

# Data and Today's Pharmacy World

June 25, 2010

# Goals/Items to Understand

- Within the context of specialty pharmacy practice, at the end of the session you should be able to:
  - Identify essential data elements, access to these data points
  - Discuss today's changing regulatory environment and the impact on
    - Patient management
    - Inventory control
  - Understand how to leveraging data to drive operational excellence

# Specialty Pharmacy

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# Specialty Pharmacy

- Specialty” products continue to be a consistent growth area
  - 2009 specialty product spend was 12% of and increase of 19.5%
    - Upwards of 70% of specialty spend is through medical benefit
  - Expansion expected over the next three year period of between 20-25%
    - Driven by both cost of products and increased utilization (compliance)
- Product growth drivers include
  - Increase in vaccines (Provenge), respiratory conditions, PAH
  - Increase in “ultra-orphan” products
  - Development of “personalized” medications
    - Combination of genetic testing and product

# Data Elements

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# Data Elements

- Sources and types of data points for the fulfillment of prescriptions include both required and “optional” elements
  - Source: Patient
    - Required items from a regulatory point include
      - Name, address, telephone, date of birth, sex, drug allergies, other prescription/non-prescription items
      - Patient insurance information such as primary/secondary plan name, insured name, policy number, group number
      - HIPAA release and authorization
    - Optional items
      - Social security number, other points of contact including email, cell number, best time to contact
      - REMS attestation (if required)
    - Avenues of accessing data include
      - Face to face (retail), mail, web portals, telephonic

# Data Elements

- Sources/data points cont'd.
  - Source: Physician
    - Required elements include
      - Address, telephone number, state license number , DEA number if controlled substance
      - Prescription items such as drug, dosage, directions, number of refills, date
    - Additional items include
      - NPI number, additional contact points such as email or fax number, primary point of contact within the office, definition of practice (e.g. specialty), tax ID number
      - Diagnosis information such as ICD-9 code(s)
      - Laboratory values
      - REMS attestations (if required)
    - Avenues of access include
      - Mail, fax, ePrescription, web portals, telephonic

# Data Elements

- Sources/data points cont'd.
  - Source: Manufacturer
    - Required elements
      - Drug NDC number
    - Optional elements include
      - Product lot number, expiration number, serial number (as available)
  - Source: Payers
    - Elements are only “required for the processing of prescriptions through currently published standards and include the data from the patient, physician and manufacturer
    - Additional items include a Prior Authorization number
  - Source: Pharmacy
    - Collection of data from clinical management of patient can include lab values, height, weight, adherence to therapy and/or disease progression measurements

# Data Elements

- Collection of data can occur in a variety of ways. For specialty products
  - **Facsimile** – Most specialty products include access to support services for which an enrollment form, or SMN, serves as the collector of the data items
  - **Mail** – with decreasing frequency given the use of technology
  - **Telephonic** – used in the collection of incomplete and missing information or to obtain authorization for the continuation or adjustment of therapy
  - **Web** – ePrescriptions and physician web portals drive physicians to provide complete information

# Regulatory Considerations

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# Regulatory Considerations

- Regulations in play
  - HIPAA – Governs the use and “exchange” of Personal Health Information
  - Patient Privacy Laws – Vary state to state and addresses the confidentiality of health information
  - HITECH – Strengthens the HIPAA body of regulations to include
    - Widens scope of privacy in anticipation of widened use of eHealth records
    - Increased fines for inappropriate disclosure of PHI
    - Increases enforcement

# Regulatory Considerations

- Effect on patient management
  - Exchange of PHI from patient to physician to pharmacy not greatly affected
  - Access impacted with
    - REMS programs typically managed through and outsourced, third party
    - HUB patient support program and ancillary support services such as adherence programs or clinical/nursing support services
  - Exchange of PHI between organization allowed with:
    - Full patient consent and release (rare)
    - Business Associate Agreement between covered entity and service partner (e.g. REMS program and specialty pharmacy)

# Regulatory Considerations

- Product pedigree regulations currently do not trace product movement to the patient level
- Proposed and delayed regulation in California “stirred the pot”
  - Track and trace of inventory through the supply chain down to the patient level
  - Access to unit movement throughout the supply chain –  
Serialization
  - Currently in use by EMD Serono for Serostim
- Strategic planning for the management of serialized product needs to be in place today.

# Leveraging Data to Drive Operational Excellence

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# Leveraging Data

- A specialty pharmacy is the collection point for these various segments of data
  - Therapy related data
    - Different diagnosis codes (IDC-9) for product
    - Therapeutic outcomes measurements for competitive products
  - Financial reporting
    - Days Sales Outstanding (DSO) – connection of submission of payment request to insurance organization and receipt of funds
    - Inventory accuracy and shrinkage
    - Product wastage
  - Turn around times
    - Order receipt to dispense turn around time (full cycle of services)
    - Order receipt to authorization to dispense (receipt of Prior Authorization from payer, if required)

# Leveraging Data

- The creation of a longitudinal data base provides for the creation of performance measurements including:
  - Outcomes based reimbursement tracking
    - Combination of product usage, lab data and/or therapeutic measurements
  - Adherence programs and intervention planning and results measurements
  - Performance based manufacturer partnerships

# Data and Today's Pharmacy World

- Plan today for tomorrow's changes
- Considerations should be given to:
  - Increase in the number and types of data elements to be collected with variation by disease state
  - Security of data and interfacing with outside companies
  - Create value from your data

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Thank You