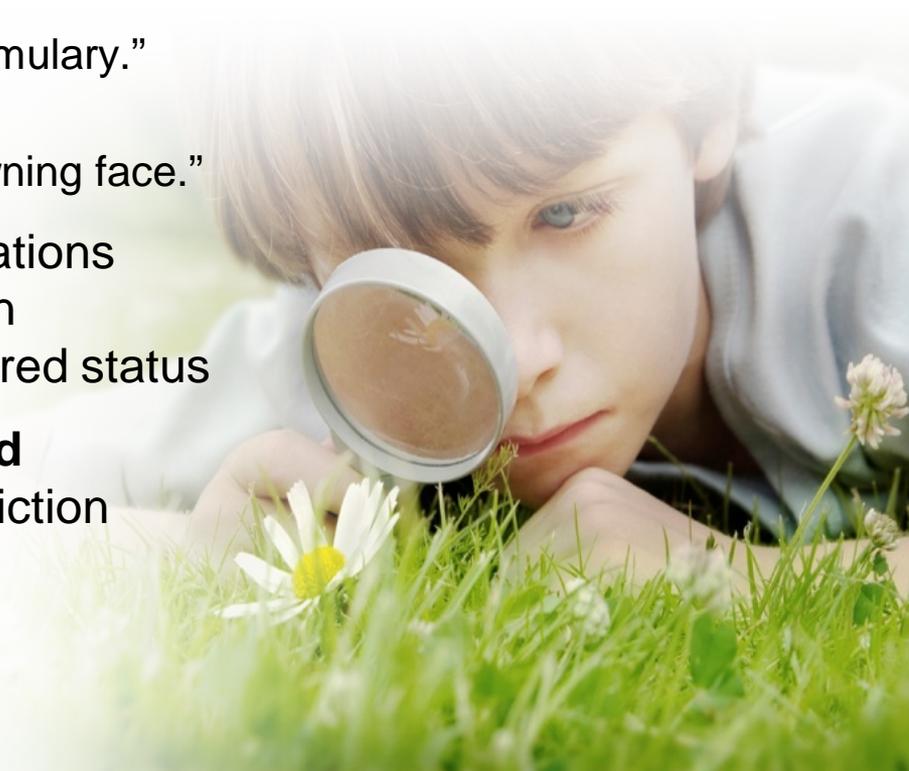
Example: 1 of 2 in preferred brand status, PA acceptable if all PA'd



Consequences of Inaccurate eFormularies



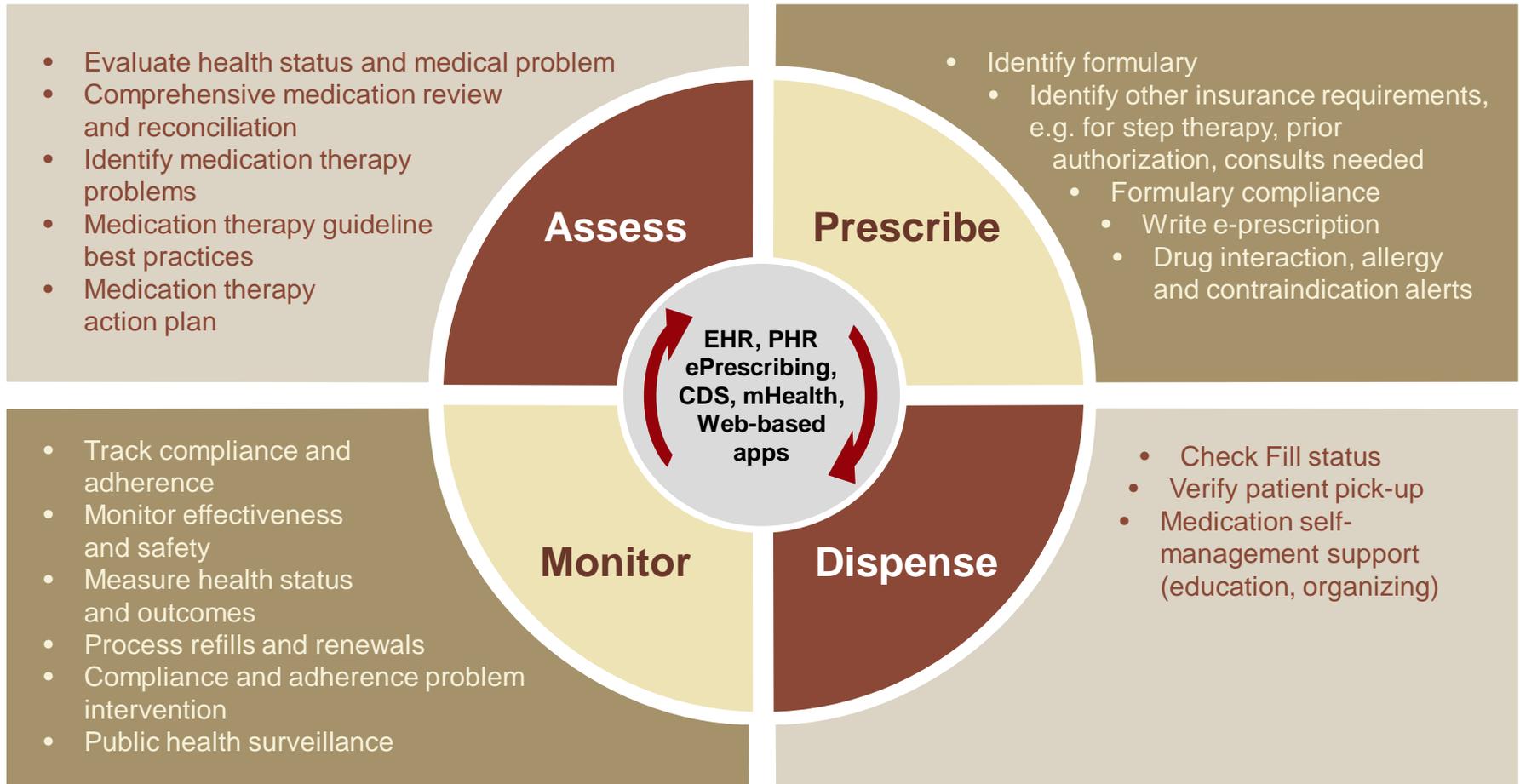
- ▶ Electronic formulary information is used by prescribers in over 37% of all prescriptions today and is expected to grow to 50% of prescriptions in 2012
 - “We’re about 80% accurate and that is good enough for most physicians.”
- ▶ Prescriber **confusion about formulary status** reduces impact of formulary positioning
 - Dr. Smith, “Well, the product is not on formulary.”
 - Payer, “We have placed it on Tier 2.”
 - Dr. Smith, “See, look here. It is a red frowning face.”
- ▶ Inaccurate formularies could create situations where **rebate payments** are made when product is incorrectly listed in non-preferred status
- ▶ Inaccurate formularies **distort perceived effects** of formulary and coverage restriction
 - As ePrescribing increases, inaccuracies may be magnified



The Future of ePrescribing



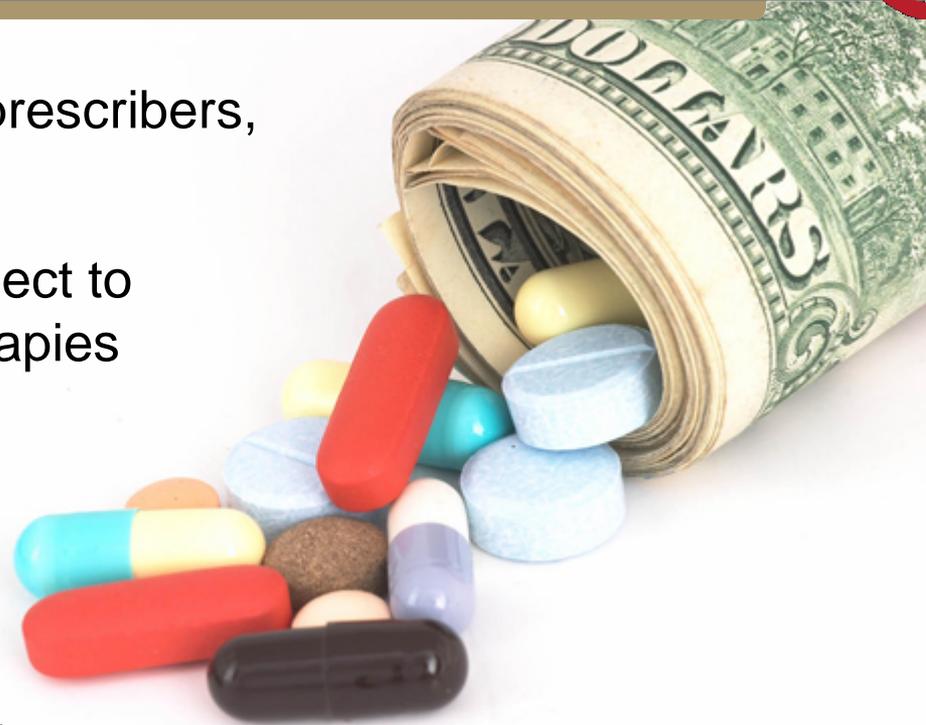
Evolution of ePrescribing to eMedication Management



Electronic Prior Authorization (ePA)



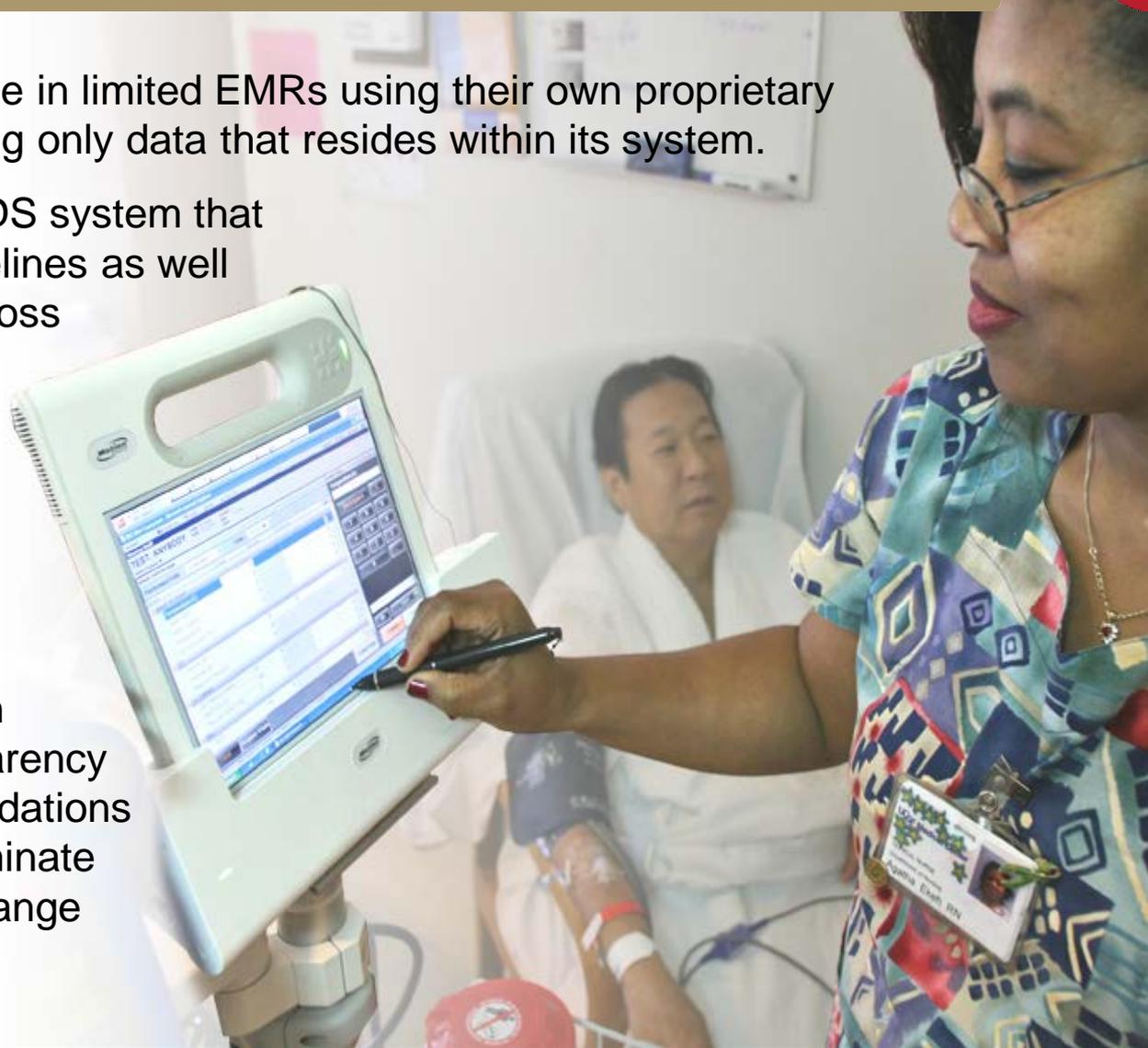
- ▶ PA is an administrative burden for prescribers, pharmacies, patients, and payers
- ▶ More drugs are expected to be subject to PA as the average cost of new therapies increases (ie specialty)
- ▶ ePA legislation has appeared in multiple states over the last year
- ▶ An ePA standard was created by NCPDP by 2009; awaiting pilot testing
- ▶ ePA pilots are being launched by CVS Caremark, Humana, and others



Clinical Decision Support (CDS)



- ▶ Currently, CDS is available in limited EMRs using their own proprietary mechanism and leveraging only data that resides within its system.
- ▶ Create a standardized CDS system that leverages the latest guidelines as well as clinical information across care givers.
- ▶ This can substantially improve adherence to guidelines within both the inpatient and ambulatory settings.
- ▶ A robust CDS system can help bring greater transparency behind clinical recommendations to prescribers and disseminate best practices to a wide range of clinicians.



Incorporating Laboratory Data into ePrescribing



- ▶ Lab values are becoming more relevant in determining treatment options and monitoring whether they are effective, especially as we move to personalized medicine and pharmacogenomics.
- ▶ Providing laboratory results data similar to how medication history data is delivered to ePrescribing systems.
- ▶ Some lab vendors have already established connectivity to ePrescribing networks. This connectivity could be expanded and lab results could be synthesized with prescription history data to provide a more robust set of clinical information for providers.



Risk Evaluation and Mitigation Strategy (REMS)



- ▶ With more and more drugs being approved by the FDA with REMS requirements, the future of ePrescribing should plan to accommodate the various REMS requirements.
- ▶ REMS requirements include:
 - distribution of medication guides
 - enrollment into a tracking program
 - lab value monitoring
 - other requirements
- ▶ ePrescribing should be able to accommodate and help oversee that these requirements have been fulfilled.



Medication Adherence and Persistency

- ▶ One-third to one-half of patients do not take their medications as prescribed.
- ▶ Medication non-adherence costs the health care system \$290 billion annually.
- ▶ Leveraging medication history information more intelligently to provide adherence and persistency rates that can be tracked and incorporated into ePrescribing systems.
- ▶ Providing fill status notification to providers can help identify first-fill and on ongoing compliance issues.



Conclusions



- ▶ ePrescribing is well on the way to becoming the standard of care
- ▶ Gains in patient safety and efficiency are certainly being achieved today
- ▶ More hard work is ahead to refine and mature the products to raise the bar for quality and usability
 - Accommodations for specialty drugs
 - eFormulary quality
 - Data Latency
 - Alert Fatigue
- ▶ ePrescribing is just one component on the spectrum of eMedication Management

DISCUSSION



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