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Navigating Therapy Guidelines, Prior Authorization and Copays in the Integrated System

May 2018

Background

Jocelyn Keegan
Payer Practice Lead

- NCPDP Specialty MC task group leader to act as a clearinghouse to coordinate activities across SDO
- Product manager to bring ePA draft standard live via pilot between NaviNet, CoverMyMeds, Caremark and Surescripts
- Former owner NaviNet Authorizations suite
- HL7 Da Vinci Project Manager, focused on driving critical data upstream in provider workflows to support value based contract for providers and payers
- 25 years product management and software development experience, 8 years in HIT including ePA pilot leadership

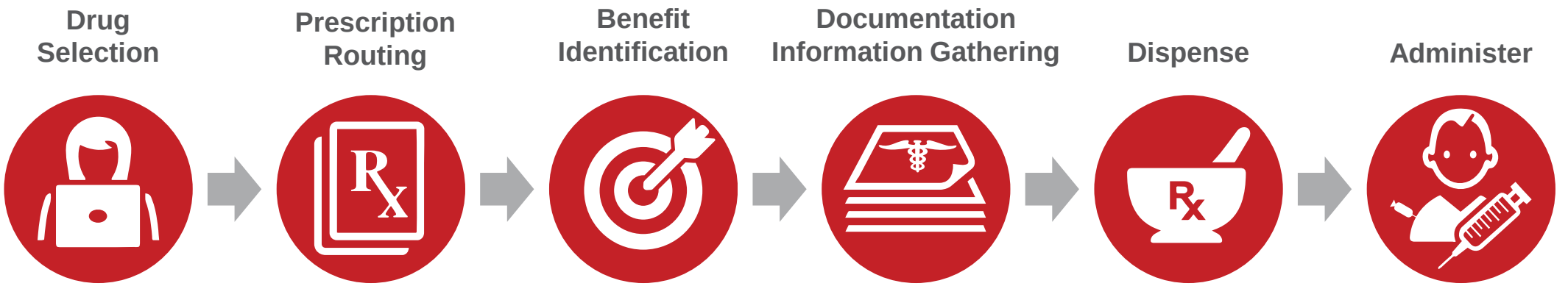
Agenda

- Understanding Challenge
- Market Forces
- Pharmacy Benefit Determination
- Medical Benefit Determination
- Standards Activities
- Opportunities and Impacts

Intersection of Pharmacy and Medical Benefits

SPECIALTY PHARMACY

HUBS



- Drug in mind
- Formulary review

- Faxed to specialty pharmacy or HUB

- Pharmacy Benefit
- Medical Benefit
- HUB

- Prescription
- Prior Authorization
- Patient information
- Financial information
- REMS

- Dispense
- Ship to office
- Drop-Ship

- In-Office
- Infusion Center
- Self-Administer

IDNs

Market Forces

Shift to Consolidation of Benefits

Three market forces help explain the push to integrate health insurers and their pharmacy benefit management under the same entity:

1. **Expansion of value-based contracting**. **Almost half** of Aetna's medical spend is paid under value-based contracts. Thirty percent of **United Healthcare's** members receive care from providers where value-based arrangements are in place, with UHG's medical expenditures for value-based care projected to increase almost 20% by 2019.

2. **Growth of drug spend under the medical benefit**. **One-half** of specialty drug reimbursement – the **fastest growing** segment of medications – was billed under the medical benefit in 2016. Most medications administered under the medical benefit are for oncology and autoimmune disorders – medical conditions where adherence, coordinated care, and ongoing medication therapy management are critical factors in patients' health outcomes.

3. **The growing chronic disease crisis**. Half of the U.S. population in 2025 will have at least one chronic medical condition requiring coordinated care to control health care expenses. Adding to this challenge, one-in-four adults are **affected by multiple chronic diseases**, which often require complex medication therapies.

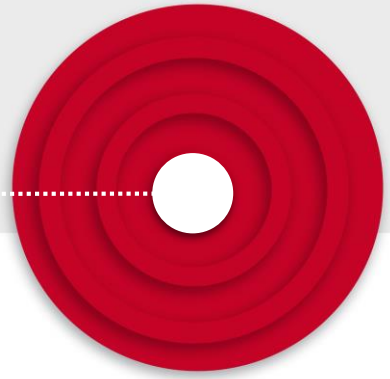
Drug Selection, Rx Routing and Benefit Identification

Information gaps in existing EHR workflow affect specialty medications, leading to delay in therapy

- No indicator to identify “specialty” status of a medication
- Benefit coverage not available if medication is covered under medical benefit
- Network restrictions and/or mandatory Hub information not available for Limited Distribution Drugs (LDD)
- No transparency on additional information required; clinical, administrative and other for payer approval of medication
- Patient consent often not collected in EHR at time of prescribing

NCPDP Specialty Workgroup working to identify specialty medication and network restrictions during prescribing workflow

Pharmacy Benefit



NCPDP Formulary & Benefit Standard Data Files

Formulary List	Coverage List	Copay List	Alternatives List
• Status • 0= Not reimbursed • 1= Non formulary • 2 = Preferred 1 • 3 = Preferred 2 • 99 = Preferred 99	• Prior authorization • Step therapy • Quantity limits • Age/gender limits • Not covered	• Tier per status • Copay per status - Retail and mail • Tier per drug • Copay per drug	• Target Drug • Alternative Drug

Resulting EHR Data Drive Display of the Available Data

Drug Formulary Displays

Name	Formulary Status
Product 1	Preferred Level 3
Product 2	Preferred Level 1
Product 3	Preferred Level 1
Product 4	On Formulary, Non-Preferred
Product 5	Non Formulary
Product 6	Unknown

Name	Formulary Status
Product 1	$ 4 copay
Product 2	$30 Copay
Product 3	$30 Copay
Product 4	$80 Copay
Product 5	50% Co-insurance
Product 6	Unknown

Name	Formulary Status
Product 1	Tier 1
Product 2	Tier 2
Product 3	Tier 2
Product 4	Tier 3
Product 5	Non Formulary Tier 4
Product 6	Unknown

Name	PA	Formulary Status
Product 1		$ 4 copay
Product 2		$30 Copay
Product 3	PA	$30 Copay
Product 4	PA	$80 Copay
Product 5	PA	50% Co-insurance
Product 6		Unknown

Formulary status display

- *Best for generics and preferred drugs*
- *Other brands at lesser levels*
- *Tiers and copay levels*

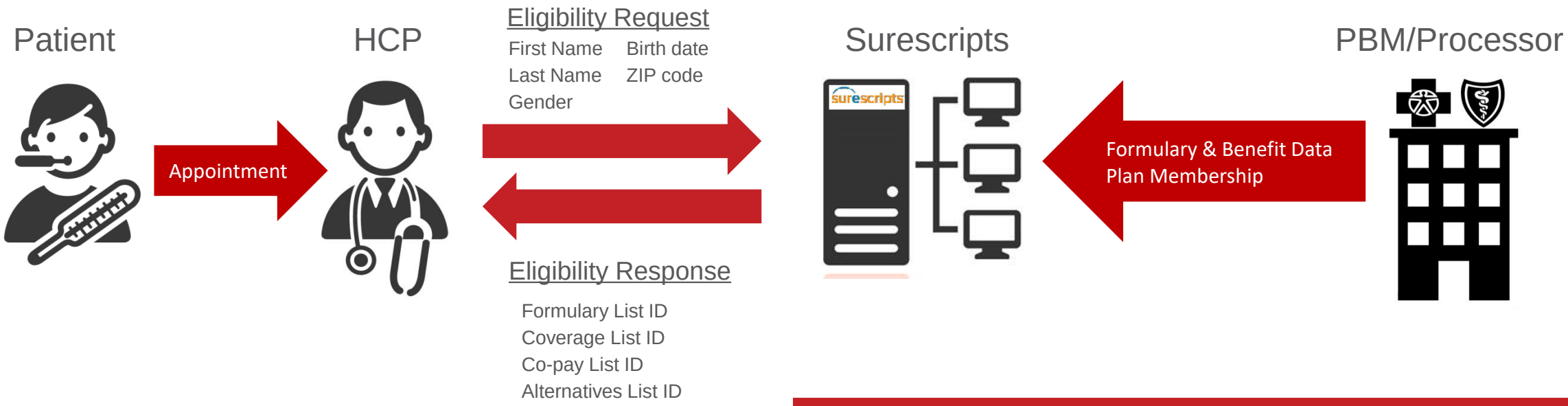
Other requirements may display

- *Prior authorization*
- *Step therapy*
- *Quantity limits*

Deficiencies In Current Formulary and Benefit Information

Challenges with accuracy of current Formulary & Benefit data led to a search for a better solution

- Formulary data is based on “Plan” level; not patient specific
- Prior Authorization flag often missing or inaccurate
- Formulary tier/preferred level often not accurately displayed for HCP
- Products on medical benefit remain largely manual



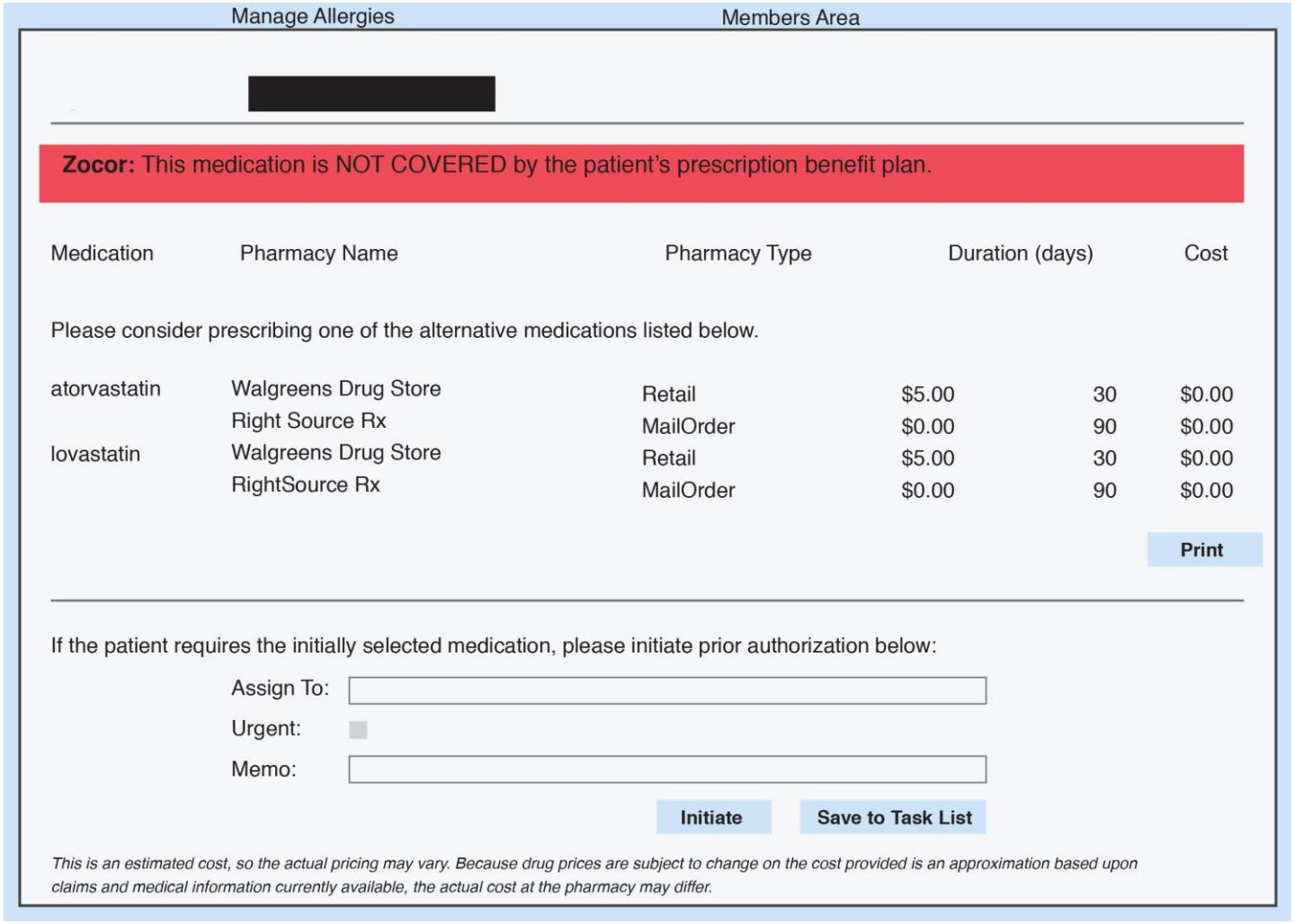
Estimated 60%-70% of eligibility requests result in successful identification due to several reasons: Plan not participating (i.e., Medicaid, regional payers), Multiple matches for a patient or patient demographics mismatch

RTBC Provides Patient Specific Benefit Information

Real-Time Benefit Check provides patient specific benefit information, improving transparency and ensuring accurate display of tier/preferred information to HCPs

Formulary status	**Tier or Preferred Level**
Coverage alerts	**Age and Quantity Limits, PA, Step Therapy**
Channel options	**Retail, Mail Order, Specialty**
Member Price	**Member Copay and Cost Sharing Details**
Alternative drugs	**Preferred Formulary/ Lower Cost Options**

Sample RTBC Results: Drug Not Covered by Prescription Benefit



Manage Allergies Members Area

[redacted]

Zocor: This medication is NOT COVERED by the patient's prescription benefit plan.

Medication	Pharmacy Name	Pharmacy Type	Duration (days)	Cost
Please consider prescribing one of the alternative medications listed below.				
atorvastatin	Walgreens Drug Store	Retail	$5.00	30	$0.00
	Right Source Rx	MailOrder	$0.00	90	$0.00
lovastatin	Walgreens Drug Store	Retail	$5.00	30	$0.00
	RightSource Rx	MailOrder	$0.00	90	$0.00

Print

If the patient requires the initially selected medication, please initiate prior authorization below:

Assign To:

Urgent:

Memo:

Initiate Save to Task List

This is an estimated cost, so the actual pricing may vary. Because drug prices are subject to change on the cost provided is an approximation based upon claims and medical information currently available, the actual cost at the pharmacy may differ.

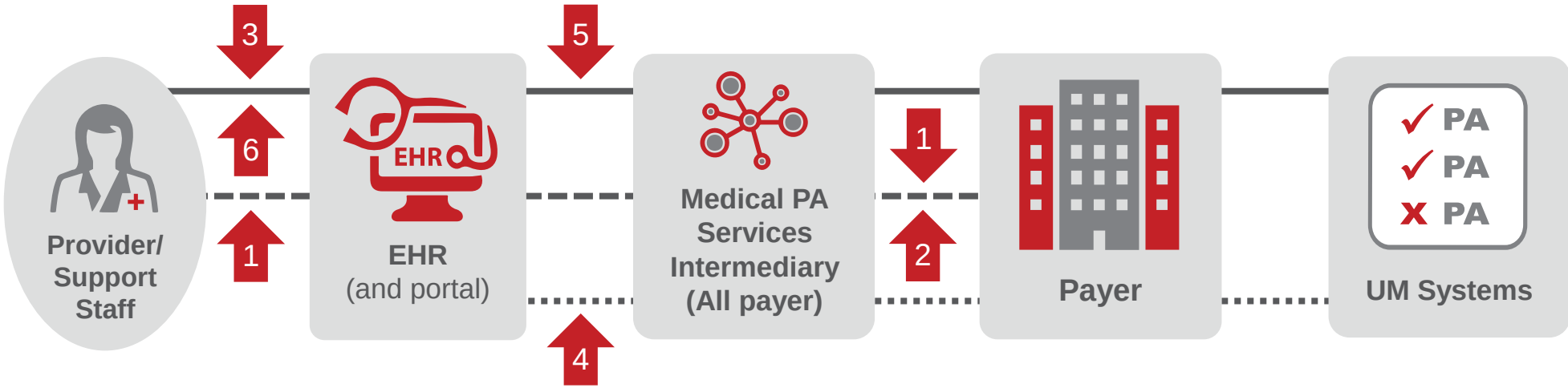
Medical Benefit

Not all Eligibility Requests are Equal

- Mandated by HIPAA , ANSI X12 270/271
- Covers basic “does patient have current coverage?”
- Quality of provider data by payer data varies by vendor and payer capabilities
  - Details on specific services covered
  - PBM benefit owner
  - Authorization Requirements
- Low automation, availability of medical pharmacy automation

- Increasing complexity of plan design, high deductible plans, and members in at risk contracts increasing pressure on plans to improve available provider tools
- Key to move knowledge of benefit data prospectively in workflow is critical

Current State of Medical PA: Potential Points of Failure



Any of these potential points of failure could cause providers to lose trust in the data and abandon the ePA channel

Eligibility/benefit provider inquiry/payer response (x12n 270/271)

Medical PA provider request/payer response (x12n 278)

Question set & PA attachment (documentation) (x12n 275; other non-standard tx.)

Potential Points of Failure

#1: Eligibility Errors: Patient Not Found; Patient Mismatch

#2: Incomplete PA indicators at patient benefit (procedure) level

#3: Incomplete/inconsistent question sets prompt confusion and errors by the provider

#4: Incomplete/inaccurate provider responses to question sets/clinical documentation submission due to data limitations of the EHR (and overreliance on the data extraction)

#5: Lag in response time from Payer; failure to update EHR with PA determination in a timely manner

#6: Inappropriate provider abandonment due to delay in response from payer, inaccurate/incomplete documentation submission

Standards Activities

Pharmacy Prior Authorization (ePA)

Transactions within the NCPDP SCRIPT Standard

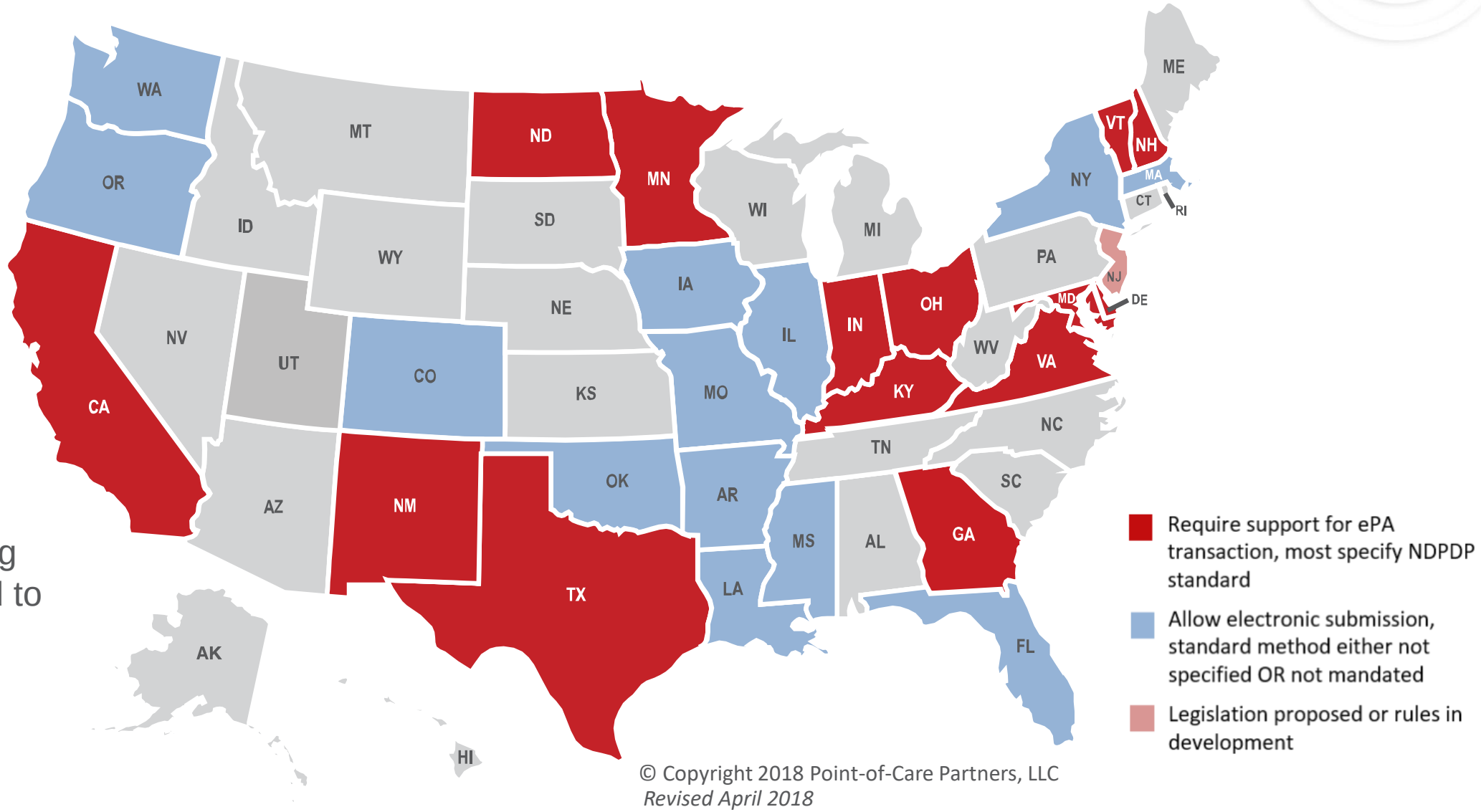
- First published in July 2013
- Supports prospective and retrospective models
- Allows for cancel and appeal functions
- Supports pharmacist-initiated requests; trading partner agreements may determine applicability
- Enhancements continue to be brought forth

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

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

Pharmacy ePA State Mandates

33 States have current or pending mandates related to the use of ePA



Revised April 2018

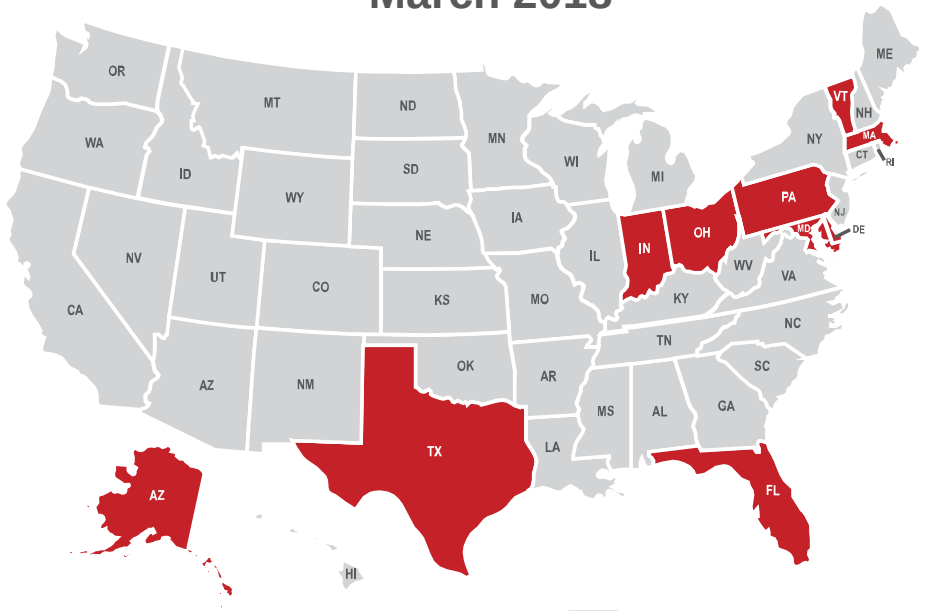
Medical PA Legislation

- **Visibility of PA rules on health insurer's website i.e., Transparency**
  - Services requiring PA
  - PA requirements i.e., criteria
  - Notification when requirements change
- **"Standardization" of PA forms**
  - Single form per state for all plans
    - Developed and maintained by state agency (e.g., Dept. of Insurance)
  - Single form per plan, provided to state
- **Defining methods of PA communication & required acceptance by health insurers**
  - Fax and phone
  - Electronic methods (web-based form; x12 278)

States have taken varied approaches for PA Reform. Each state's approach is a patchwork of at least one, or several of these approaches

- **Defining turnaround times for plans to respond to PA requests**
  - Urgent, Non-urgent
  - PA request submitted by the provider must meet the PA requirements

Medical Prior Authorization Laws
March 2018



Real-Time Benefit Check (RTBC) 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.

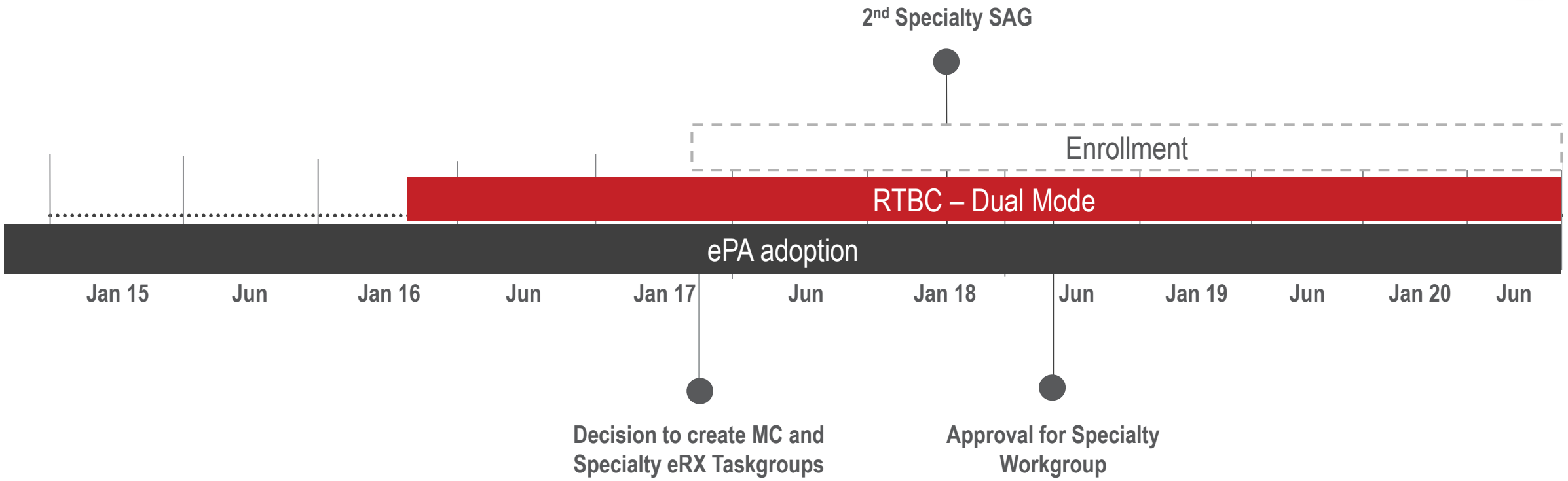
Efforts focused on facilitating the healthcare industry's adoption by providing expertise and education

Enrollment Transaction

- Active work underway at NCPDP eRx Specialty task group
- Inventory of all steps of eRX, focus on “enrollment”

- Bi-directional transaction to include: Patient, Demographic, Prescriber, Medication, Clinical, Insurance and Consent
- Evaluating hybrid transaction using NCPDP and HL7© FHIR© to pull clinical data from EHRs

NCPDP Driving Specialty Pharmacy Focus



Significant commercial movement on Medical PA, but little focus on upstream challenges. Work underway at HL7 to move clinical data for Pharmacy and Medical workflows

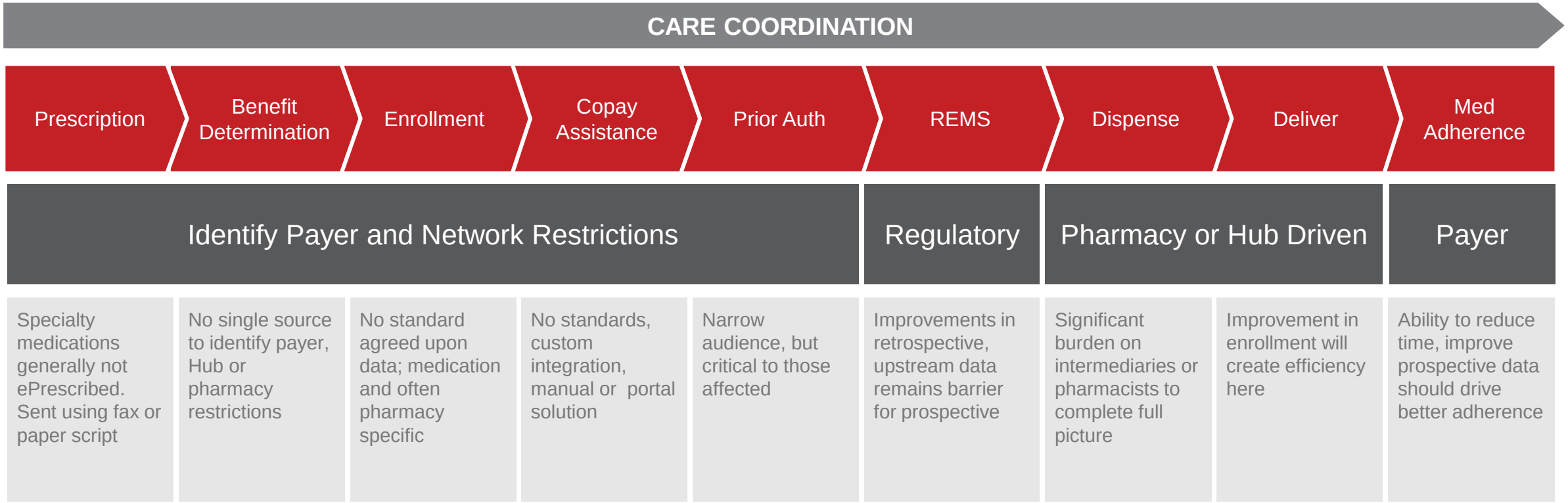
Restart RTBC

ePA

Enrollment

Opportunities and Impacts

Progress Across Care Continuum



ePA adoption continues, HUBS/IDNs continual to improve "manual automation" while work begins in earnest on Enrollment and Medical PA

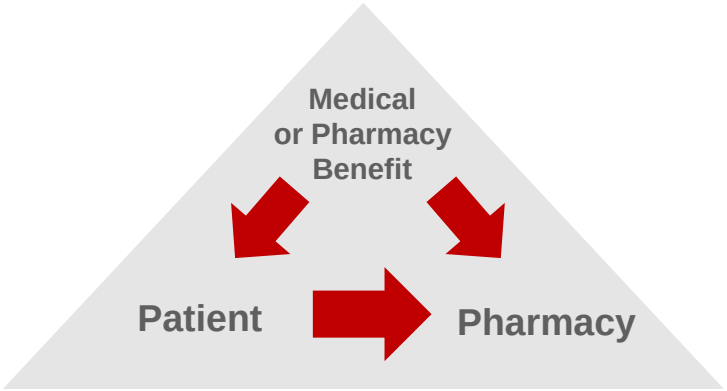
Specialty Requirements for ePrescribing

- 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
  - HL7 FHIR within NCPDP
  - Da Vinci initiative exploring prospective need for authorization in clinical workflow

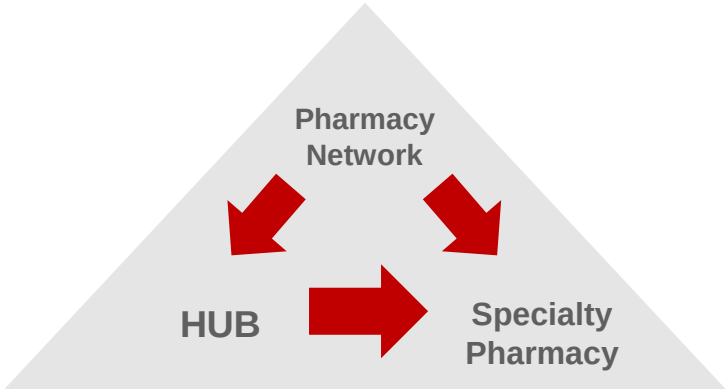
Two key specialty enrollment transactions identified:

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

IS SPECIALTY MEDICATION?

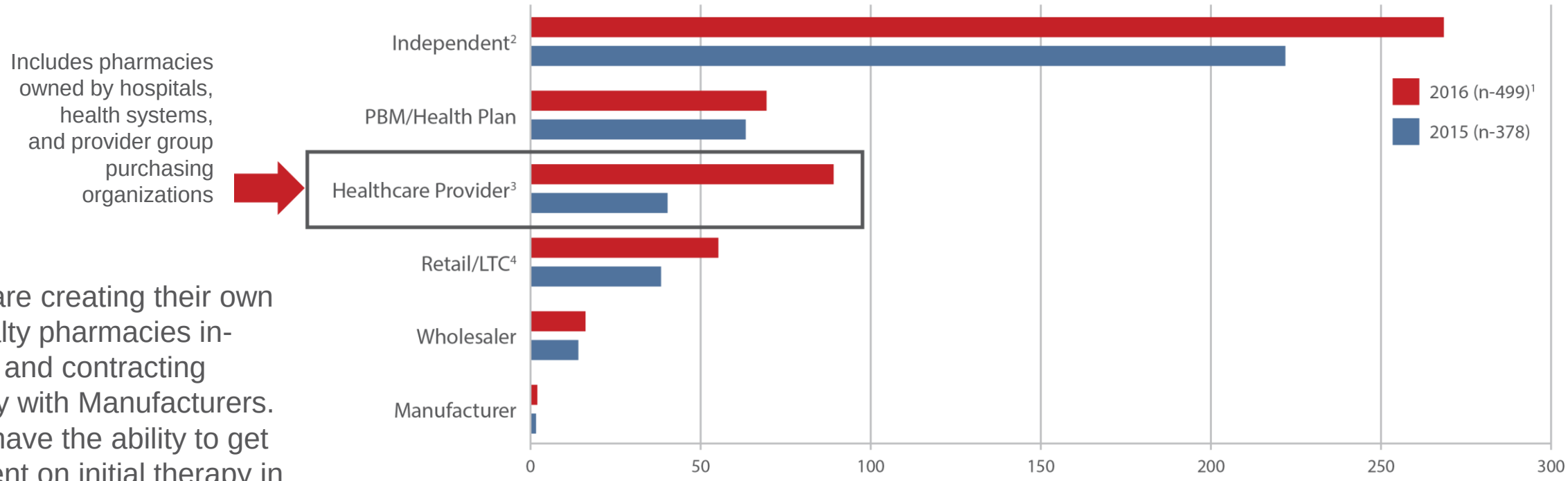


PRESCRIPTION AND ENROLLMENT ROUTING?



Integrated Delivery Networks (IDNs)

PHARMACY LOCATIONS WITH SPECIALTY PHARMACY ACCREDITATION, BY CORPORATE OWNERSHIP, 2015 VS. 2016



IDNs are creating their own specialty pharmacies in-house and contracting directly with Manufacturers. IDNs have the ability to get a patient on initial therapy in days versus weeks given they usually have all of the required patient and clinical data in-house

LTC = Long-term care
1. Excludes 2,051 newly accredited retail pharmacies within the supermarket chains Albertsons, Meijer, and Price Chopper.
2. Includes private independent pharmacies, pharmacies owned by private equity firms, and independently owned franchise locations
3. Includes pharmacies owned by hospitals, health systems, physician practices, and providers' group purchasing organizations
4. Includes pharmacy locations owned by chair drugstores, grocery chains, and national long-term care pharmacy chains
Source: *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,* Exhibit 44. Includes pharmacy locations accredited by URAC and ACHC.

Summary

Key Take Aways:

- No clear single source to guide providers to right payer.
- Significant movement on individual steps inside NCPDP and emerging standards like HL7© FHIR©
- Ecosystems that can exchange clinical data are advancing, differentiating
- Renewed focus on Medical Prior Authorization should provide momentum for pharmacy on medical benefit

Conclusion:

- While realization of the benefits of integrated medical/pharmacy benefit management will take time, huge potential is on the horizon to avoid suboptimal care and improve the patient's experience.
- The health systems and payer who delivers has the opportunity to dramatically improve the health outcomes/cost equation and establish itself as a market leader in the new era of value-based care.

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RTBC Impact to Manufacturers

- RTBC will provide more accurate information on specific drug selected for specific patient
- Prescriber will have information needed to discuss prescription with patient
- Some alternatives are included in the response
- PA flag can be patient specific and obvious approvals waived
- Retail and mail pharmacy information (some preferred pharmacy but not specialty)

- Will provide more tools to PBM's to control formulary messaging
  - Limit information regarding patient savings card reductions
  - Messaging for alternatives
  - Ability to include more PAs
  - Provider could waive PA when a there is a high likelihood of approval
- No pharma copay assistance is noted
- Transaction costs per inquiry which could lead to increased demand of rebates and/or implementation of costly "alternatives" programs
- RTBC has a limited view of 'alternatives' to what the PBM chooses not the full class of medications
- Dedicated Hubs and Brand sponsored pharmacies may be removed from consideration with more real time information