Stakeholder Action Group: Specialty Prescribing

February 2018

Agenda

8:30am Introductions: Lee Ann Stember, President, NCPDP

8:45am NCPDP Overview: Phillip Scott, SVP, Business Development, NCPDP

9:00am Situation Review/Level Set: Pooja Babbrah, Point of Care Partners

10:00am Break

10:15am Open forum: Moderator: Jocelyn Keegan, Point of Care Partners

12:00pm Lunch

1:00pm Open forum (continued)

2:45pm Break

3:00pm Plan for the Future

4:00pm Close of Session

Goals and Objectives:

1. *Identify specific Specialty Pharmacy industry challenges which interfere with the efficient and optimal delivery of SP stakeholder services*

2. *Identify, at a high level, those Specialty Pharmacy workflows and transactions that would most benefit from standardization*

3. *Prioritize the workflows and transactions for standardization*

Open Forum

- What are we trying to resolve?
- What are the needs?
- Can the needs be addressed by NCPDP?
- What are the barriers?
- Can the barriers be overcome?
- Identify stakeholders to ensure all impacted parties are involved

Facilitators

Jocelyn Keegan
Senior Consultant

- NCPDP Specialty task group leader
- HL7 Da Vinci Project Manager
- Former Owner NaviNet Authorizations suite
- 25 years software development experience, 8 years in HIT including ePA pilot leadership

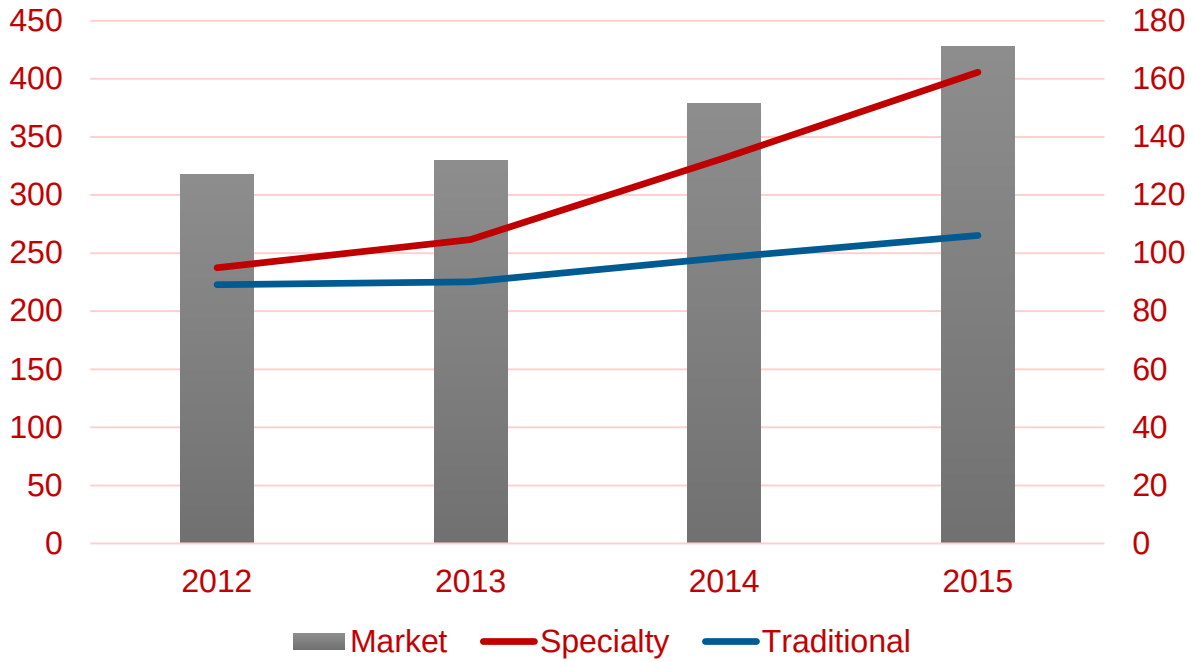
Pooja Babbrah
Senior Consultant

- NCPDP Specialty and Biologics/Biosimilar Access and Traceability task group leader
- Former Head of Product Management at DrFirst
- 25 years HIT product management and strategy experience

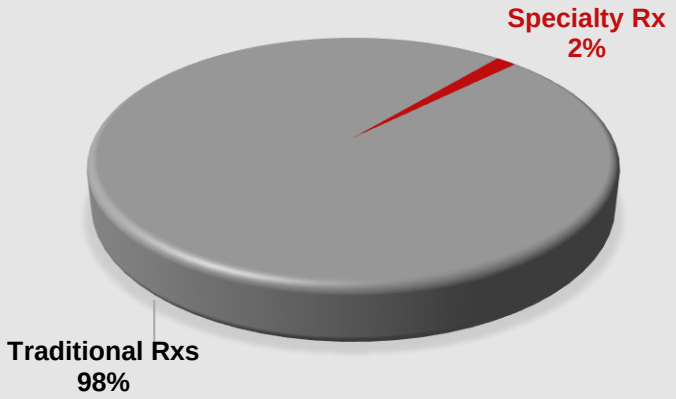
Overall Spend and Volume Trends

Specialty medications continue to be a growing part of overall drug spend, yet Rx volume remains low. Due to the nature of these medications, the “value” of a single transaction is high

Total Drug Spend by Category



Percent of Total Prescription Volume by Category*



*…but there are other transactions that are and could be facilitated to support the process

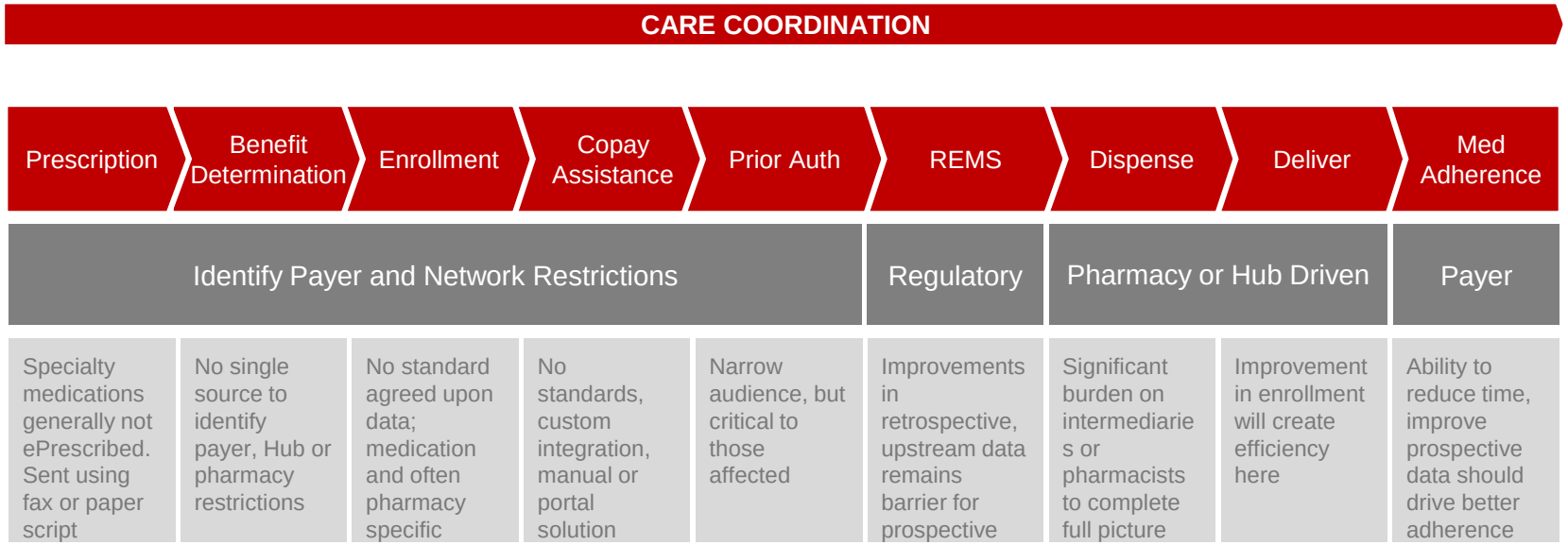
Source: IQIVA Institute Report; Medicines Use and Spending in the U.S. A Review of 2016 and Outlook to 2021 – May 2017

Specialty Market Defined

- **No universal definition of specialty**
  - High-cost, complex regimens
  - Special handling, special monitoring
  - Trend towards outcomes-based payer contracts
- **Newly created category of medications: Limited Distribution Drugs (LDDs)**
  - Created based on supply chain & contracting
  - Contract defines dispensing pharmacy
- **No universal reimbursement, dispensing or administration model**
  - Covered under pharmacy or medical benefit depending on payer
  - Dispensing may occur from specialty pharmacy, hubs, retail pharmacies and physician offices
  - Administration may occur in physician's office, infusion centers, home care, LTC or by the patient with product shipment varying for each location

Specialty medications do not follow a traditional path of prescribing; with a few recent exceptions, prescribing transactions completed via **paper, fax and phone**

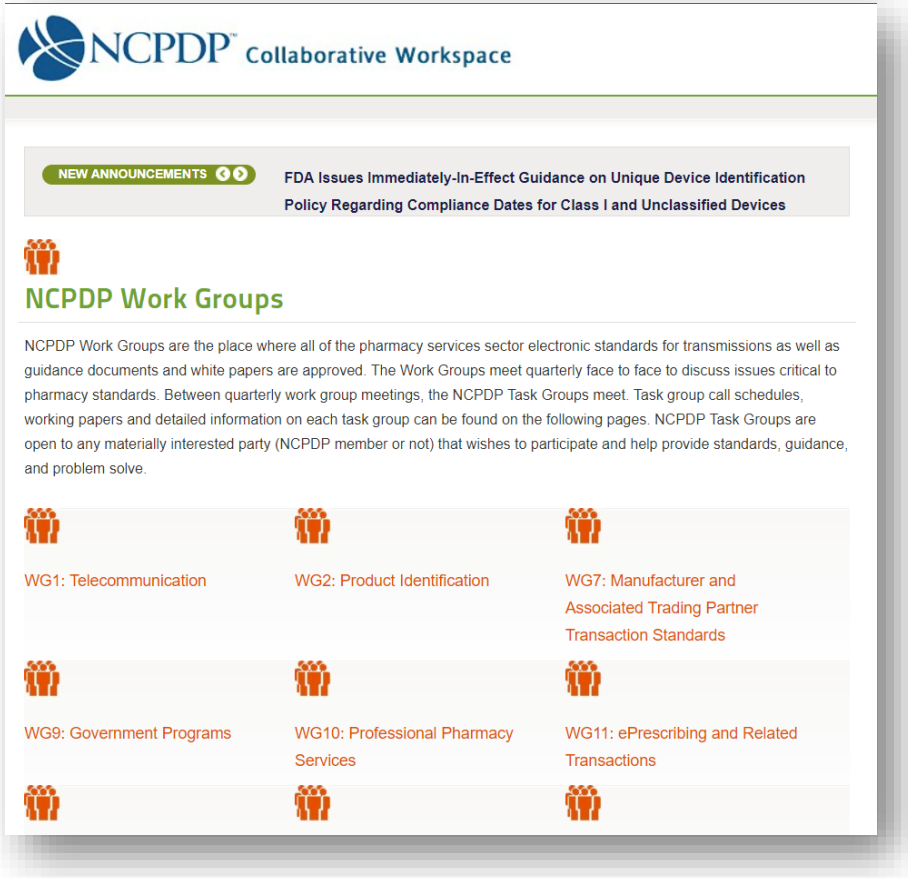
Specialty ePrescribing Complexity



There is a significant amount of complexity involved with ePrescribing of Specialty medications and a **number of areas to focus on in regards to standards and moving processes electronic**

NCPDP Specialty Related Activity Overview

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



Electronic Prior Authorization (ePA)

Transactions within the NCPDP SCRIPT Standard

- First published in July 2013
- Supports prospective and retrospective models
- Allows for cancel and appeal functions
- Supports pharmacist-initiated requests; trading partner agreements may determine applicability

- Enhancements continue to be brought forth
- Guidance from industry implementation available in NCPDP's SCRIPT Implementation Recommendations Document
- NCPDP and other continue to advocate to have ePA will be named for pharmacy, but not included in current NPRM

ePA experiencing high levels of adoption by industry regardless of delays on regulation

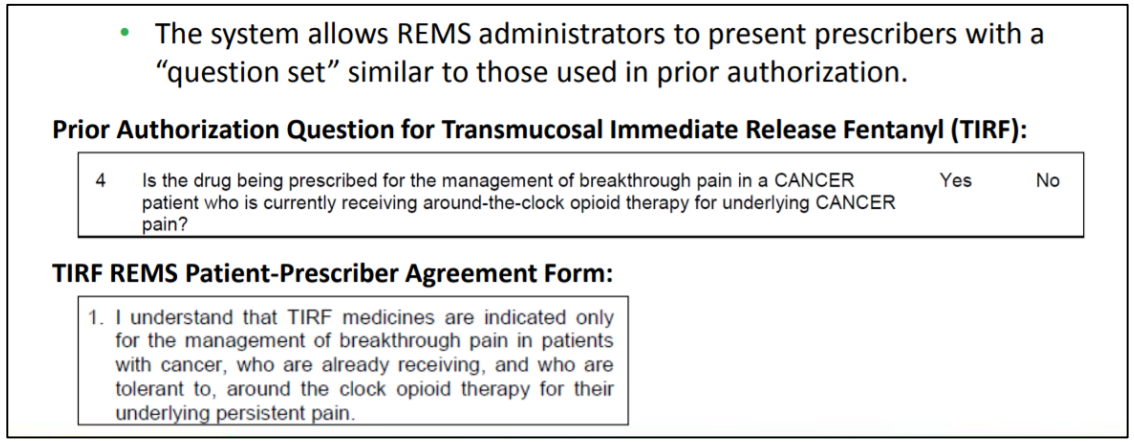
Risk Evaluation and Mitigation Strategy (REMS)

HISTORY

- NCPDP released implementation guide for REMS Transaction for the **Telecomm standard** in 2011
  - Telecomm standard is used by pharmacies to process claims; allowed pharmacies to use claims transaction to **electronically confirm that REMS requirement has been met and pharmacy can dispense the medication**
- Currently not a "named" standard in legislation, but most pharmacies and intermediaries implemented the transaction through trading partner agreements

CURRENT EFFORTS

- SCRIPT standard allows for REMS administrators to present prescribers with "question set" similar what is used in electronic prior authorization (ePA)



- The system allows REMS administrators to present prescribers with a "question set" similar to those used in prior authorization.

Prior Authorization Question for Transmucosal Immediate Release Fentanyl (TIRF):

4	Is the drug being prescribed for the management of breakthrough pain in a CANCER patient who is currently receiving around-the-clock opioid therapy for underlying CANCER pain?	Yes	No

TIRF REMS Patient-Prescriber Agreement Form:

1. I understand that TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around the clock opioid therapy for their underlying persistent pain.

REMS was named in the November NPRM from CMS. Additional task group efforts focused on review of FDA guidance document and identifying gaps in document and additional use cases

Real-Time Prescription Benefit Check (RTPBC) Standards Development Efforts

NCPDP Standards Organization Workgroup Efforts:

- Develop two standard formats and one implementation guide for the real-time exchange of data between Providers and Processor/PBM/Adjudicators to:
  - Will enable use of two syntaxes – EDI and XML
  - Request and Response model
  - Establish patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and
  - Identify coverage restrictions, alternative products, and benefit alternatives when they exist.

Efforts focused on facilitating the healthcare industry's adoption by providing expertise and education

Specialty Pharmacy Reporting and Data Exchange

- Specialty Pharmacy Data Exchange Sub-Task Group (within WG 7 - Manufacturer and Associated Trading Partner Transaction Standards)
- Developed standardized reporting to support contractual arrangements between the manufacturer and specialty pharmacy. There are four categories the group has considered:
  - Dispense
  - Patient Census (Aggregate)
  - Performance Metrics/Case Management
  - Inventory

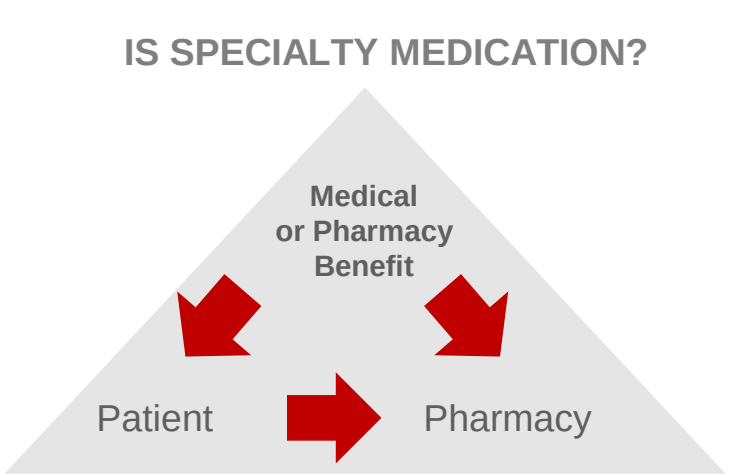
Dispense Report Standard presented to membership for approval in August 2017; publication is anticipated in early 2018

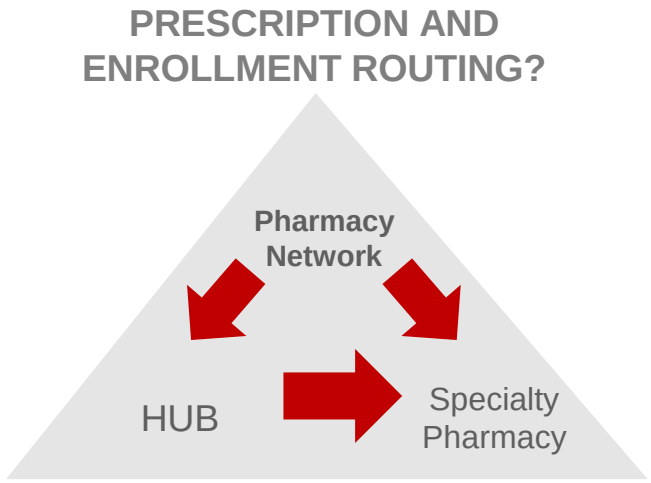
Specialty Requirements for ePrescribing

- Specialty Enrollment Transaction (SET)
  - Separate transaction under SCRIPT standard
  - Bi-directional transaction to include: Patient, Demographic, Prescriber, Medication, Clinical, Insurance and Consent
- Potential cross standards organization for clinical information
  - Looking at HL7 FHIR

Two key specialty enrollment transactions identified:

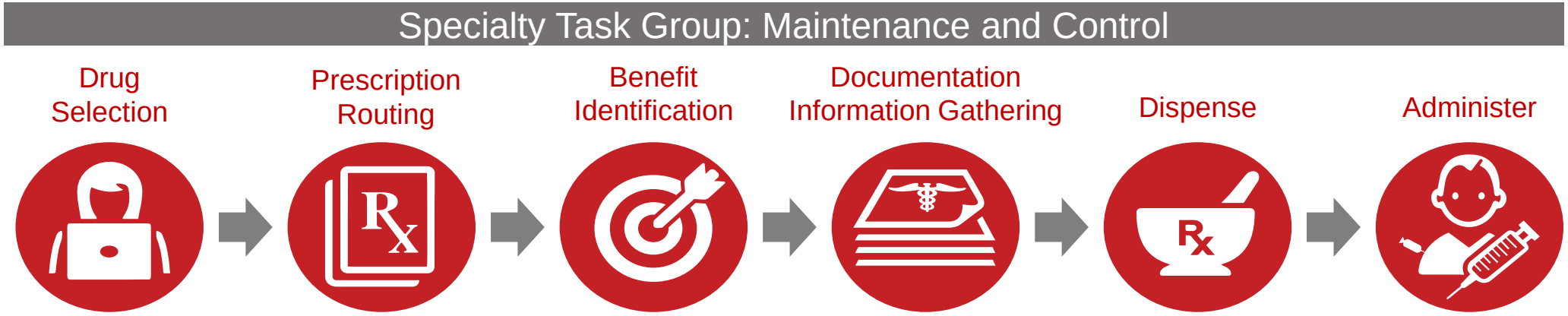
- Identification of a medication as a specialty medication
- Prescription and Enrollment transaction routing



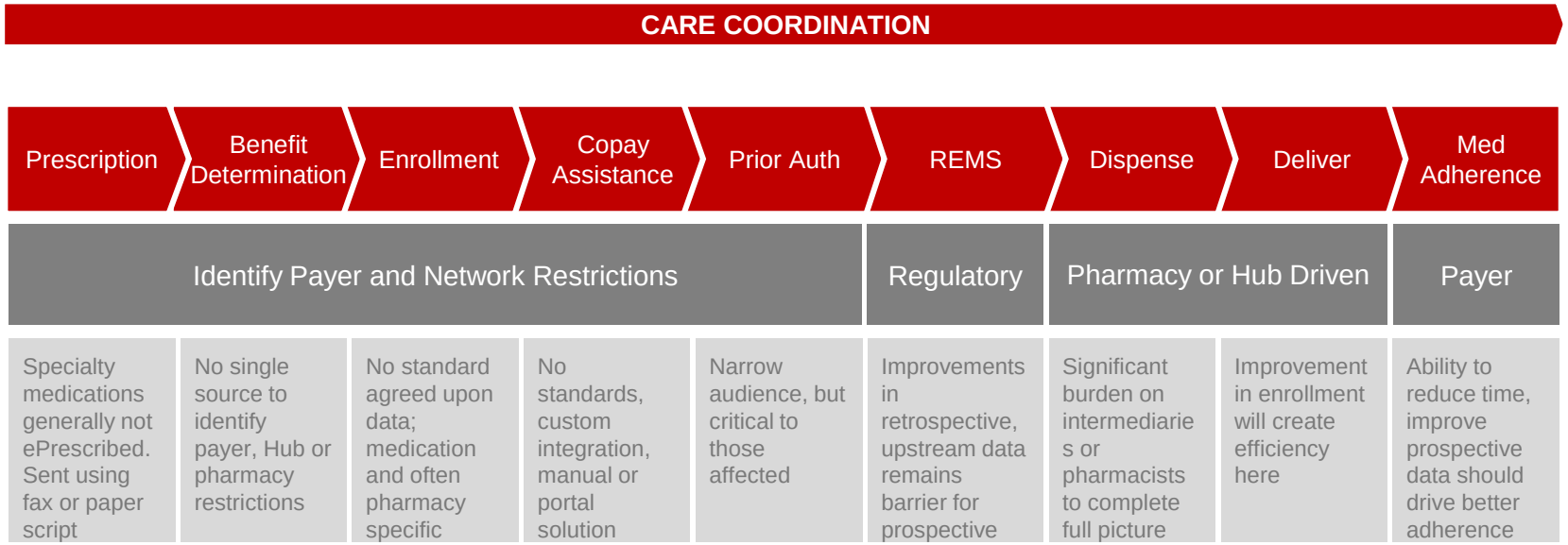


Specialty Task Group: Maintenance and Control

- New task group formed in February 2017
- Purpose:
  - Coordinate across all specialty related task groups and activity
  - Provide communications and website development to position NCPDP as relevant in regards to specialty pharmacy
  - Identify additional opportunities for standardized data exchange



Specialty ePrescribing Complexity



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Pooja Babbrah
Practice Lead, PBM Services
pooja.babbrah@pocp.com
(480) 332-2593

Jocelyn Keegan
Practice Lead, Payer
jocelyn.keegan@pocp.com
(781) 264-1630

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