NCPDP Stakeholder Action Group on the Potential for Specialty Pharmacy Automation

April 5, 2016

NCPDP Office • Scottsdale, AZ

PRESENTERS

Lynnae Mahaney
Executive Director
Center for Pharmacy Practice
Accreditation (CPPA)

Tony Schueth
CEO & Managing Partner
Point-of-Care Partners

Laura Topor
President
Granada Health

SITUATION REVIEW / LEVEL SET

9:00 am – 10:00 am

- **Specialty Pharmacy Overview**
  - Lynnae Mahaney
    Executive Director, Center for Pharmacy Practice Accreditation (CPPA)

- **The "Problem" in Specialty Pharmacy**
  - Tony Schueth
    CEO & Managing Partner, Point-of-Care Partners

- **NCPDP Activities – Specialty Medication Related**
  - Laura Topor
    President, Granada Health

Specialty Pharmacy Overview

Lynnae Mahaney, BSPharm, MBA, FASHP

SPECIALTY PHARMACY in the HEALTHCARE MARKET

Healthcare costs and spending on medications 2014

- **2014 HC spending rate increases 5.3%**

- **2013 HC spending rate increase 2.9%**

- **Primary contributors?**

  - Coverage expansion (ACA)
  - Growth in prescription drug spending

Salazar, David; Drug Store News; CMS: National health spending grew 5.3% in 2014; http://www.drugstorenews.com/article/cms-national-health-spending-grew--01; accessed 12/4/2015

SPECIALTY MEDICATIONS: A FORCE of HEALTH CARE

Medication Spending

- 2015 Rx meds 5.2% increase
- 2014 Rx meds 12.2% increase
- 2013 Rx meds 2.4% increase

Primary Contributors?

- New Active Substances
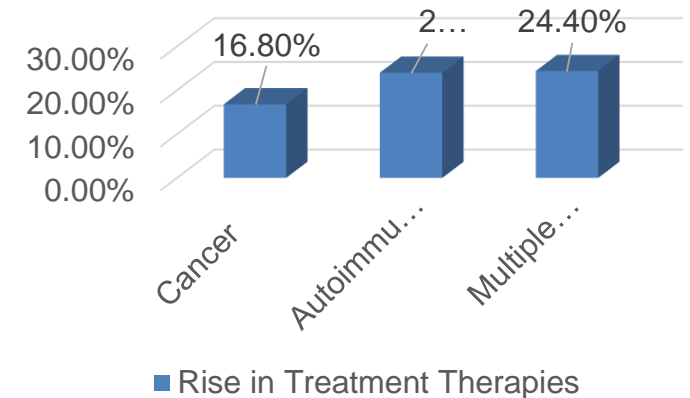- Specialty medications
- Hep C treatments

Express Scripts 2015 Drug Trend Report 20th Edition

IMS Institute for Healthcare Informatics; Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014; April 2015.

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.

Rise in Treatment Therapies

| | 16.80% | 2… | 24.40% |

- 30.00%
- 20.00%
- 10.00%
- 0.00%

Cancer Autoimmu… Multiple…
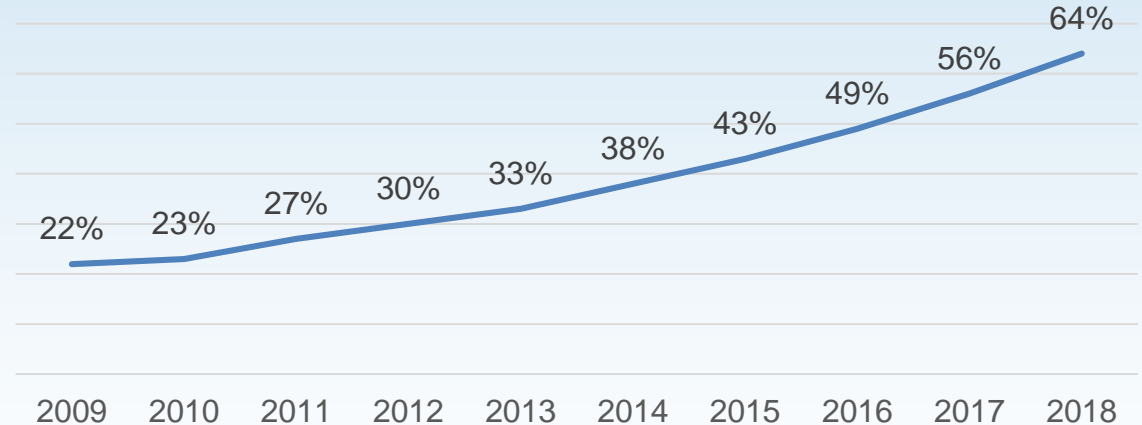
■ Rise in Treatment Therapies

SPECIALTY DRUGS CONTINUE TO GROW

- In 2015, specialty medications accounted for 37.7% of total drug spending and a 17.8% overall trend, according to the annual Express Scripts Drug Trend Report. See more at:

  http://www.specialtypharmacytimes.com/news/top-10-specialty-drug-therapeutic-classes#sthash.Q9qqC0of.dpuf

- 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 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.

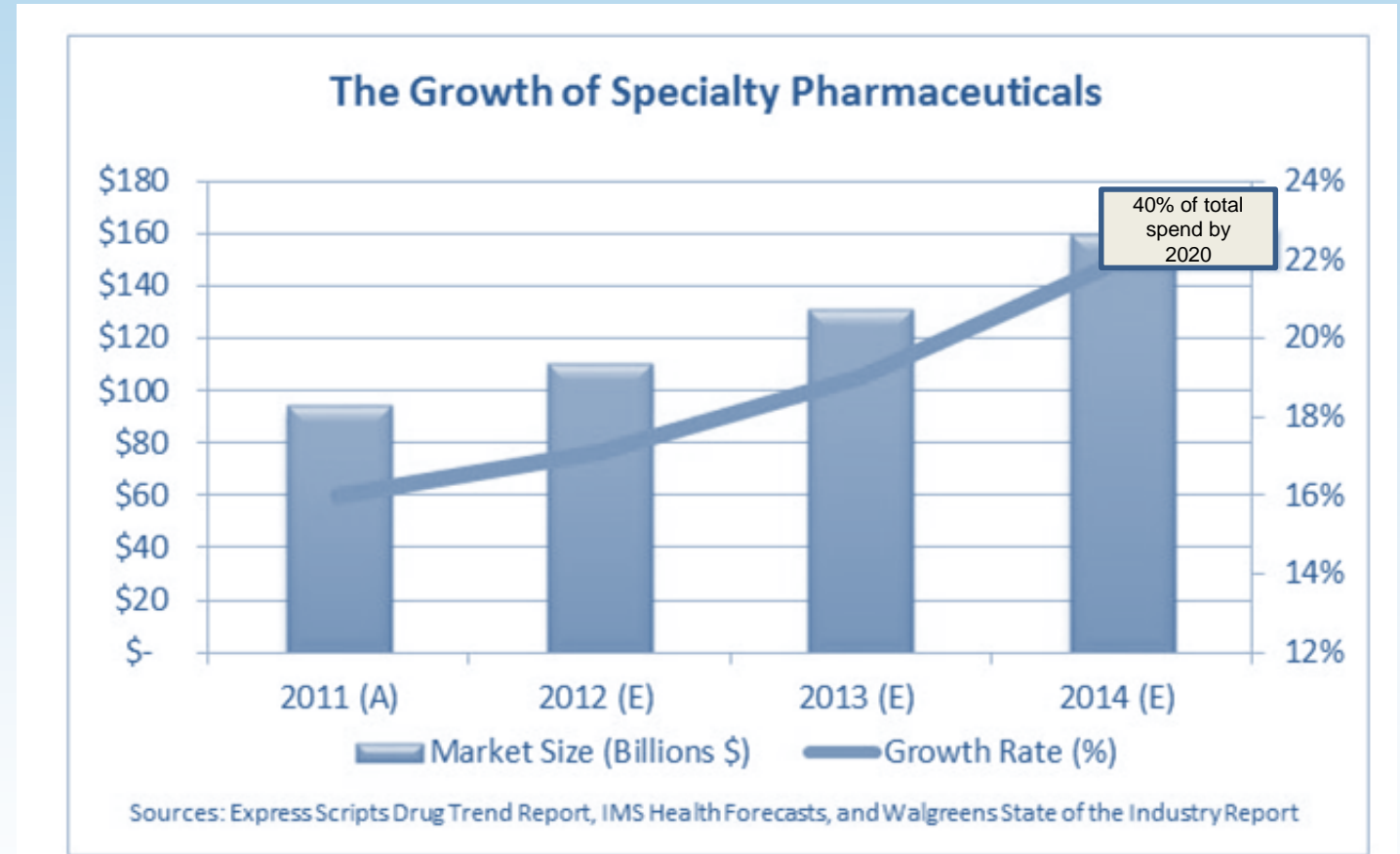**Specialty Med Spending:** **67%** growth end 2015

Specialty Drugs as % of Total Drug Spend

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

2009 2010 2011 2012 2013 2014 2015 2016 2017 2018

Source: Prime Therapeutics

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.**

The Growth of Specialty Pharmaceuticals

40% of total spend by 2020

Market Size (Billions $) — Growth Rate (%)

2011 (A)   2012 (E)   2013 (E)   2014 (E)

Sources: Express Scripts Drug Trend Report, IMS Health Forecasts, and Walgreens State of the Industry Report

CHALLENGES IN SPECIALTY PHARMACY

- **Multiple stakeholders:**
  - EHR and ePrescribing solution providers
  - Pharmaceutical manufacturers
  - HUB or other service providers
  - Specialty pharmacy and pharmacy solution provider
  - Payers

- **Multiple, bi-directional information needs among stakeholders**

- **Information exchange relies on**
  - Paper
  - Phone and fax

CHALLENGES IN SPECIALTY PHARMACY

Processes are:

- Cumbersome
- Incomplete
- Redundant
- Exceptionally inefficient
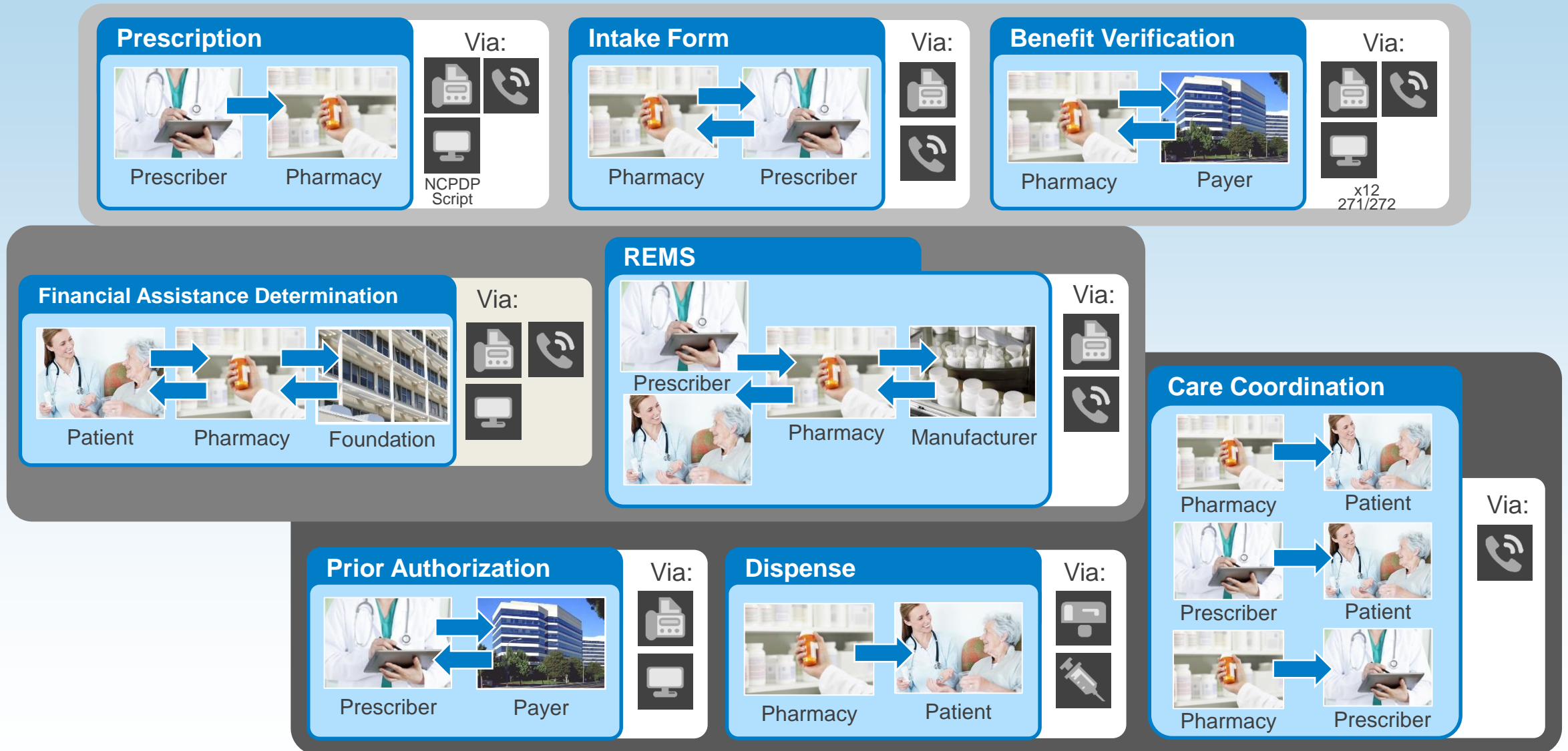- **Barrier to optimal delivery of patient care**

The "Problem"

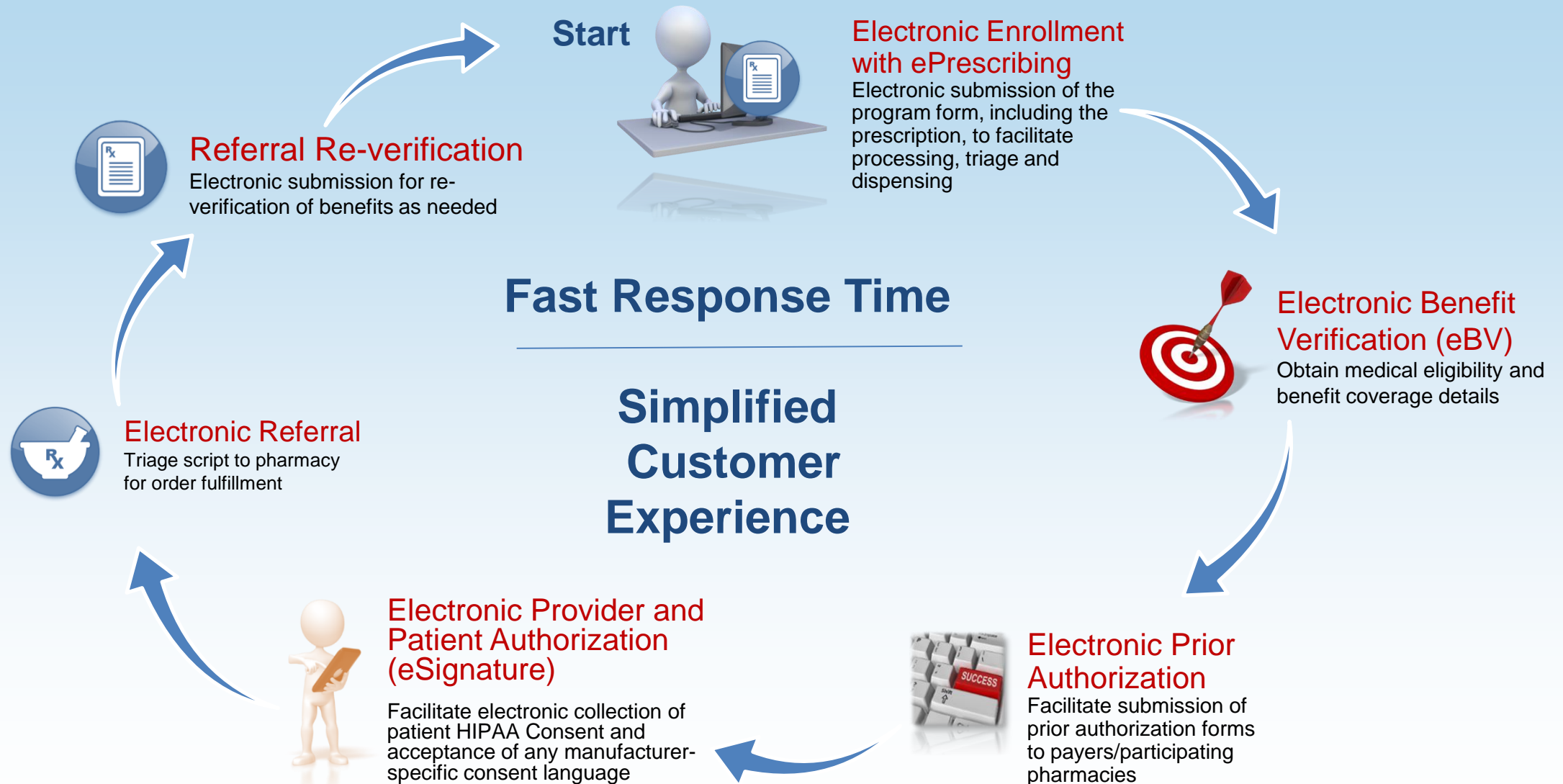**Tony Scheuth, CEO & Managing Partner, Point-of-Care Partners**

TYPES OF SPECIALTY PRESCRIPTION TRANSACTIONS

© 2016 Point-of-Care Partners, LLC

REIMBURSEMENT HUB GOALS

Start

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

Referral Re-verification
Electronic submission for re-verification of benefits as needed

Fast Response Time

Simplified Customer Experience

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

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

Drill-down:

ePrescribing of Specialty Medications

REMS

ePrior Authorization

THE INFRASTRUCTURE IS IN PLACE

80%
Physicians Today

More than 80% of physicians ePrescribe today

700
EHRs Enabled

More than **700** EHRs enabled for ePrescribing

100%
Retail Pharmacies

Nearly **100%** retail pharmacies

ePRESCRIBING via NCPDP SCRIPT

Developed for the **oral-solid, single molecule medications** traditionally dispensed in retail or mail service pharmacy.
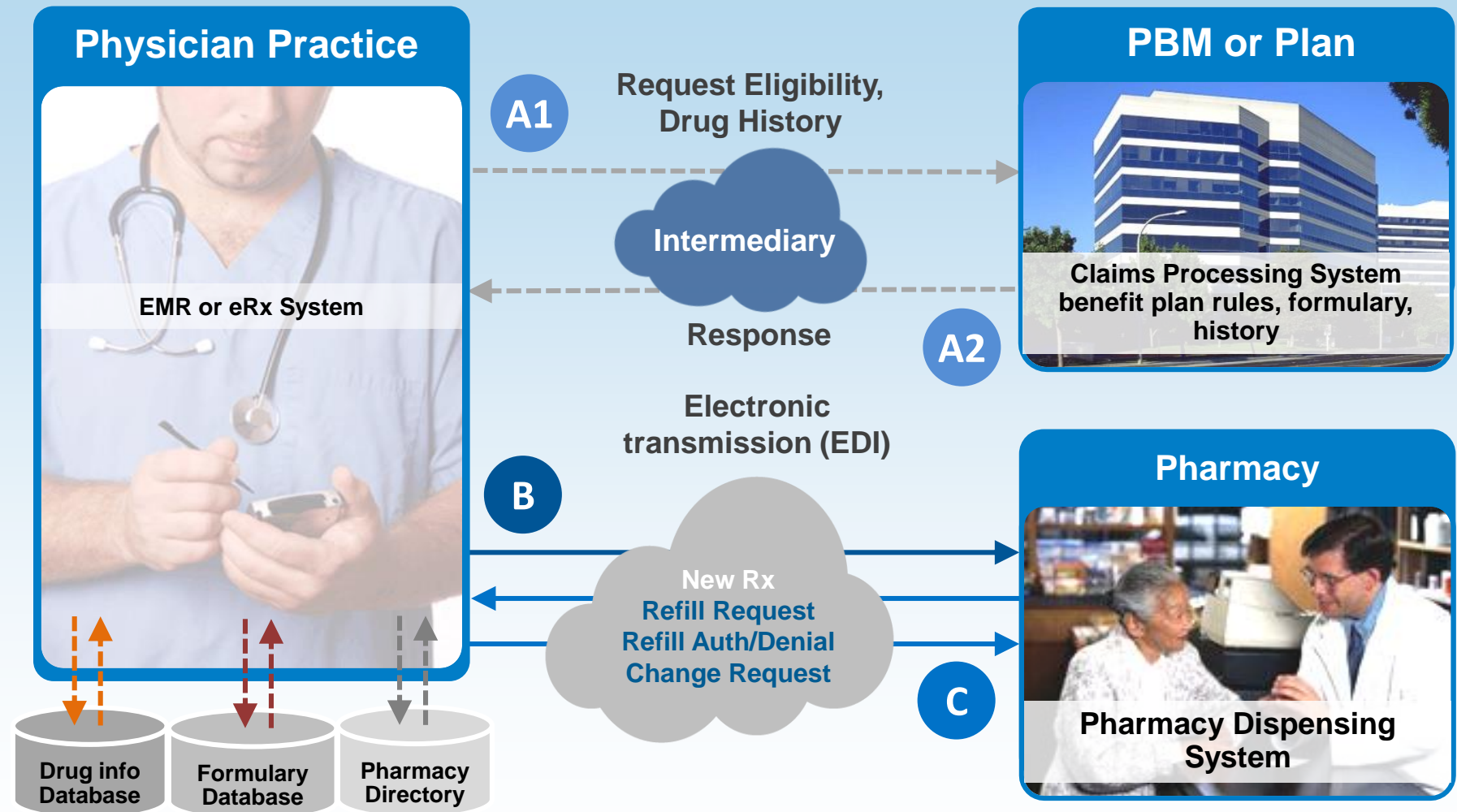
Designed to accommodate **data elements the retail or mail pharmacy requires** (drug name, dosage, quantity and *sig*).

Insurance eligibility determined **before** patient arrives at physician's office.

Formulary and some benefit information is presented to prescriber before drug selection.

Pharmacy Directory provided by Surescripts to EHRs prior to prescribing.

CURRENT ePRESCRIBING FLOW

Physician Practice

EMR or eRx System

Drug info Database

Formulary Database

Pharmacy Directory

A1 Request Eligibility, Drug History

Intermediary

Response

A2

PBM or Plan

Claims Processing System benefit plan rules, formulary, history

Electronic transmission (EDI)

B

New Rx
Refill Request
Refill Auth/Denial
Change Request

C

Pharmacy

Pharmacy Dispensing System

GAPS IN ePRESCRIBING THAT PERTAIN TO SPECIALTY

The prescriber doesn't know which pharmacies are part of the limited distribution or plan's network.

Data required to ultimately dispense a specialty medication is not included in the original prescription; in fact, SCRIPT may not even have the fields to accommodate.

There is no standard definition of specialty, so no specialty medications are flagged leading to specialty drugs being prescribed in the same manner as non-specialty.

The process requires coordination between the pharmacy and prescriber, and there are no transactions that facilitate status updates, and those that can be used for coordination may be sub-optimal.

Drill-down:

ePrescribing of Specialty Medications

REMS

ePrior Authorization

CHALLENGES WITH REMS

- Prescriber doesn't know if REMS is required … or to what degree.

- Structured Product Label (SPL) is supposed to have REMS information. Compendia would, then, provide to EHRs/eRx companies. EHRs would have to purchase the module, and there are latency issues.

- Patient enrollment rarely in-office (generally given a brochure, and directed to visit a portal); practice generally doesn't have terminals for patients to enroll on-site.

- If not properly enrolled, claim will reject at POS.

- If REMS is educational, pharmacies have internal processes; however, if it's a lab, pharmacy must have results before dispensing.

- There are patient access challenges, especially after discharge.

- Reporting to FDA is challenging because of gaps in process and different formats.

Drill-down:

ePrescribing of Specialty Medications

REMS

ePrior Authorization

A LOOK AT THE ePA ROAD SO FAR

1996 HIPAA Passes, names 278 as standard for ePA

2003 MMA Passes

2004 Multi-SDO Task Group formed

2005 NCVHS Hearings

2006 MMA ePrescribing Pilots involving ePA

2007 Report to Congress recommending a new standard

2008 Expert Panel Formed/Roadmap Created

2009 Minnesota Law Passes New ePA Standard Created
using SCRIPT

2011 CVS Caremark Pilot

2013 New Standard Published

2015 Implementation of SCRIPT-based Standard
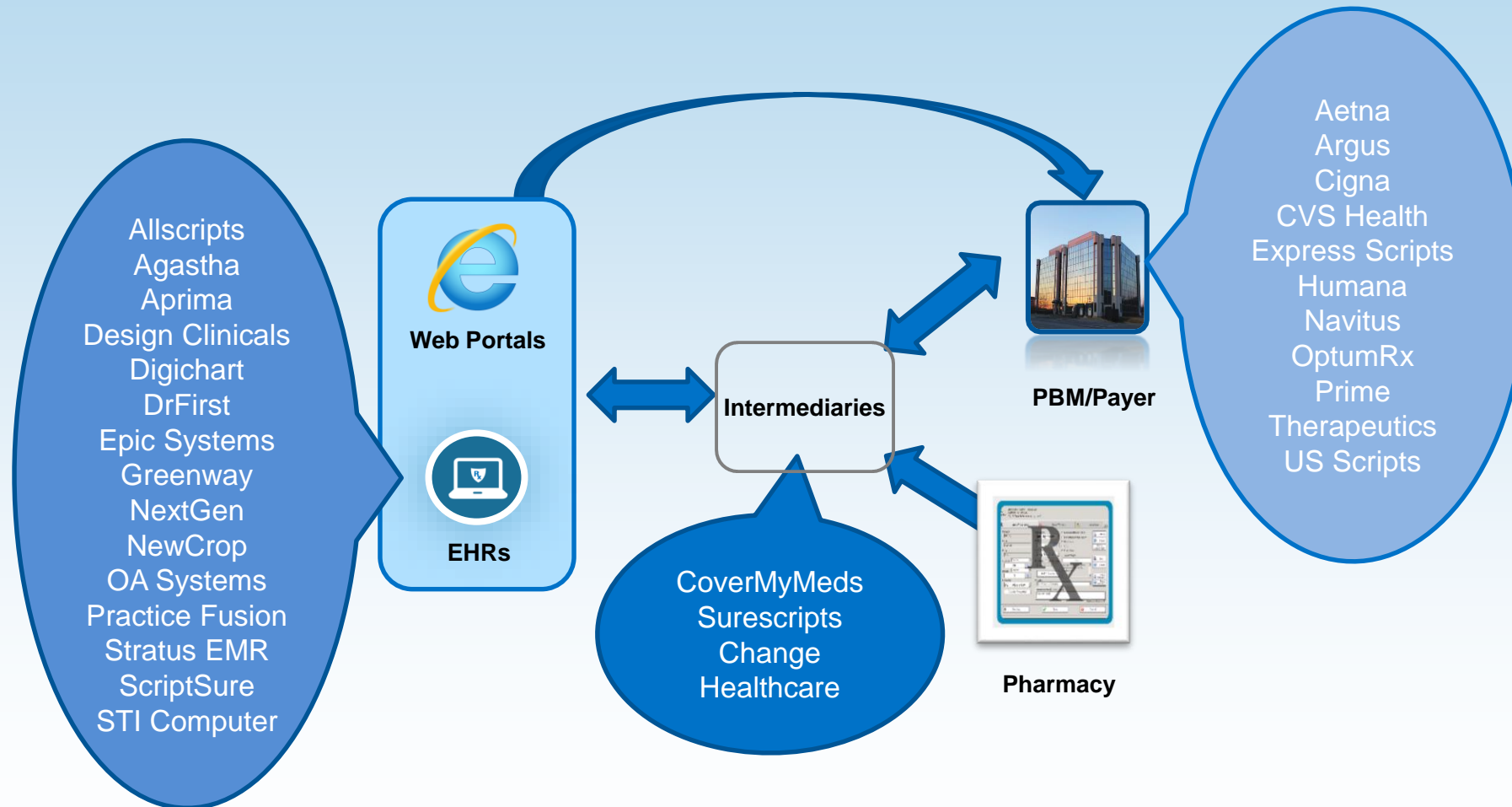
2016 Expansion and EHR integration

NEW STANDARD ENABLES MULTIPLE WORKFLOWS
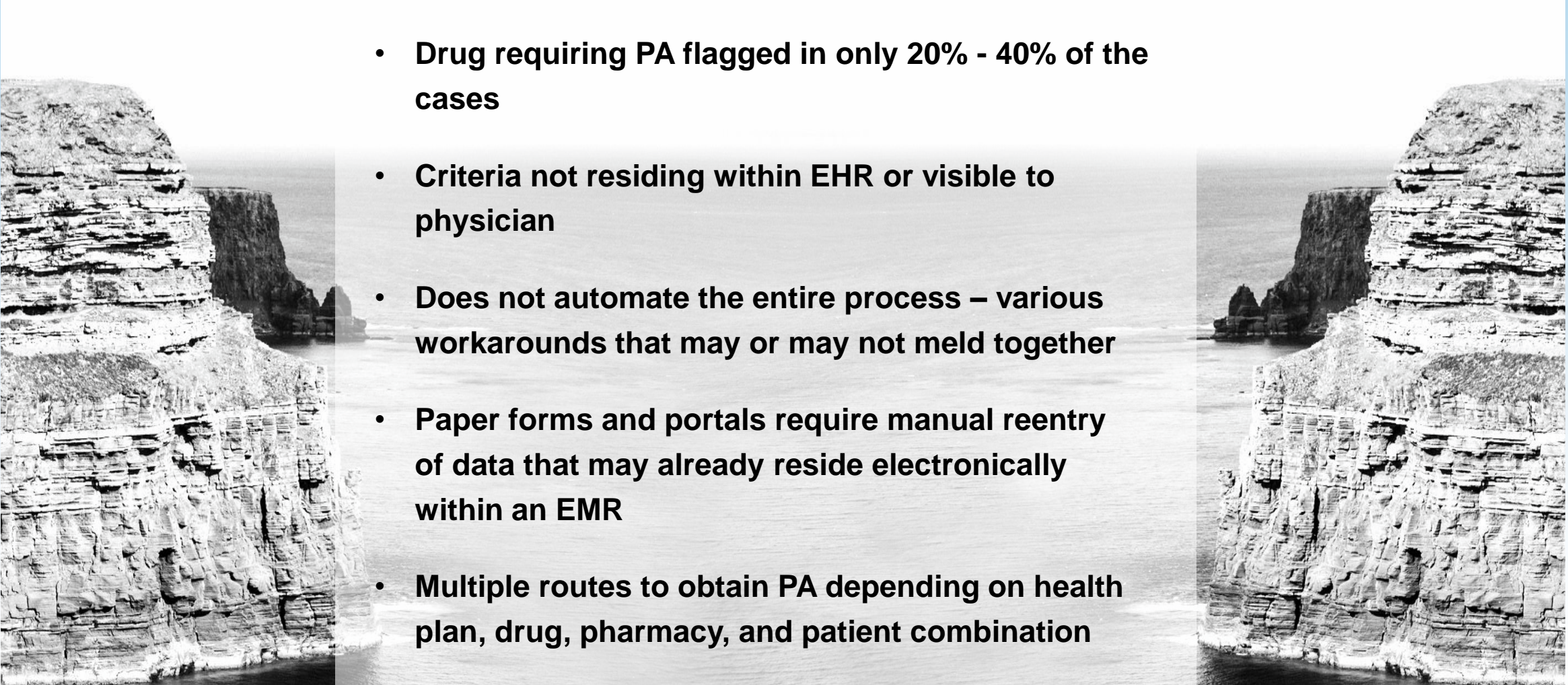
Retrospective **vs.** Prospective

Retrospective PA – Without PA info at time of prescribing

Rx without PA info
Processing
Request for info for PA
Rejected: PA Needed

Prescriber   Pharmacy   Payer

PA Info
Processing
Advises PA Approval
Advises PA Approval

Prescriber   Pharmacy   Payer

Rx with PA info
Processing
Advises PA Approval
Advises PA Approval

Prescriber   Pharmacy   Payer

CURRENT LANDSCAPE

Allscripts
Agastha
Aprima
Design Clinicals
Digichart
DrFirst
Epic Systems
Greenway
NextGen
NewCrop
OA Systems
Practice Fusion
Stratus EMR
ScriptSure
STI Computer

Web Portals

EHRs

Intermediaries

CoverMyMeds
Surescripts
Change
Healthcare

Pharmacy

PBM/Payer

Aetna
Argus
Cigna
CVS Health
Express Scripts
Humana
Navitus
OptumRx
Prime
Therapeutics
US Scripts

GAPS IN CURRENT PA ACTIVITIES

- Drug requiring PA flagged in only 20% - 40% of the cases

- Criteria not residing within EHR or visible to physician

- Does not automate the entire process – various workarounds that may or may not meld together

- Paper forms and portals require manual reentry of data that may already reside electronically within an EMR

- Multiple routes to obtain PA depending on health plan, drug, pharmacy, and patient combination
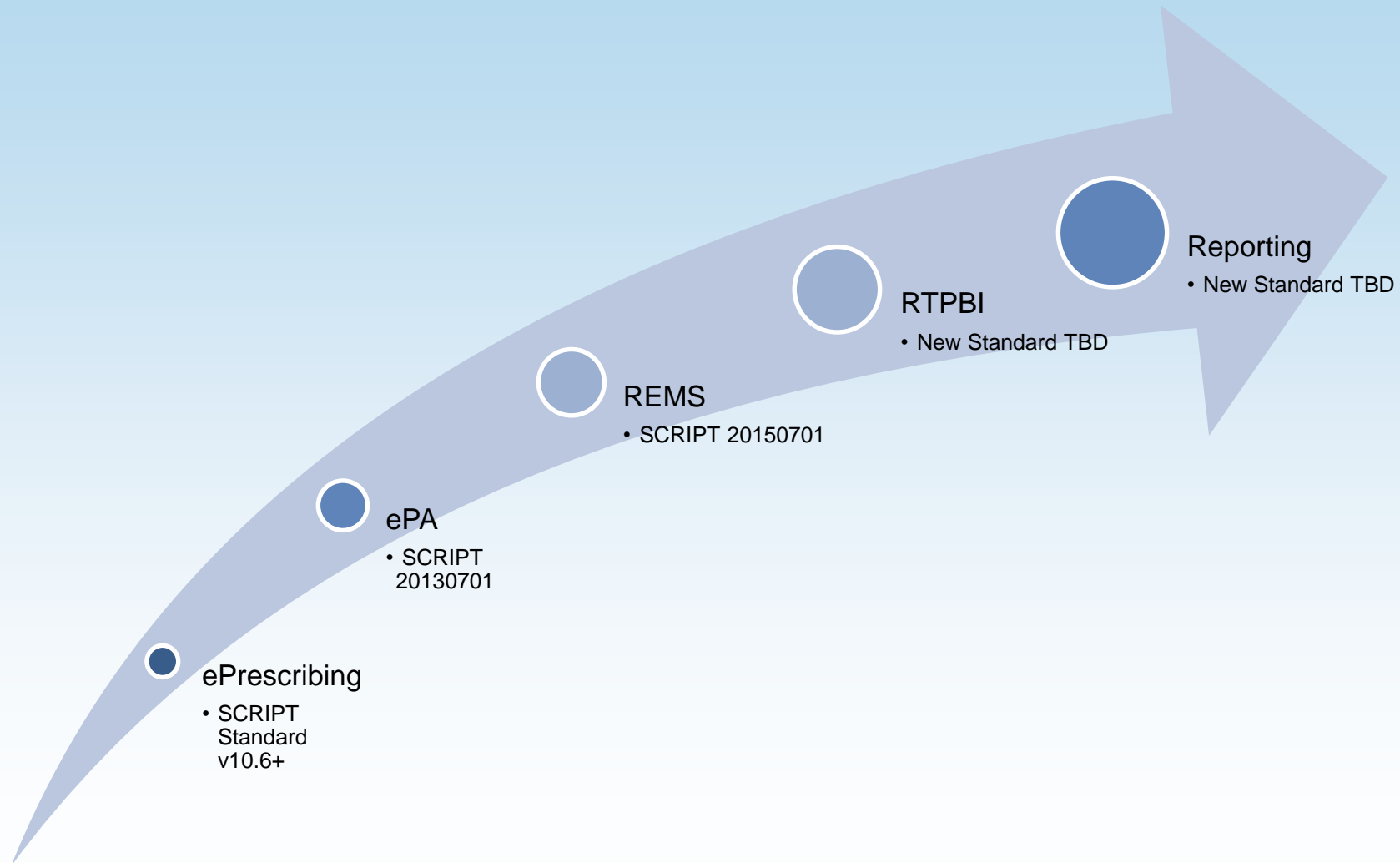
NCPDP ACTIVITIES – SPECIALTY MEDICATION RELATED

Laura Topor, President, Granada Health

NCPDP EFFORTS

- **Electronic Prescribing**

- **Prior Authorization**

- **REMS**

- **Real Time Pharmacy Benefit Inquiry**

- **Reporting**

STANDARDS CONTINUUM

Reporting
- New Standard TBD

RTPBI
- New Standard TBD

REMS
- SCRIPT 20150701

ePA
- SCRIPT 20130701

ePrescribing
- SCRIPT Standard v10.6+

ELECTRONIC PRESCRIBING (eRx)

- **Added guidance to Recommendations Document to improve use of existing elements in SCRIPT 10.6**
  - Diagnosis
  - Height/Weight
  - Insurance Information

- **Added elements to SCRIPT Standard to support:**
  - e-prescribing of specialty medications
    - Agency and service information
    - IV administration
    - Patient information (i.e. hospice status, alternate contact)
  - Clinical information specific to wound care
  - Enhanced e-prescribing of compounded medications

- **Regulation to name new version of SCRIPT expected to be published November 2016**
  - Implementation anticipated in 2018

ELECTRONIC PRIOR AUTHORIZATION (ePA)

- **Included in NCPDP SCRIPT Standard**

- **First published in July 2013**

- **Supports prospective and retrospective models**

- **Allows for cancel and appeal functions**

- **Enhancements continue to be brought forth**

- **Guidance from industry implementation available in NCPDP's SCRIPT Implementation Recommendations Document**

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

- **FDA has authority to enforce these programs**

- **Industry needed a way to exchange information related to Elements to Assure Safe Use (ETASU) requirements**

- **FDA agreed to modifications to the Structured Product Label requirements so that REMS information could be supported by drug knowledge databases (compendia) and be readily available within EMRs**

- **NCPDP created new message types, modeled on ePA, and enhanced existing messages to support information exchange**

- **Regulation to name new version of SCRIPT expected to be published November 2016**
  - Messages from prescriber to REMS Administrator prior to sending prescription
  - Telecommunications Standard was modified to allow REMS processing to leverage claim adjudication process

- **The changes were initially approved by NCPDP members at the August 2015 Work Group meetings and will be published spring 2016**

REAL TIME PHARMACY BENEFIT INQUIRY (RTPBI)

- **Task Group investigating options to support a real time benefit check initiated by the prescriber**

- **Interest from ONC**

- **11 use cases have been identified, with associated data elements**

- **Further work includes analysis of technical options (EDI, XML, FHIR, etc.) and standard option (new, existing)**

- **Industry pilots underway; feedback will be shared with NCPDP**

REPORTING - SPECIALTY PHARMACY INITIATED

- **Specialty Pharmacy Data Exchange Sub-Task Group (within WG 7 - Manufacturer and Associated Trading Partner Transaction Standards)**

- **Develop standardized reporting to support contractual arrangements between the manufacturer and specialty pharmacy. There are four categories the group will address:**

  - **Order fulfillment**

  - Patient Census (Aggregate)

  - Performance Metrics/Case Management

  - Inventory

- **Current focus is to identify all needed data elements, then map to existing NCPDP data dictionary. If not in data dictionary, additions will be requested and the format will be presented to the membership for approval.**

The End

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