Presented at CBI Conference: Pharmacy Channel Strategies for Specialty Products

ePrescribing (eRx) of Specialty Medications — Where We Are and Where We’re Going
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.

$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.
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.

National studies showed that specialty pharmacy had grown upwards of 20% per year, a trend projected to continue, and that by 2020 specialty was estimated to account for 40% of all drug spend.

Prescription is typically faxed to pharmacy.

Prescriber “unknowns”:
- patient copayment
- contracted pharmacies
- prior authorization
- REMS
- financial assistance

Time intensive for pharmacy:
Multiple calls to determine coverage, if prior authorization/REMS is required.
Types of Specialty Prescription Transactions

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

**Intake Form**
- **Via:**
- **Pharmacy** → **Prescriber**

**Benefit Verification**
- **Via:**
- **Pharmacy** → **Payer**

**Financial Assistance Determination**
- **Via:**
- **Patient** → **Pharmacy** → **Foundation**

**REMS**
- **Via:**
- **Prescriber** → **Pharmacy** → **Manufacturer**

**Care Coordination**
- **Via:**
- **Pharmacy** → **Patient** → **Prescriber**
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.*
## Specialty ePrescribing Drivers

<table>
<thead>
<tr>
<th>Medication Compliance</th>
<th>Medication Non-Adherence: 100,000 unnecessary deaths and costs $200 billion.</th>
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<tbody>
<tr>
<td><strong>Patient safety</strong></td>
<td>Improves first fill rates, facilitates renewals and improves prescription legibility.</td>
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<td><strong>Government incentives</strong></td>
<td>Help prescribers meet Meaningful Use thresholds.</td>
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<td><strong>Improve workflow and efficiencies</strong></td>
<td>Eliminates tedious manual processes, dramatically reducing administrative costs.</td>
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<td><strong>Cost containment</strong></td>
<td>Helps all stakeholders monitor and control specialty drug spending.</td>
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Specialty ePrescribing:
The Infrastructure is in place

80% Physicians Today

Nearly 80% of physicians ePrescribe today

700 EHRs Enabled

Approximately 700 EHRs enabled for ePrescribing

100% Retail Pharmacies

Nearly 100% retail pharmacies
Current ePrescribing Flow

Physician Practice
- EMR or e-Rx System

A1 Request Eligibility, Drug History
- Intermediary

Response

A2 Electronic transmission (EDI)

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

Pharmacy
- Pharmacy Dispensing System

PBM or Plan
- Claims Processing System
  - benefit plan rules, formulary, history

Drug info Database
- Formulary Database

Pharmacy Channel Strategies for Specialty Products
Reimbursement Hub Goals

**Start**

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

**Fast Response Time**

**Simplified Customer Experience**

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

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

Referral Re-verification

Electronic Referral

Electronic Provider and Patient Authorization (eSignature)

Electronic Prior Authorization

Electronic Enrollment with ePrescribing
Pharmacy Channel Strategies for Specialty Products

Hub services help patients navigate all of the potential discount programs and also provide resources to patients.

Most Hubs today are run and managed by pharmaceutical manufacturers and specialty pharmacies. HUBS continue to evolve and will play an important role in the consumer discount space.
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.

PA can now be done **electronically** through NCPDP SCRIPT Standard; prescribers can complete PA at point of prescribing, **eliminating need for pharmacy go-between.**
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 prior authorization request to facilitate the billing and delivery of the specialty medication.
Pharmacy Channel Strategies for Specialty Products

- Retrospective and prospective models emerging in the marketplace
- Retrospective being conducted in a proprietary manner
- Industry movement toward **prospective**
- Prospective ePA officially approved as part of the SCRIPT standard in July, 2013
- Standardized retrospective process on-hold
- Standardized questions being addressed
- Need for standardization, evidence-based PA criteria

**Electronic Prior Authorization**

By the Numbers: PA Volume

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharmacy</th>
<th>Physician</th>
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<tbody>
<tr>
<td>2010</td>
<td>0.5</td>
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<tr>
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<tr>
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</tr>
<tr>
<td>2014</td>
<td>6.0</td>
<td>6.0</td>
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Source: CoverMyMeds
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
Specialty ePrescribing

- Task Group formed during Fall 2013 Workgroup Meeting
- Co-lead by Laura Topor and Tony Schueth
- Goal is to include data elements needed by specialty pharmacy in the original prescription
- Accomplishments include recommendations for:
  - Diagnosis Code
  - Patient Contact Information
  - Height/Weight
  - Inclusion of Patient Insurance Information
- Working on identifying other data elements that can be included in the transaction and means of transmittal
### REMS

**WG 1 – Telecommunications D.0**
- 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 – SCRIPT**
- Standardizing the REMs process using ePrescribing transactions
- Streamline the electronic processing of REMS prescriptions from prescriber to pharmacy
- SPL “triggers” transaction in prescriber system
EHR Modifications for Specialty Medications

Addition of **data fields** needed for fulfillment of specialty medications.

Physician selection of more drugs than may be currently presented.

Access to participating specialty pharmacy networks.

**Timely updates** to specialty formularies.
Making ePrescribing for specialty medications a mandatory requirement for Medicare Part D. Medicaid can help reduce costs, as well as help track expenditures, improve outcomes and mitigate safety issues. Private sector would likely follow, and also mandate ePrescribing of specialty medications.

Additional work by standards developers and vendors is needed to create needed infrastructure modifications and enhancements. Providers need to understand the value proposition for specialty ePrescribing, such as:

- better workflows
- reduced overhead
- improved quality of care
- patient safety
Current Opportunities

Additional stakeholder input is needed to ensure the emerging NCPDP standard works for all parties involved in the dispensing of specialty medications.

Next Calls:
Monday, July 13 and Monday, July 27 3-4 EST
Register at NCPDP Collaborative Workspace:
http://dms.ncpdp.org/
The time is right
and it is the right thing to do.
Thank You.

www.pocp.com