# Automating Specialty Pharmacy

POINT-OF-CARE PARTNERS

HIT Strategy & Management Consultants

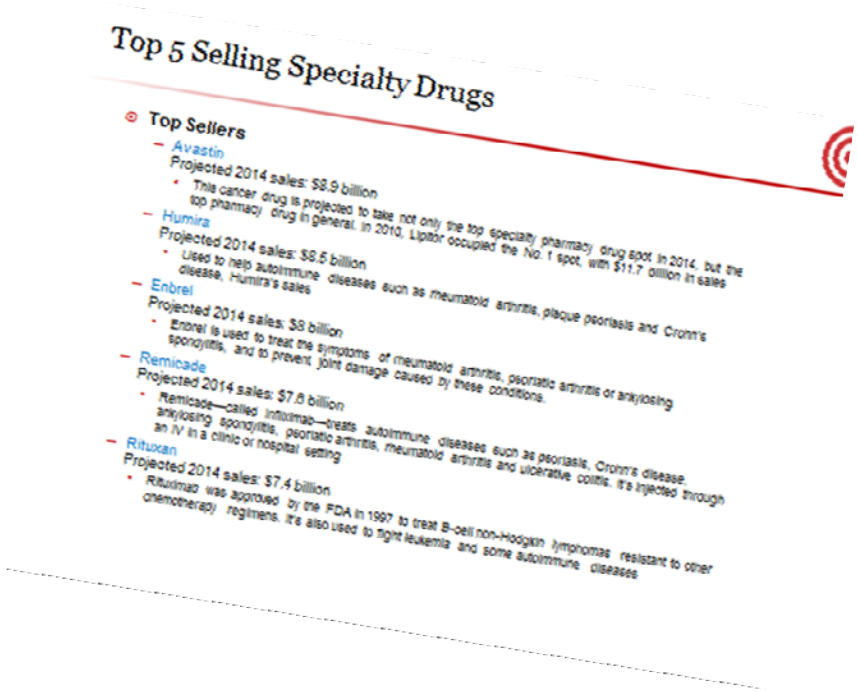
# Agenda

- Specialty Trends/Drivers
- How are Specialty Medications …
  - Ordered
  - Dispensed
  - Paid for
- Current Specialty Flows
- What problems/challenges can be solved by HIT
  - REMS
  - ePA

# What is a Specialty Medication?

There is NO universally-accepted definition of a “specialty medication,” however they generally fit under one or more of these definitions:

- Usually injectable; ‘large molecule’ biological drugs (‘biotech drugs’)
- ‘High’ Cost (>$600 per month)
- Require unusual or resource-intensive dispensing processes (i.e. cold/frozen like injection aids)
- Require focused clinical management




- Other characteristics:
  - Can have limited distribution network (i.e. one sometimes billed under medical, not pharmacy plan)
  - Often require Prior Authorization
  - May Require REMS (Risk Evaluation and Mitigation Strategies)
    - FDA-mandated http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm
    - Communication plan; medication guide; elements to assure safe use; implementation plan

# *Diseases/Conditions* are treated with Specialty

- **Categories**
  - Inflammatory conditions such as rheumatoid arthritis (RA)
  - Multiple Sclerosis
  - Cancer
  - HIV
  - Hepatitis C
  - Growth Deficiency
  - Anticoagulants
  - Pulmonary Hypertension
  - Respiratory Conditions
  - Transplant

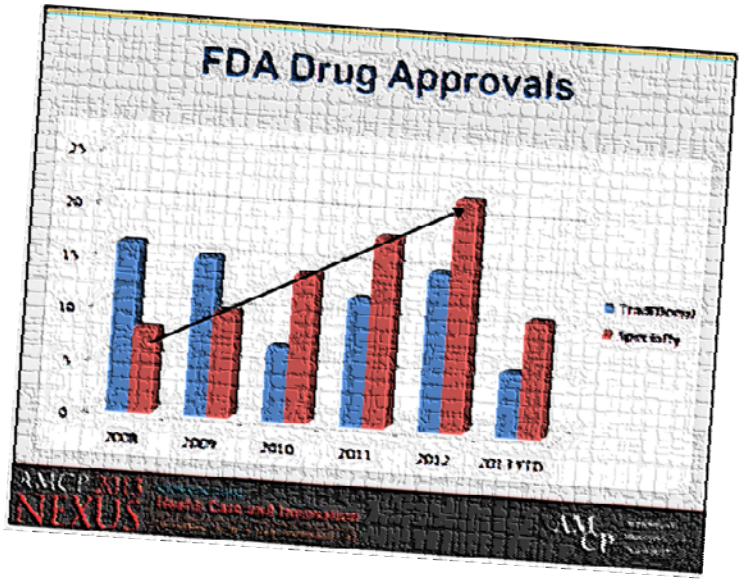
These 3 categories make up > 50% of Specialty cost

- Although some of these conditions have non-specialty drugs as treatment options, most are treated with the specialty drugs

# Why are Specialty Medications Important?

- They are the largest driver of 'trend' of any category
  - Less than 1% of prescriptions filled in 2012 were for specialty medications, yet they accounted for 25% of total prescription drug expenditures
  - By 2020, Specialty Pharmacy costs could make up **40% of total drug costs**

- Of all the new drugs being approved today by FDA > 50% are specialty
  - Right now there are some 900 new drugs in the specialty pipeline, and about 40 percent of those are oncology drugs
  - By 2014, seven of the nation's top 10 drugs will be biotech, compared to five in 2008, and just one in 2000.




- 57 million working-age Americans with chronic illnesses are able to stay on the job due to advances in biotechnology and the development of specialty pharmaceuticals.

# Common Characteristics of Specialty

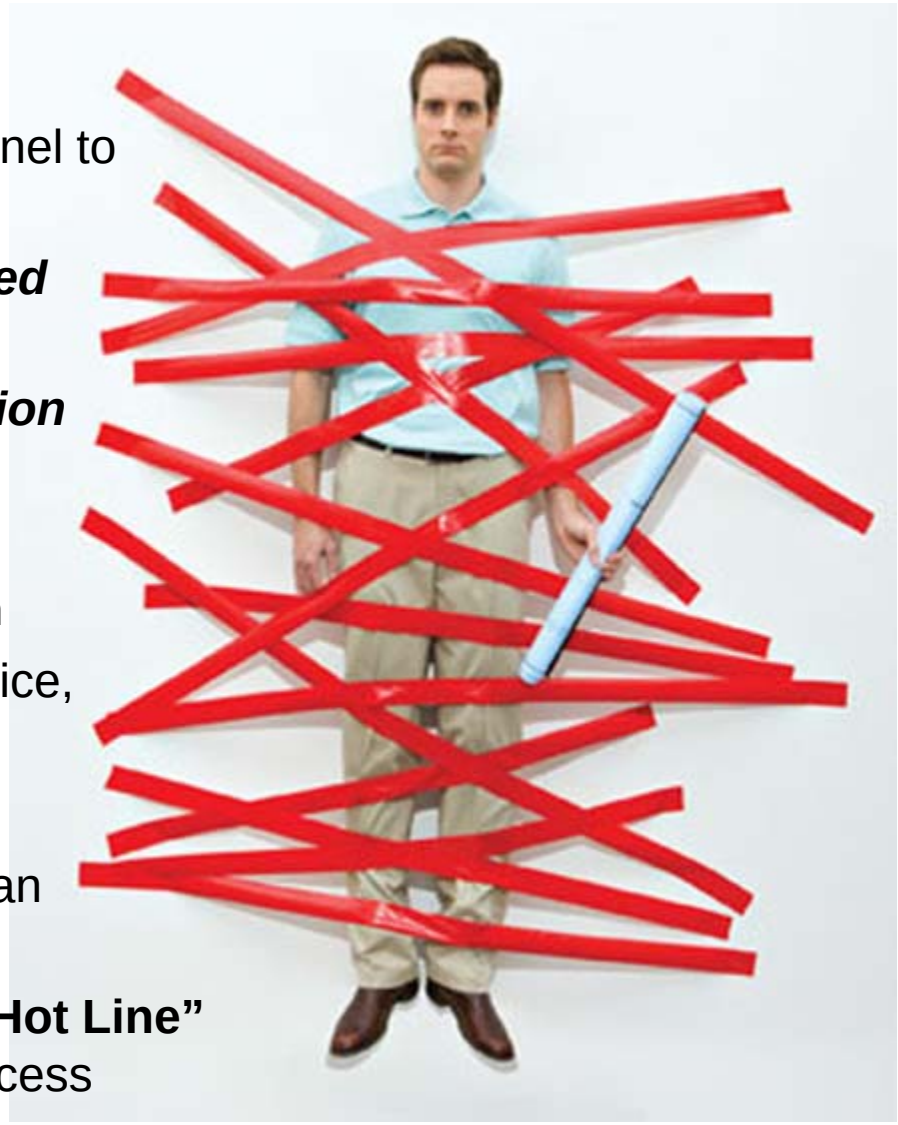
- Some specialty drugs have a limited distribution network
- Patient/Caregiver education about the use of the specialty drug requires more ‘hands on’ than a typical drug
- Payment & reimbursement is much more complicated for Specialty Drugs
- Specialty drugs can and are ePrescribed, however they have been slower to move from Fax/Hand-written/Verbal channels to ‘e’ due to several reasons:
  - Non-tablet/capsule products are traditionally harder to ePrescribe due to drug selection issues on the EHR
  - Selection of the proper pharmacy to route to is problematic
  - Different drug coverage rules require more communication with the pharmacy

***“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 CMO, HIT company, regarding ordering HepC meds

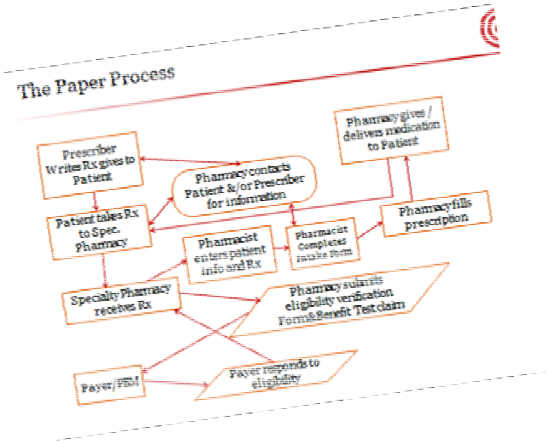
# The Specialty Pharmacy Business Problem

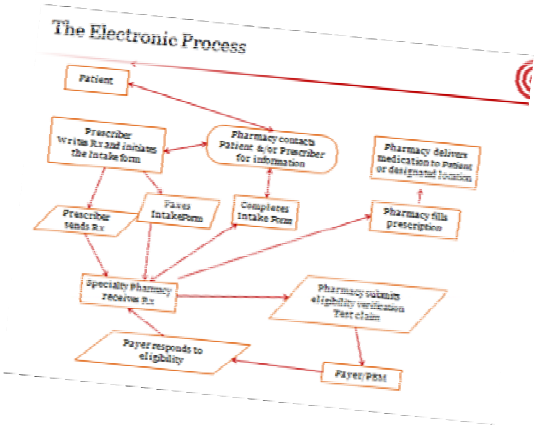
- A very ***complex***, bureaucratic process
- Manufacturer may limit distribution channel to ***specialty pharmacies***
- Plans require dispensing by a ***designated*** specialty pharmacy
- Most therapies require ***prior authorization***
- Each specialty pharmacy has a unique ***intake/order form***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

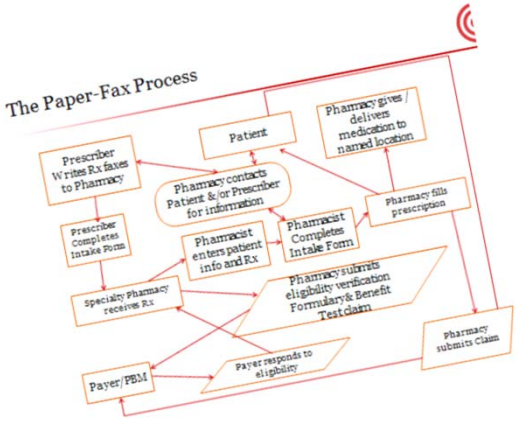


# Current State of Automation

- Most specialty pharmacies have the ability to accept 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
- 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 Rx flow
- REMS is being worked on within NCPDP
- Prior Authorization is only now being automated



# Risk Evaluation & Mitigation Strategies (REMS)

# Overview

- Created by the Food and Drug Administration Amendments Act of 2007
- Gives FDA broad powers to:
  - Control drug marketing and labeling
  - Require post-approval studies
  - Establish active surveillance systems
- May be required as part of a new or abbreviated new drug application or a biologics license application
- As a condition of drug approval, allows the FDA mitigate risk based on:
  - Size of the targeted population
  - Disease or condition treated by the drug
  - Duration of therapy
  - Known or potential adverse events that may be related to the drug
  - New molecular entity FDA claims requires monitoring
- If FDA requires REMS, it can also require:
  - Medication Guide
  - Patient Package Insert (PPI)
  - Specific Communication Plan
  - Additional Elements to Assure Safe Use (ETASU)

# The Functional Workflow

**Maximize**:

- Patient access
- Prescriber participation & benefits
- Support and endorsement of key partners
- Efficiency
- Satisfaction of FDA

**Minimize**:

- Cost
- Disruption of existing workflows
- Liability
- Risk of failure

## Prescriber & Dispenser Workflow

Prescriber is notified of Opioid REMS and prescriber benefits in partnership w/ medical society & liability carrier

Prescriber is registered, authenticated and certified online via w/ CME credits

Prescriber questions, support and follow up survey provided online, via an 800# & print

Prescriber writes Rx for Opioid and gives patient Rx + Opioid REMS Contract to sign

Patient or caregiver signs Opioid REMS contract and takes Rx to Pharmacy

Pharmacist /Dispenser confirms prescriber REMS certification as part of Rx claims transaction . Denial if not confirmed

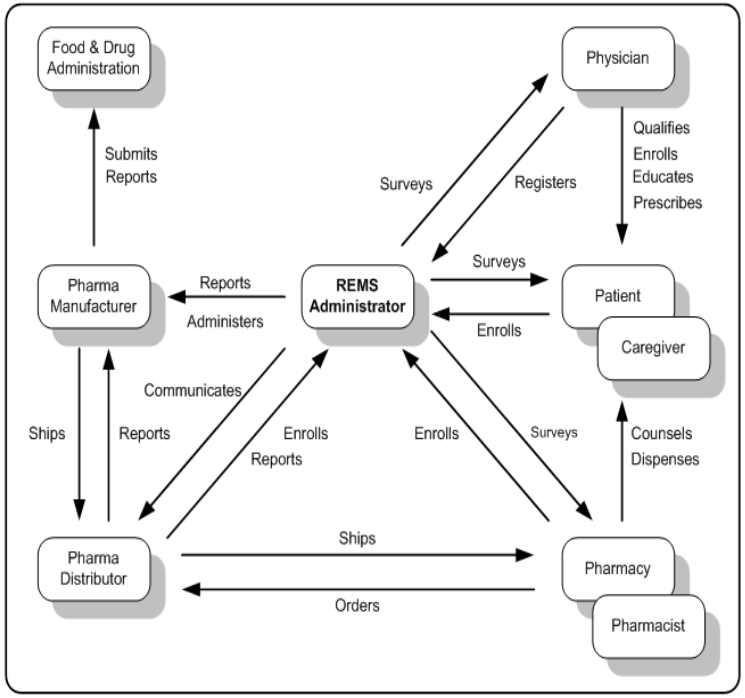
Pharmacist /Dispenser contacts help desk if there are questions regarding prescriber certification

Prescription filled including patient's medication guide as per Opioid REMS

# WG 1 – FDA REMS TG

**NCPDP Telecommunications Standard (aka pharmacy billing):**

- Supports an "in workflow" REMS solution
- Currently supports a class-wide TIRF REMS (i.e. Transmucosal Immediate Release Fentanyl)
- Enhancements successfully balloted (Version E.3) for future use
  - Also supports real-time and in workflow prescription drug monitoring program (PDMP) reporting



# WG 11 – eRx REMS Transaction

- Standardizing the REMs process using ePrescribing transactions
- Streamline the electronic processing of REMS prescriptions from prescriber to pharmacy
- SPL “triggers” transaction in prescriber system
- Transactions being covered by this process:
  - REMS eligibility
  - Verification requirements
  - Refill requests
  - Prescription transfers
  - Changes in drug therapy

# WG 11 – eRx REMS Transaction

**Prescriber System to Intermediary Option for NewRx**

This flow separates the REMS requirements from the NewRx process.

Prescriber chooses patient, medication. The selected medication triggers the REMS "eligibility process". (*Solution requires prescriber system to recognize medications requiring REMS. Structured Product Label (SPL) is assumed to provide this information.)* A query to the drug database (or other control mechanism) indicates that a REMS approval is needed for this medication. The REMSInitiationRequest is from the prescriber to the REMS Administrator to verify REMS is needed. The REMSIntiationResponse is from the REMS Administrator answering if REMS is required, and if yes, the REMS questions to be answered or information to be provided. The REMSRequest is from the prescriber system to the REMS Administrator with the fulfillment information to the questions/information to produce a REMS approval. The REMS Administrator generates a REMSResponse. If Approved, the prescribing system can generate the NewRx. If Denied, the prescribing system must alert the prescriber to modify something and submit a new REMSRequest.

Sets patient expectations before they leave prescriber of whether they are accepted for the REMS before the NewRx is generated.

If an Intermediary is involved, the Intermediary would need a table of which medications are handled by which REMS Administrator. There is a 1 medication to 1 administrator relationship. 1 REMS Administrator may handle many medications. The Intermediary cannot perform REMS transactions on behalf of prescribing system because they would not have the information to fulfill the questions.

**ASSUMPTION: ALL transactions are real-time and synchronous.** (Mailbox could be used.) If no intermediary involved, see Prescriber or Dispensing Provider Direct diagrams.

Prescriber system recognizes need for REMS based upon selected product (SPL)
1) Prescriber system sends REMSInitiationRequest to Intermediary.
2) Intermediary sends REMSInitiationRequest to REMS Administrator
3) REMS Administrator sends REMSInitiationResponse to Intermediary.
4) Intermediary sends REMSInitiationResponse to Prescriber system.
5) Prescriber system sends REMSRequest to Intermediary
6) Intermediary sends REMSRequest to the REMS Administrator
7) REMS Administrator sends REMSResponse to intermediary (approved or denied)
8) Intermediary sends REMSResponse to Prescriber system
If Approved:
9) Prescriber system sends NewRx with REMS, with REMS flag/code/auth # to Intermediary
10) Intermediary sends NewRx with REMS flag/code/auth # to Dispensing Provider system
11) Dispensing Provider system sends Status/Error back to Intermediary
12) Intermediary sends Status/Error back to Prescriber system

**Other Considerations:**

Goal: use of RxNorm as the code set for the medication.

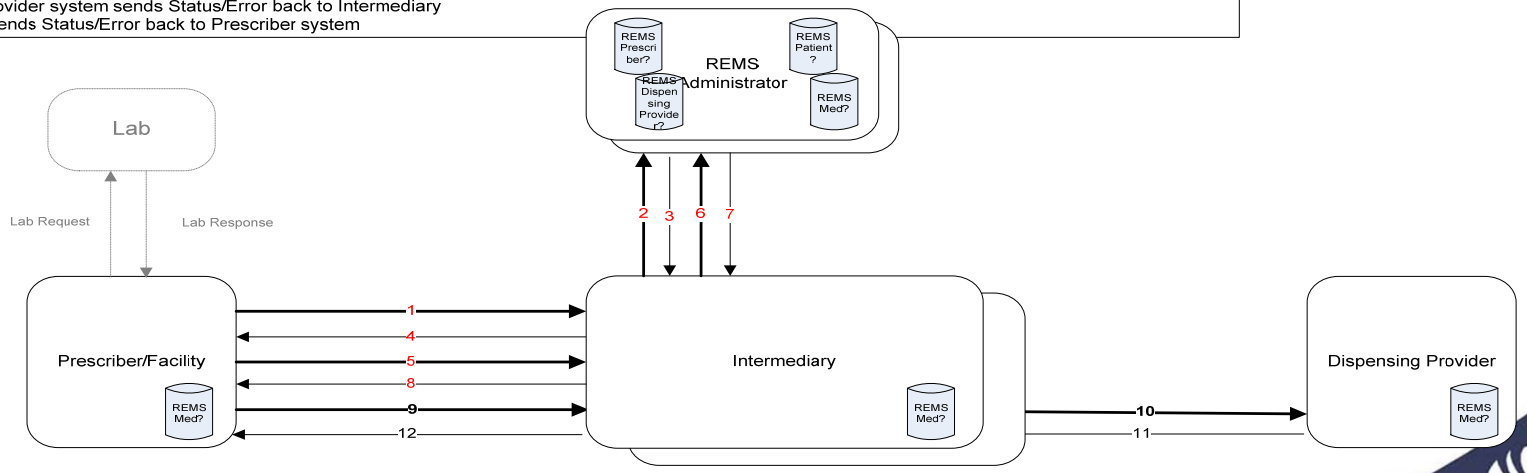
Need to include guidance that to support REMS, the entities have to support the version that supports REMS.

Patient/Dispensing Provider/ Prescriber/Medication – REMS program determines which piece is a failure (one or more than one piece).

REMS Administrator might be able to suggest an alternative Dispensing Provider if the one chosen is not approved.

SPL is working on standardized information from the manufacturers.

2 = New transaction
9 = Current transaction



# Electronic Prior Authorization

# Impact of Prior Authorization

**Pharmacy hassle**

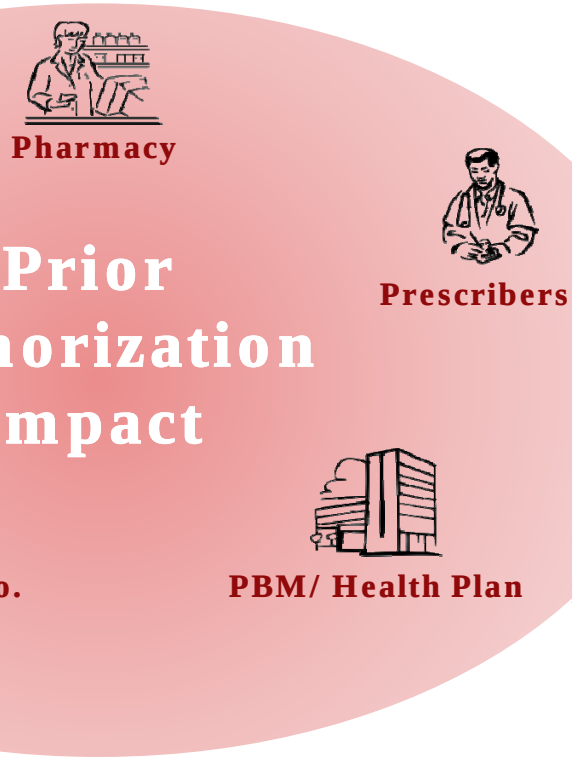
- Pharmacy must call prescriber's office, and sometimes the plan

**Patient hassle and treatment delay**

- PA unknown until patient has already left office
- Treatment might be delayed for days

**Prescriber hassle and disruption**

- Call back from pharmacy, must call plan, wait for faxed form, completes form and sends it back
- Turnaround time can be 48 hours or more



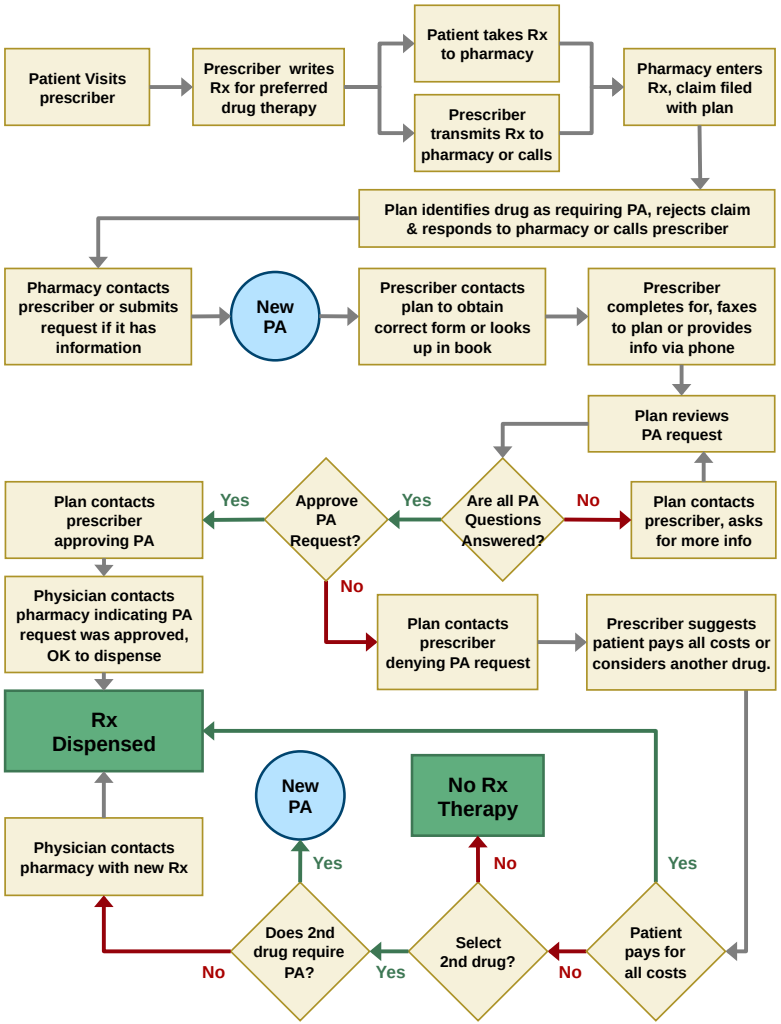

**Pharmaceutical Obstacles**

- Delayed and abandoned prescriptions
- Extensive outlay for physician and patient administrative assistance

**PBM/Health plan inefficiency**

- Expensive and labor intensive process that creates animosity

# Prior Authorization Process




- PA criteria vary by plan
  - Prescriber often needs to provide patient demographics, Dx, and Med Hx
  - May require lab values, other relevant parameters
  - Additional communications often required by health plan and prescriber
- PA criteria are seldom disclosed and considered proprietary, particularly by PBMs and, to a lesser degree, by payers.
- Largely a manual process requiring a combination of paper, fax, and phone for communication and documentation.

# Value of Electronic PA to Constituencies

| | Reduce administrative costs (processing and accuracy) | Reduce drug spend | Improve drug utilization controls | PA Clinical Guidance | Improve patient/member satisfaction | Patient safety (timeliness and adherence) | Automation of data exchange using existing EHR technology | Reduce overall healthcare Costs | Trends/Size |
|---|---|---|---|---|---|---|---|---|---|
| **PBM** | +++ | + | + | | + | + | + | | Top 25 PBMs represent 95% of market[1] |
| **Health Plan** | ++ | ++ | + | ++ | + | | + | +++ | ~32 Million newly covered lives through the Affordable Care Act. |
| **Provider** | ++ | | - | +++ | +++ | ++ | +++ | | 24 to 31 Million already receive care through an ACO. |
| **Patient** | | | | ++ | ++ | +++ | | + | |
| **Pharmacy** | ++ | | | + | ++ | +++ | | | ~80-120M transactions requiring PA per year. |
| **Pharma** | | - | | +++ | | +++ | ++ | | U.S. spent $307.4B on drugs in 2010.[2] |
| **EHRs** | ++ | | | + | + | + | + | | More than 1500 different products certified to perform key medication-related functions |

+++ : Very valuable
++ : Valuable
+ : Somewhat helpful
: Not relevant
- : Disincentive

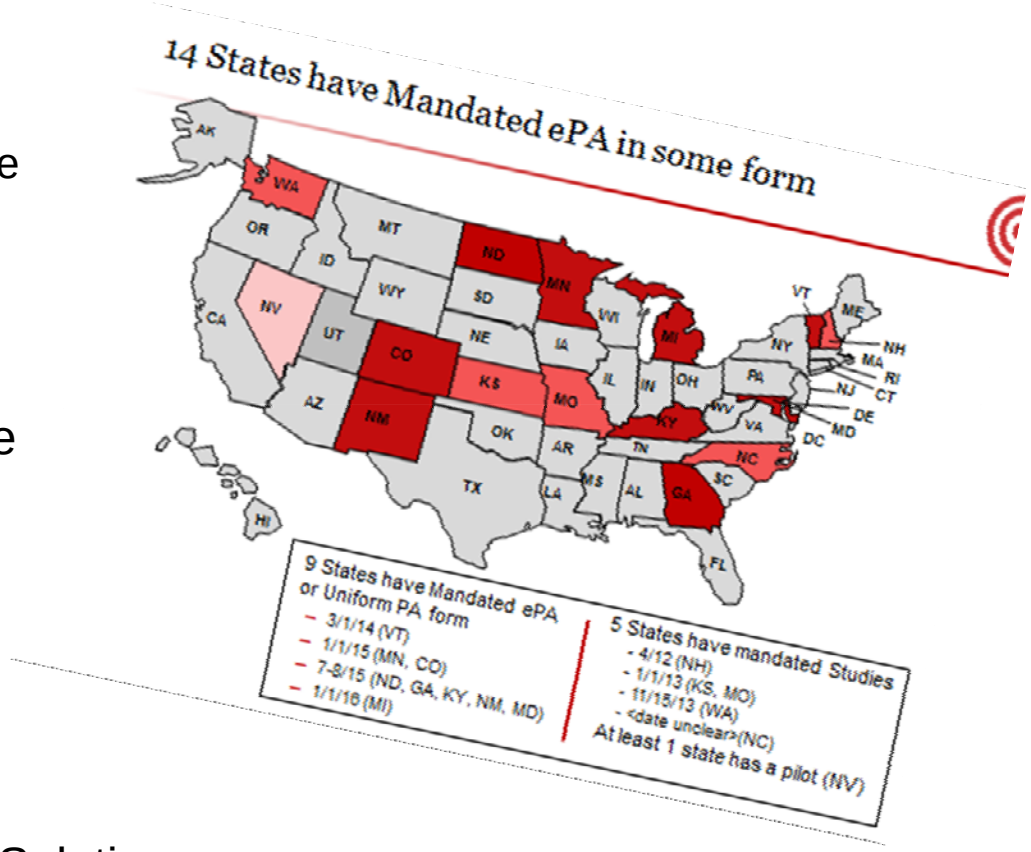
Notes:
1 Atlantic Information Services' (AIS) exclusive quarterly survey of pharmacy benefit management companies conducted by **Drug Benefit News** during the 3rd quarter of 2010.
2 *IMS Institute Reports U.S. Spending on Medicines Grew 2.3 Percent in 2010, to $307.4 Billion*, IMS Institute for Healthcare Informatics, 2011

# Quantifying the Problem

| Metric | Impact |
|---|---|
| PA submission rate | On average, 15% of PA-requiring Rxs have a PA submitted. |
| PA approval rate | About 80% of submitted PAs are approved. |
| Rx loss rate | (15%) * (80%) = 12% filled; which means ~88% of PA-eligible Rxs are lost. |
| Loss to drug manufacturers | $40 billion per year. |
| Time wasted by providers | 15-35 minutes per PA. Consisently cited as one of the worst parts of Managed Care. |
| Cost to plans | $25-$45 per PA. |

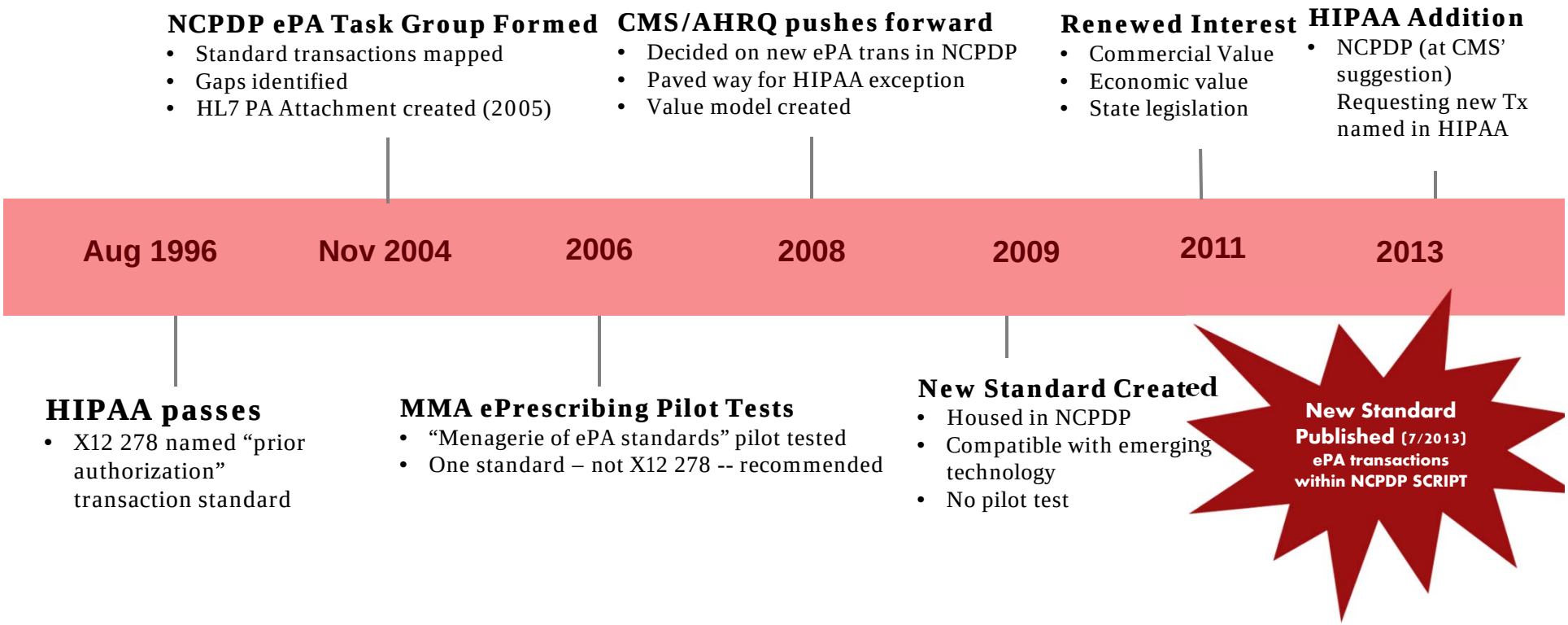
# The Drivers of ePA

- Specialty Pharmacy
  - Impact on Specialty Drug Trend
  - Pervasiveness of Specialty in the drug Pipeline
- State Mandates
- Health Plans/Payers desire for more affordable care and reduce costs
- Competition
  - CVS Caremark Pilot
- Health Reform
- Maturation of stakeholder systems and ePrescribing/EHR Solutions



# Electronic Prior Authorization Milestones

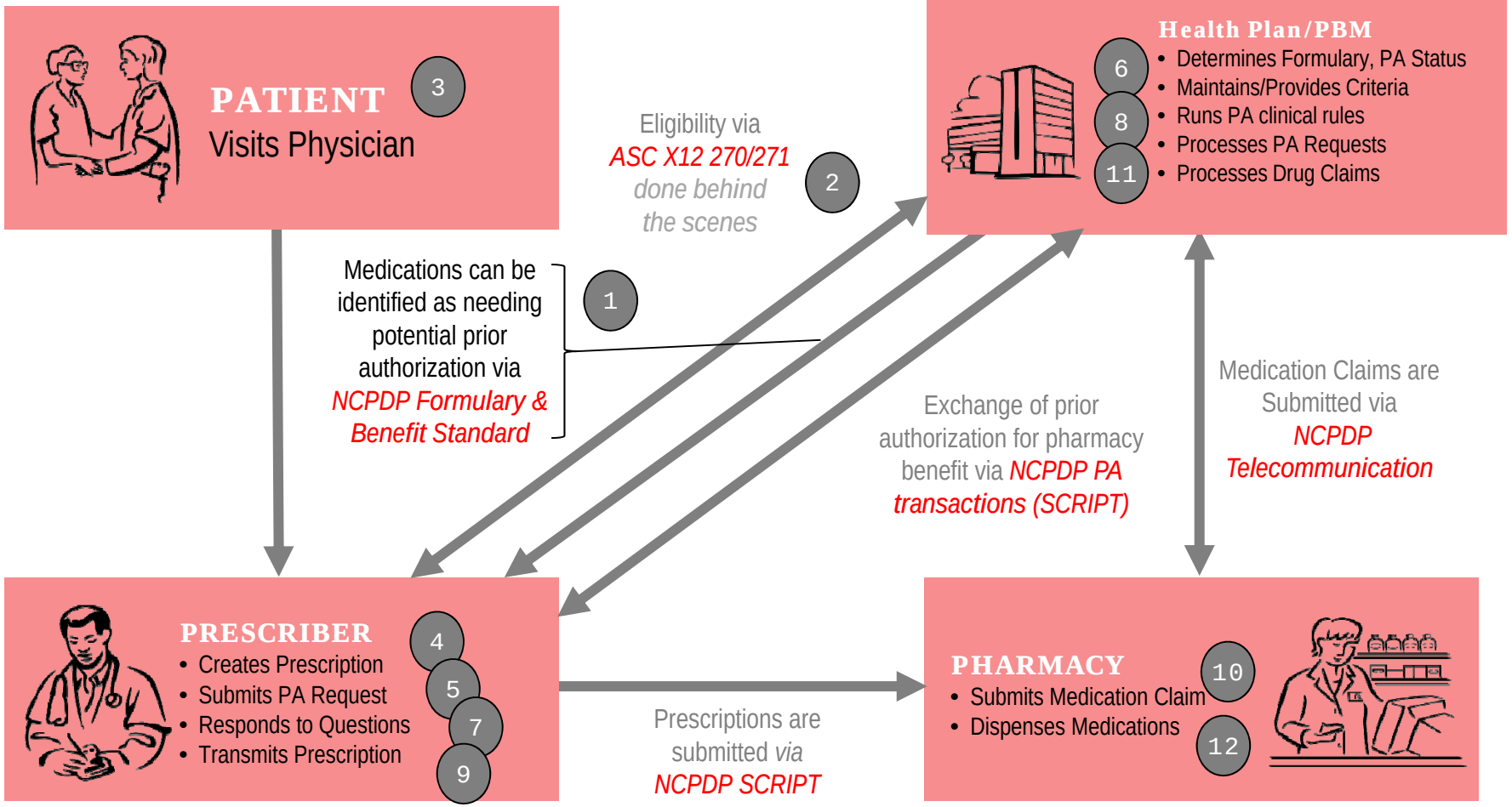
***Federal and state government (HIPAA, MMA, CMS/AHRQ) efforts to encourage development and adoption of ePA has brought us to the precipice.***



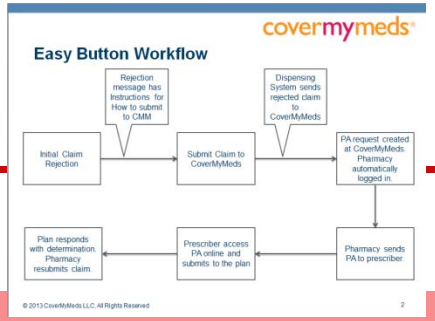
# Latest Developments

- NCPDP working to get SCRIPT named as ePA standard for HIPAA
  - Appropriate paperwork filed in July 2013
  - CMS Office of eHealth Standards and Services (OESS) helping
  - Approval expected by 4Q2014
- DERF to standardize other workflows to be submitted tomorrow

# Standardized ePA Vision/Process



# Claims Rejection Workflow



**PATIENT**
Visits Physician

3

Eligibility via *ASC X12 270/271* *done behind the scenes*

2

**Health Plan/PBM**
- Determines Formulary, PA Status
- Maintains/Provides Criteria
- Runs PA clinical rules
- Processes PA Requests
- Processes Drug Claims

10

Medications can be identified as needing potential prior authorization via *NCPDP Formulary & Benefit Standard*

1

8

Exchange of prior authorization for pharmacy benefit via *NCPDP PA transactions (SCRIPT)*

7

Medication Claims are Submitted via *NCPDP Telecommunication*

**PRESCRIBER**
- Creates Prescription
- Submits PA Request
- Responds to Questions
- Transmits Prescription

4

9

5

Prescriptions are submitted *via* *NCPDP SCRIPT*

**PHARMACY**
- Submits Medication Claim
- Dispenses Medications

6

11

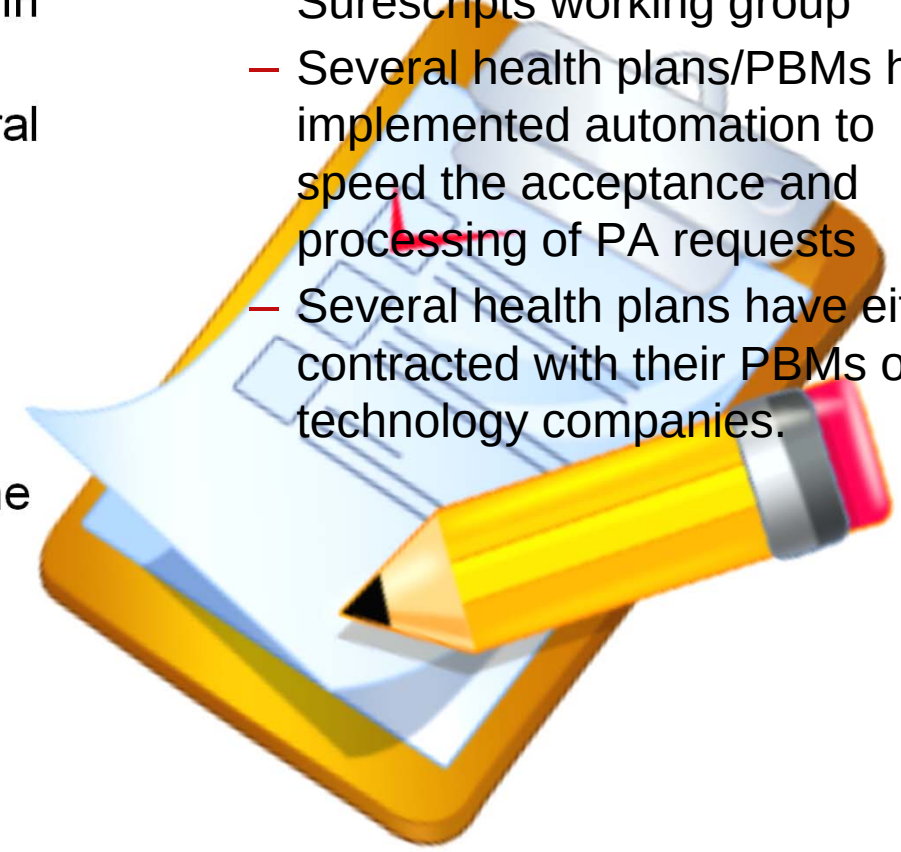
# Vendors and Payers making it happen (finally!)

## Vendor involvement in ePA

- Two vendors (Allscripts, Navinet) are involved in CVS Caremark pilot
- Six (or more) EHRs involved in Surescripts working group
- One multi-payer portal, several single-payer portals
- 2-3 large workflow solution providers
- 3-4 medium-sized workflow solution providers
- Two vendors that intercept the rejected pharmacy claim and forward forms

## Payer involvement in ePA

- One PBM (CVS Caremark) has Piloted ePA transactions
- Four (or more) PBMs involved in Surescripts working group
- Several health plans/PBMs have implemented automation to speed the acceptance and processing of PA requests
- Several health plans have either contracted with their PBMs or technology companies.



# In Conclusion

- Specialty is a growing area of pharmacy that is ripe for process improvement
- The automation that has been introduced is spotty and partitioned, so it's impact is minimal
- The industry is making progress on automating REMS, which is currently live in the pharmacy and planned for ePrescribing. Both require intermediaries.

- We've made the most headway in prior authorization, where standards have been tested, a different direction taken and new standards have now been introduced.
- ePA solutions are REAL. If you don't have a strategy, it may be time to develop one.