Automating Specialty Pharmacy: Identifying Gaps

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November 3, 2015
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Kevin James
Disclosures

• Kevin James, R.Ph., MBA, has no Conflicts of Interest to Disclose.
• Jeff Spafford has no Conflicts of Interest to Disclose.
• Anthony Schueth, MS, has no Conflicts of Interest to Disclose.
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ACPE program numbers are:
0459-0000-15-073-L04-P & 0459-0000-15-073-L04-T
Initial release date is November 3, 2015.
Learning Objectives

• Describe the **growth trend** for specialty medications and the drivers for specialty ePrescribing.

• **Delineate key differences** in data needs between specialty and non-specialty medications and provide examples of how NCPDP Standards are evolving to support specialty automation.

• **Categorize** types of **specialty transactions** and the entities involved in processing them.

• Identify how payers and PBMs could **better identify PA needs** in formulary and benefit information to facilitate specialty automation.

• Discuss **impact of drugs covered under the medical or dual benefit** and how that modifies the approach to capturing and transmitting the patient benefit.

• **Explain the role of third parties agencies** that provide clinical services to patients to educate, train or comply with REMs and additional dispensing requirements and how delays in those services impact speed to therapy.

• Map the **distribution of products through the supply chain** for specialty medications requiring specific devices, starter/titration kits, and other limited distribution models that determine patient access to medications.

• **Describe the role of reimbursement hubs** and how technology is being used to determine optimal benefit coverage and improve patient access to medications based on benefit coverage.
Specialty Medications: A Force of Health Care

- Administered to small populations with **rare and chronic diseases**.
- Expanding to larger populations and therapeutic areas.
- Complex, large molecule and biologic drugs distributed through **multiple pharmacy models**.
- Majority require **clinical management** and **special handling**.

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

![Graph showing Rise in Treatment Therapies](image)

- **$374 billion** in 2014 (IMS, April 2015)
- **$12.3 billion** Hepatitis C

**Health plans and PBMs can better monitor and control specialty drug spending through ePrescribing, electronic prior authorization and formulary data improvements.**
Specialty Drugs Continue to Grow

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 to jump two-thirds by 2015, and **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**.

Specialty Med Spending: **67% growth end 2015**

Specialty Drugs as % of Total Drug Spend

22% 23% 27% 30% 33% 38% 43% 49% 56% 64%


Source: Prime Therapeutics
Types of Specialty Prescription Transactions

**Prescription**
- Prescription
- Prescriber
- Pharmacy
- Via: NCPDP Script

**Intake Form**
- Intake Form
- Pharmacy
- Prescriber
- Via: NCPDP Script

**Benefit Verification**
- Benefit Verification
- Pharmacy
- Payer
- Via: 271/272

**Financial Assistance Determination**
- Financial Assistance Determination
- Patient
- Pharmacy
- Foundation
- Via: NCPDP Script

**REMS**
- REMS
- Prescriber
- Pharmacy
- Manufacturer
- Via: NCPDP Script

**Care Coordination**
- Care Coordination
- Pharmacy
- Patient
- Via: NCPDP Script

**Prior Authorization**
- Prior Authorization
- Prescriber
- Payer
- Via: NCPDP Script

**Dispense**
- Dispense
- Pharmacy
- Patient
- Via: NCPDP Script

Source: Point-of-Care Partners
Challenges in Specialty Prescribing

Manual processes cause excess time delays*

- Paper Forms: **19.2 minute** manual input
- Benefits Verification: **1 week** backlog; 60% accuracy
- PA Forms: **1 week** submission to results delay
- REMS: 1/3 orders delayed **7+ days** by patient sign-off
- Payment/Shipping: **2 day** delay for patient confirmation
- Refills: **10 day** average turnaround

*Delays result in fewer patients served*

Bottlenecks accumulate –
It currently takes an average of **3-6 weeks** for a patient to receive their specialty medication after it is prescribed.

Source: ZappRx, Inc.
ePrescribing uptake

- Physician adoption increasing drastically from 68 million scripts in 2008 to 1 billion in 2014
- 80% of physicians utilize
- Standard route for prescriptions in retail
- **Fax is still the standard in specialty**
  - < 5% e-prescriptions
  - >40% require call back to physician

Source: ESI Network Pharmacy Weekly September 17, 2015
Points of entry for specialty prescriptions

- Prescriber
  - Fax, Portal, e-prescription
- Hub
  - Data Feeds
  - REMS requirements
- Other specialty pharmacies
  - LD requirements
- Retail pharmacies
  - Partnerships
- Health Systems
  - 340b
Referral Forms

<table>
<thead>
<tr>
<th>PATIENT INFORMATION (please print clearly)</th>
<th>PRESCRIPTION</th>
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<tbody>
<tr>
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<tr>
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<tr>
<td>Social Security No.</td>
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<td>GLEEVEC®</td>
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<td>MedicaID Insurance (Fax Copy of Card)</td>
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<tr>
<td>BIN / PCN</td>
<td>REVLIMID®</td>
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<tr>
<td>Patient Weight</td>
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<tr>
<td>Allergies:</td>
<td>Other:</td>
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<tr>
<td>Secondary ICD 10:</td>
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<tr>
<td>Meds Tried &amp; Failed (Include Drug Name &amp; Date of Therapy):</td>
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<tr>
<td>Other Concurrent Therapy Regimens:</td>
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I authorize US Bioservices Corporation to act as my representative and on behalf of myself and my patient to initiate any authorization processes from applicable health plans, if needed, including the submission of any necessary forms to such health plans.

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Referral Forms

Pathpoint HCV
a US Bioservices program

FAX: 1-888-418-7248
PHONE: 1-866-225-7814
Account Manager:

US Bioservices
Amerspend/AmerisourceBergen Specialty Group

PATIENT INFORMATION (please print clearly)

Last Name
First Name
Social Security No.
Date of Birth
Guardian/Caregiver
Home Phone
Work or Mobile Phone
Home Address
City, State, Zip

PATIENT INSURANCE INFORMATION

Medical Insurance (Fax Copy of Card)
Medical Insurance Phone
Subscriber Name
Policy #
Group #
Prescription Card (Fax copy of card)
Prescription Card Phone
Policy #
BIN / PCN
Medicare Number
Medicaid Number

PRESCRIBER INFORMATION

Prescriber Name (please print)
Prescriber Address
City, State, Zip
Practice Name
Phone
Fax
License #
NPI #
DEA #

Supervising Physician (if applicable)

Office Contact:
Backline Phone Number:

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Home Address
City, State, Zip

PATIENT INSURANCE INFORMATION

Medical Insurance (Fax Copy of Card)
Medical Insurance Phone
Subscriber Name
Policy #
Group #
Prescription Card (Fax copy of card)
Prescription Card Phone
Policy #
BIN / PCN
Medicare Number
Medicaid Number

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Practice Name
Phone
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License #
NPI #
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Office Contact:
Backline Phone Number:

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PRESCRIPTION

HARVONI (ledipasvir 90mg/sofosbuvir 400mg) Tab
Take one tab PO once daily without food
28 days supply

VIKIRA Pak (ombitasvir 12.5 mg / paritaprevir 75 mg / ritonavir 50 mg, dasabuvir 250mg) Tab
Take two ombitasvir, paritaprevir, ritonavir tabs (pink) PO once daily (in the morning) and one dasabuvir tab (beige) twice daily (morning and evening). Take Viekira Pak with a meal.
28 days supply

SOVALDI (sofosbuvir) 400mg Tab
Take one 400mg tab PO once daily without food.
28 days supply

Olysio (simeprevir) 150mg Cap
Take one capsule PO once daily with food.
28 days supply

DAK LINZA (daclatasvir) 60mg Cap
Take one 60mg Cap PO once daily with food.
Decrease dose to 30mg daily when given with strong CYMPA inhibitors, increase to 90mg daily when given with moderate CYMPA inducers.
28 days supply

TECHNIVIE (ombitasvir 12.5mg, paritaprevir 75mg, ritonavir 50mg) with RIBAVIRIN
Take two tablets PO once daily in the morning with a meal.
28 days supply

RIBAPAK (ribavirin) MODERIBA (ribavirin, USP) Dose Pack
28 days supply

Total duration of therapy: __ Weeks

Fibrosarcoma Score: ________ Fibrousure Score: ________

Biopsy Score: ________ Metavir: ________ Knodell: ________ Ishak: ________

Primary ICD-10 Code: ________ Secondary ICD-10 Code: ________

LABWORK* and NURSING

HCV RNA: Date: ________ PLT: ________
ALT: AST: HB: ________

G60K Polymorphism: ________ Other: ________

*please include a hard copy of all labwork

O Patient opts out of telephonic nurse counseling

PRESCRIBER SIGNATURE

Prescriber Signature - Dispense as Written Date
Prescriber Signature - Substitution Permissible Date

No Stamps. Signature and date must be completed by Prescriber. NY Prescriptions must be submitted on NY State Rx form. OK Limits one prescription per page.
Hub Services

- Receive referrals for specific manufacturer programs
- Educate offices on program offering
- Services include:
  - Eligibility Request
  - Product Benefit Verification
  - Prior Authorization Support
  - Copay Support
  - SP Triage
  - Nurse Support
  - Ongoing program communication
  - Data transfer from SP and to program sponsor
US Bioservices Case Study

Friday, September 25th

• Received eRx for abiraterone acetate and prednisone from MD
• Prednisone Rx written for #30 1 BID; sent to exception que for follow up with MD
• Ran test claim for abiraterone acetate and determined PA needed
• Contacted patient to notify a PA was needed
• Contacted insurance company to request that PA forms be faxed to MD
• MD office closed; faxed office to notify that insurance company would be faxing PA forms

Monday, September 28th

• Left voice mail with MD to clarify quantity on prednisone Rx

Tuesday, September 29th

• MD office sent new eRx for prednisone #60 1BID
• Called insurance company and confirmed PA was approved
• Adjudicated claims and sent to fulfillment

Wednesday, September 30th

• Contacted patient and scheduled delivery for Friday, October 2nd.
E-Rx challenges in specialty

- Multiple, evolving prescription data elements needed based on new treatments
- e-PA needs to occur in conjunction with eRx
- Prescriber education, training and office resources
- Limited distribution networks
- Unique REMS requirements
E-Rx advantages in specialty

• More efficient work flow
• Reduced overhead
• Improve quality
• Less prescriber outreach
• Speed to therapy
Addressing Prescriber Needs
New Prescriber Workflow

Prescriber Burden

- REMS / Assessments
- Starter Product / Kits
- Nurse Training
- Financial Assistance
- ePA
- ERX
Gaps in PBM Benefit

- Starter Product / Patient Assistance Programs
- Financial Assistance
- Medical Coverage (Dual Benefit)
- PBM Copay

Unavailable
Distribution Model

- Limited SP Network
- Single SP Starter Kit
- Maintenance Dose

- Injection Center
- REMS
- Assessments
NCPDP Efforts
NCPDP Standard for Electronic Prior Authorization (ePA) Transactions

Officially approved in July 2013 as a major advancement for e-prescribing
New Standard Enables Multiple Workflows

Retrospective vs. Prospective

Two-Step Process

Retrospective PA – without PA info at time of prescribing

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

Prescriber | Pharmacy | Payer
--- | --- | ---
PA Info | Processing | Advises PA Approval
Advises PA Approval

Prospective PA – with PA info at the time of prescribing

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

Single-Step Process

Prescriber | Pharmacy | Payer
--- | --- | ---
PA Info | Advises PA Approval | Processing
Advises PA Approval

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

Prescriber | Pharmacy | Payer
--- | --- | ---
PA Info | Processing | Advises PA Approval
Advises PA Approval

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**Electronic Prior Authorization Milestones**

When the Federal government imposed ePA on the marketplace, adoption was minimal. Then the industry decided what it wanted to implement, and progress began to be made.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1996</td>
<td>Multi-SDO ePA Task Group Formed</td>
</tr>
<tr>
<td>2004</td>
<td>HIPAA</td>
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<tr>
<td>2006</td>
<td>MMA ePrescribing Pilots</td>
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<tr>
<td>2009</td>
<td>NCPDP Facilitates Creation of New Transactions</td>
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<tr>
<td>2010</td>
<td>NCPDP Revises Transactions</td>
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<tr>
<td>2012</td>
<td>Implementation</td>
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<tr>
<td>2013</td>
<td>NCPDP SCRIPT 2013 Published</td>
</tr>
<tr>
<td>2014</td>
<td>Renewed Interest</td>
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</table>

**HIPAA**
- X12 278 named prior authorization standard
- Telecom Standard named for retail pharmacy

**MMA ePrescribing Pilots**
- Determined that the X12 278 + HL7 PA Attachment was suboptimal for ePA

**NCPDP Facilitates Creation of New Transactions**
- Based on NCPDP SCRIPT standard

**NCPDP Revises Transactions**
- Pilot results incorporated into revised standard
- Ballot
- Educational Sessions
- CMS’s OESS Apprised

**Implementation**
- With intermediaries leading the way, stakeholders start implementation

**Multi-SDO ePA Task Group Formed**
- Promotes standardized automated PA using X12 278, HL7 PA Attachment and NCPDP Formulary & Benefit

**CMS/AHRQ Pushes Forward**
- Resolution of where standard should reside
- Value model created

**Renewed Interest**
- Pilots conceived
- State legislative interest begins
- CMS’s OESS apprised

**NCPDP SCRIPT 2013 Published**
- Education Sessions
- Implementations Begin

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ePA Being Implemented Nationally

**ePA standard currently being implemented nationally**

- Task Group DERFs all about clarifying standard and adding new, unanticipated data elements
- Payers/PBMs required to be able to support ePA or a universal PA form in 14 states by July 2015
- Turn-around times for forms return improving
- Retrospective is most used means of ePA, though adoption is sub-optimal
- Adoption of prospective dependent on PA flag in formulary or RTBI and is consequently sub-optimal

For ePA to reach wide adoption, HCPs need integration within the EHR workflow, and auto-completion of ePA request with existing EHR data

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Benefits Verification

- Today still done via phone/fax
- Effort to bring a standardized electronic benefit verification to the market via the Real-Time Benefit Inquiry

Options include using:
- NCPDP Telecommunications D.0 Standard
- X12 270/271 Eligibility Request
- NCPDP SCRIPT Standard
Real Time Benefit Inquiry Milestones

The ONC Notice of Proposed Rule Making (NPRM) released in Feb 2014 was the catalyst for NCPDP efforts around RTBI.

NCPDP Task Group Created
- NCPDP Task Group created under maintenance and control workgroup.

NCPDP Use Case Development
- NCPDP Task Group focused on development of 4 use cases to present at November Workgroup Meeting.

ONC NPRM
- ONC Solicits comments on NCPDP Telecom and Formulary and Benefit Standard to support expanded use cases such as real-time benefit checks.

HITSC Meeting
- NCPDP presents at Health IT Standards Committee meeting.
- Requests for additional demonstration projects are made.

NCPDP Consensus Building
- Task Group holding bi-weekly calls to solicit input from all stakeholders on use cases.
Real Time Benefit Inquiry Today

One Target, but currently many paths…

- NCPDP workgroup efforts
  - Use Case Development
- Industry Stakeholder Pilots
  - Modification of D.0 Telecommunications standard
  - Modification of SCRIPT standard
  - Proprietary connection
- ONC and CMS requests for pilots
Risk Evaluation and Mitigation Strategy (REMS)

- REMS are required plans that use risk minimization strategies to ensure that the benefits of certain prescriptions drugs outweigh the risks
  - As of May 2015, there are 73 individual product REMS; 6 shared system REMS
- Structured REMS data can be used to provide additional information and “triggers” for pharmacies, health system and EHRs who wish to integrate REMS into their processes
REMS Timeline

The Food and Drug Administration Amendments Act (FDAAA) of 2007 granted authority to enforce REMS

NCPDP REMS Guide Released
- NCPDP REMS Reference Guide released to encourage transaction-based REMS solution

REMS Transaction approved by NCPDP
- NCPDP approves “in workflow” REMS solution for pharmacies using Telecommunications Std. D.0

Proposed SCRIPT modifications for REMS transactions
- NCPDP presentation to FDA for standard REMS transactions for SCRIPT standard

Sept 2007
- Food and Drug Administration Amendments Act
  - FDAAA passed which granted FDA authority to enforce REMS through Manufacturers

Nov 2010
- FDA and NCPDP Task Groups Created
  - FDA creates REMS Integration Initiative to focus on REMS standardization and assessment
  - NCPDP creates REMS related Task Groups under WG1, WG2 and WG11

May 2011
- FDA Federal Register Notice Released
  - FDA agrees to measure the effectiveness of REMS and to continue to develop techniques to standardize REMS

Nov 2013
- Sept 2014
- Oct 2015
Specialty ePrescribing

- Task Group formed during Fall 2013 Workgroup Meeting
- Co-lead by Laura Topor and Tony Schueth
- Initial goal was to include data elements needed by specialty pharmacy in the original prescription
- Also working on wound care
- Recently formed sub-task group on compounding
NCPDP SCRIPT: Data Elements to Support Specialty ePrescribing

Diagnosis, lab values, height, weight, allergies and other indicators needed to fill specialty prescription. Patient contact information to facilitate delivery and clinical services, and enroll patient in assistance programs.

Insurance policy number to determine eligibility – pharmacy vs. medical benefit – and coverage/copay information. The status of a PA request to facilitate the billing and delivery of the specialty medication.
Post-Test
Post-Test Question #1

1. Which of the following is not currently a challenge with e-prescribing for specialty medications?
   a) Prescriber education, training and office resources
   b) Limited Distribution networks
   c) EMR’s are not capable of sending e-prescriptions for specialty drugs
   d) Unique REMS requirements
Post-Test Answer #1

1. Which of the following is not currently a challenge with e-prescribing for specialty medications?
   a) Prescriber education, training and office resources
   b) Limited Distribution networks
   c) EMR’s are not capable of sending e-prescriptions for specialty drugs
   d) Unique REMS requirements
Post-Test Question #2

2. Advantages to e-prescriptions in specialty pharmacy include all of the following except:
   a) More efficient workflow
   b) Reduced overhead
   c) Improved quality
   d) Eliminates the need for Prior Authorizations
2. Advantages to e-prescriptions in specialty pharmacy include all of the following except:
   a) More efficient workflow
   b) Reduced overhead
   c) Improved quality
   d) Eliminates the need for Prior Authorizations
Post-Test Question #3

3. True or False: It is common for prescribers to send prescriptions for specialty medications to Hubs.
   a) True
   b) False
3. True or False: It is common for prescribers to send prescriptions for specialty medications to Hubs.
   a) True
   b) False
4. Which of the following are currently provided in the PBM Benefit for specialty medications?
   a) Starter product/patient assistance programs
   b) Financial assistance
   c) Medical coverage (dual benefit)
   d) PBM copay
Post-Test Answer #4

4. Which of the following are currently provided in the PBM Benefit for specialty medications?
   a) Starter product/patient assistance programs
   b) Financial assistance
   c) Medical coverage (dual benefit)
   d) PBM copay
Post-Test Question #5

5. Which of the following NCPDP SCRIPT data elements support specialty ePrescribing?
   a) Diagnosis
   b) Patient contact information
   c) Insurance policy number
   d) Status of a PA request
   e) All of the above
5. Which of the following NCPDP SCRIPT data elements support specialty ePrescribing?
   a) Diagnosis
   b) Patient contact information
   c) Insurance policy number
   d) Status of a PA request
   e) All of the above
Questions?

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