NCPDP Stakeholder Action Group on the Potential for Specialty Pharmacy Automation

April 5, 2016
NCPDP Office • Scottsdale, AZ
9:00 am – 10:00 am

Specialty Pharmacy Overview
- Lynnae Mahaney
  Executive Director, Center for Pharmacy Practice Accreditation (CPPA)

The “Problem” in Specialty Pharmacy
- Tony Schueth
  CEO & Managing Partner, Point-of-Care Partners

NCPDP Activities – Specialty Medication Related
- Laura Topor
  President, Granada Health
Specialty Pharmacy Overview

Lynnae Mahaney, BSPharm, MBA, FASHP
Healthcare costs and spending on medications 2014

- 2014 HC spending rate increases 5.3%
- 2013 HC spending rate increase 2.9%
- Primary contributors?
  - Coverage expansion (ACA)
  - Growth in prescription drug spending

Medication Spending
- 2015 Rx meds 5.2% increase
- 2014 Rx meds 12.2% increase
- 2013 Rx meds 2.4% increase

Primary Contributors?
- New Active Substances
- Specialty medications
- Hep C treatments

Specialty medications are a growing and significant part of the nation’s drug spend.

$374 billion in 2014 (IMS, April 2015)

$12.3 billion Hepatitis C

Rise in Treatment Therapies
- 16.80%
- 24.40%
- 0.00%
- 10.00%
- 20.00%
- 30.00%

Health plans and PBMs can better monitor and control specialty drug spending through ePrescribing, electronic prior authorization and formulary data improvements.

IMS Institute for Healthcare Informatics; Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014; April 2015.
In 2015, specialty medications accounted for 37.7% of total drug spending and a 17.8% overall trend, according to the annual Express Scripts Drug Trend Report. See more at: http://www.specialtypharmacytimes.com/news/top-10-specialty-drug-therapeutic-classes#sthash.Q9qqC0of.dpuf

While the volume of specialty medications is less than 1% of total prescriptions, US spending on specialty drugs is projected to grow 67% by the end of 2015.

Specialty medications are the fastest-growing sector in the American healthcare system, expected account for half of all drug costs by 2018.

Specialty medications can run at $2,000 per month per patient; those at the high-end cost upwards of $100,000 to $750,000 per year.
QUICK FACTS ON SPECIALTY PHARMACEUTICALS

- Cost per month generally ranges from $2,500 to $50,000.
- Two-thirds of new FDA approvals are for specialty drugs.
- 8 of the 10 top highest revenue drugs in 2016 will be specialty.
- Patients on these medications are complex, high-cost, and require regular follow-up.
Multiple stakeholders:
- EHR and ePrescribing solution providers
- Pharmaceutical manufacturers
- HUB or other service providers
- Specialty pharmacy and pharmacy solution provider
- Payers

Multiple, bi-directional information needs among stakeholders

Information exchange relies on
- Paper
- Phone and fax
CHALLENGES IN SPECIALTY PHARMACY

Processes are:
- Cumbersome
- Incomplete
- Redundant
- Exceptionally inefficient
- **Barrier to optimal delivery of patient care**
The “Problem”

Tony Scheuth, CEO & Managing Partner, Point-of-Care Partners
REIMBURSEMENT HUB GOALS

Fast Response Time

Referral Re-verification
Electronic submission for re-verification of benefits as needed

Electronic Referral
Triage script to pharmacy for order fulfillment

Electronic Provider and Patient Authorization (eSignature)
Facilitate electronic collection of patient HIPAA Consent and acceptance of any manufacturer-specific consent language

Electronic Prior Authorization
Facilitate submission of prior authorization forms to payers/participating pharmacies

Simplified Customer Experience

Electronic Enrollment with ePrescribing
Electronic submission of the program form, including the prescription, to facilitate processing, triage and dispensing

Electronic Benefit Verification (eBV)
Obtain medical eligibility and benefit coverage details

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Drill-down:

ePrescribing of Specialty Medications
REMS
ePrior Authorization
The infrastructure is in place

80% Physicians Today

More than 80% of physicians ePrescribe today

700 EHRs Enabled

More than 700 EHRs enabled for ePrescribing

100% Retail Pharmacies

Nearly 100% retail pharmacies
Developed for the **oral-solid, single molecule medications** traditionally dispensed in retail or mail service pharmacy.

Designed to accommodate **data elements the retail or mail pharmacy requires** (drug name, dosage, quantity and *sig*).

**Insurance eligibility** determined **before** patient arrives at physician’s office.

**Formulary and some benefit information** is presented to prescriber before drug selection.

**Pharmacy Directory** provided by Surescripts to EHRs prior to prescribing.
CURRENT ePRESCRIBING FLOW

Physician Practice

- EMR or eRx System

A1. Request Eligibility, Drug History

Intermediary

A2. Electronic transmission (EDI)

PBM or Plan

- Claims Processing System: benefit plan rules, formulary, history

Pharmacy

- Pharmacy Dispensing System

B. New Rx
- Refill Request
- Refill Auth/Denial
- Change Request

C. Pharmacy Directory

Drug info Database

Formulary Database

Pharmacy Directory

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The prescriber doesn’t know which pharmacies are part of the limited distribution or plan’s network.

Data required to ultimately dispense a specialty medication is not included in the original prescription; in fact, SCRIPT may not even have the fields to accommodate.

There is no standard definition of specialty, so no specialty medications are flagged leading to specialty drugs being prescribed in the same manner as non-specialty.

The process requires coordination between the pharmacy and prescriber, and there are no transactions that facilitate status updates, and those that can be used for coordination may be sub-optimal.
Drill-down:

ePrescribing of Specialty Medications
REMS
ePrior Authorization
CHALLENGES WITH REMS

- Prescriber doesn’t know if REMS is required … or to what degree.

- Structured Product Label (SPL) is supposed to have REMS information. Compendia would, then, provide to EHRs/eRx companies. EHRs would have to purchase the module, and there are latency issues.

- Patient enrollment rarely in-office (generally given a brochure, and directed to visit a portal); practice generally doesn’t have terminals for patients to enroll on-site.

- If not properly enrolled, claim will reject at POS.

- If REMS is educational, pharmacies have internal processes; however, if it’s a lab, pharmacy must have results before dispensing.

- There are patient access challenges, especially after discharge.

- Reporting to FDA is challenging because of gaps in process and different formats.
Drill-down:

ePrescribing of Specialty Medications
REMS
ePrior Authorization
A LOOK AT THE ePA ROAD SO FAR

1996  HIPAA Passes, names 278 as standard for ePA
2003  MMA Passes
2004  Multi-SDO Task Group formed
2005  NCVHS Hearings
2006  MMA ePrescribing Pilots involving ePA
2007  Report to Congress recommending a new standard
2008  Expert Panel Formed/Roadmap Created
2009  Minnesota Law Passes New ePA Standard Created using SCRIPT
2011  CVS Caremark Pilot
2013  New Standard Published
2015  Implementation of SCRIPT-based Standard
2016  Expansion and EHR integration
NEW STANDARD ENABLES MULTIPLE WORKFLOWS

Retrospective PA – Without PA info at time of prescribing

- Prescriber
  - Rx without PA info
  - Request for info for PA
- Pharmacy
  - Processing
  - Rejected: PA Needed
- Payer

Prospective

- Prescriber
  - Rx with PA info
  - Advises PA Approval
- Pharmacy
  - Advises PA Approval
- Payer
  - Processing
  - Advises PA Approval

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CURRENT LANDSCAPE

Web Portals

EHRs

Intermediaries

PBM/Payer

Pharmacy

CoverMyMeds
Surescripts
Change
Healthcare

Allscripts
Agastha
Aprima
Design Clinicals
Digichart
DrFirst
Epic Systems
Greenway
NextGen
NewCrop
OA Systems
Practice Fusion
Stratus EMR
ScriptSure
STI Computer

Aetna
Argus
Cigna
CVS Health
Express Scripts
Humana
Navitus
OptumRx
Prime
Therapeutics
US Scripts

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• Drug requiring PA flagged in only 20% - 40% of the cases

• Criteria not residing within EHR or visible to physician

• Does not automate the entire process – various workarounds that may or may not meld together

• Paper forms and portals require manual reentry of data that may already reside electronically within an EMR

• Multiple routes to obtain PA depending on health plan, drug, pharmacy, and patient combination
NCPDP ACTIVITIES – SPECIALTY MEDICATION RELATED

Laura Topor, President, Granada Health
NCPDP EFFORTS

- Electronic Prescribing
- Prior Authorization
- REMS
- Real Time Pharmacy Benefit Inquiry
- Reporting
STANDARDS CONTINUUM

- **ePrescribing**
  - SCRIPT 20130701

- **ePA**
  - SCRIPT 20150701

- **REMS**
  - New Standard TBD

- **RTPBI**
  - New Standard TBD

- **Reporting**
  - New Standard TBD
**ELECTRONIC PRESCRIBING (eRx)**

- Added guidance to Recommendations Document to improve use of existing elements in SCRIPT 10.6
  - Diagnosis
  - Height/Weight
  - Insurance Information

- Added elements to SCRIPT Standard to support:
  - e-prescribing of specialty medications
    - Agency and service information
    - IV administration
    - Patient information (i.e. hospice status, alternate contact)
  - Clinical information specific to wound care
  - Enhanced e-prescribing of compounded medications

- Regulation to name new version of SCRIPT expected to be published November 2016
  - Implementation anticipated in 2018
ELECTRONIC PRIOR AUTHORIZATION (ePA)

- Included in NCPDP SCRIPT Standard
- First published in July 2013
- Supports prospective and retrospective models
- Allows for cancel and appeal functions
- Enhancements continue to be brought forth
- Guidance from industry implementation available in NCPDP’s SCRIPT Implementation Recommendations Document
FDA has authority to enforce these programs

Industry needed a way to exchange information related to Elements to Assure Safe Use (ETASU) requirements

FDA agreed to modifications to the Structured Product Label requirements so that REMS information could be supported by drug knowledge databases (compendia) and be readily available within EMRs

NCPDP created new message types, modeled on ePA, and enhanced existing messages to support information exchange

Regulation to name new version of SCRIPT expected to be published November 2016

- Messages from prescriber to REMS Administrator prior to sending prescription
- Telecommunications Standard was modified to allow REMS processing to leverage claim adjudication process

The changes were initially approved by NCPDP members at the August 2015 Work Group meetings and will be published spring 2016
Task Group investigating options to support a real time benefit check initiated by the prescriber

Interest from ONC

11 use cases have been identified, with associated data elements

Further work includes analysis of technical options (EDI, XML, FHIR, etc.) and standard option (new, existing)

Industry pilots underway; feedback will be shared with NCPDP
Specialty Pharmacy Data Exchange Sub-Task Group (within WG 7 - Manufacturer and Associated Trading Partner Transaction Standards)

Develop standardized reporting to support contractual arrangements between the manufacturer and specialty pharmacy. There are four categories the group will address:

- **Order fulfillment**
- Patient Census (Aggregate)
- Performance Metrics/Case Management
- Inventory

Current focus is to identify all needed data elements, then map to existing NCPDP data dictionary. If not in data dictionary, additions will be requested and the format will be presented to the membership for approval.
The End

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