Automating Specialty Pharmacy: Identifying Gaps

Kevin James, R.Ph., MBA | VP, Payer Strategy| US Bioservices

Jeff Spafford | President and CEO | AssistRx

Tony Schueth, M.S. | CEO & Managing Partner | Point-of-Care Partners

November 3, 2015

Speakers

Tony Schueth

Jeff Spafford

Kevin James

Disclosures

- Kevin James, R.Ph., MBA, has no Conflicts of Interest to Disclose.
- Jeff Spafford has no Conflicts of Interest to Disclose.
- Anthony Schueth, MS, has no Conflicts of Interest to Disclose.

NCPDP

Accreditation Statement

The Institute for Wellness and Education, Inc., is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants of the session who complete the evaluation and provide accurate NABP e-Profile information will have their credit for 1.0 contact hours (0.10 CEU) submitted to CPE Monitor within 60 days of the event. Please know that if accurate e-Profile information is not provided within 60 days of the event, credit cannot be claimed after that time.

ACPE program numbers are:
0459-0000-15-073-L04-P & 0459-0000-15-073-L04-T
Initial release date is November 3, 2015.

Learning Objectives

- Describe the **growth trend** for specialty medications and the drivers for specialty ePrescribing
- **Delineate key differences** in data needs between specialty and non-specialty medications and **provide examples of how NCPDP Standards are evolving** to support specialty automation.
- **Categorize** types of **specialty transactions** and the entities involved in processing them.
- Identify how payers and PBMs could **better identify PA needs** in formulary and benefit information to facilitate specialty automation
- Discuss **impact of drugs covered under the medical or dual benefit** and how that modifies the approach to capturing and transmitting the patient benefit.
- **Explain the role of third parties agencies** that provide clinical services to patients to educate, train or comply with REMs and additional dispensing requirements and how delays in those services impact speed to therapy.
- Map the **distribution of products through the supply chain** for specialty medications requiring specific devices, starter/titration kits, and other limited distribution models that determine patient access to medications.
- **Describe the role of reimbursement hubs** and how technology is being used to determine optimal benefit coverage and improve patient access to medications based on benefit coverage.

Specialty Medications: A Force of Health Care

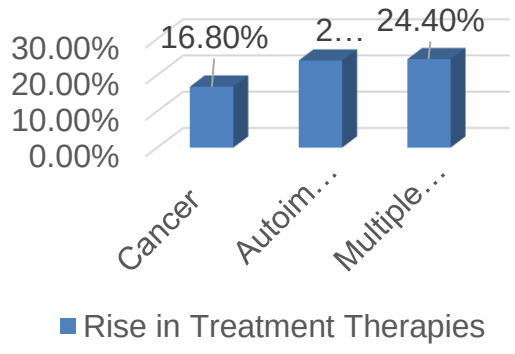
- Administered to small populations with **rare and chronic diseases**.
- **Expanding to larger populations** and therapeutic areas.
- Complex, large molecule and biologic drugs distributed through **multiple pharmacy models**.
- Majority require **clinical management** and **special handling**.

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

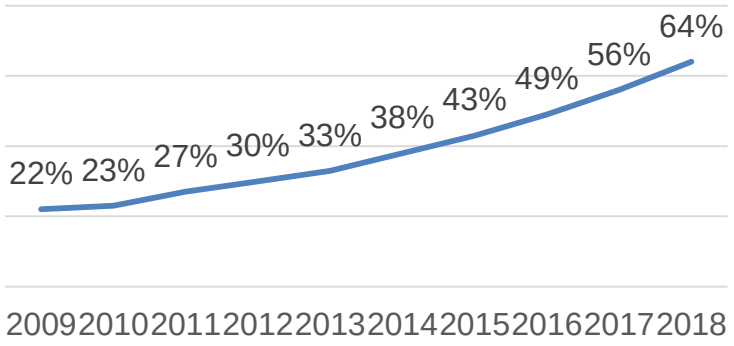
While the volume of specialty medications is less than 1% of total prescriptions, US spending on specialty drugs is projected to **grow 67% by the end of 2015.**

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.**

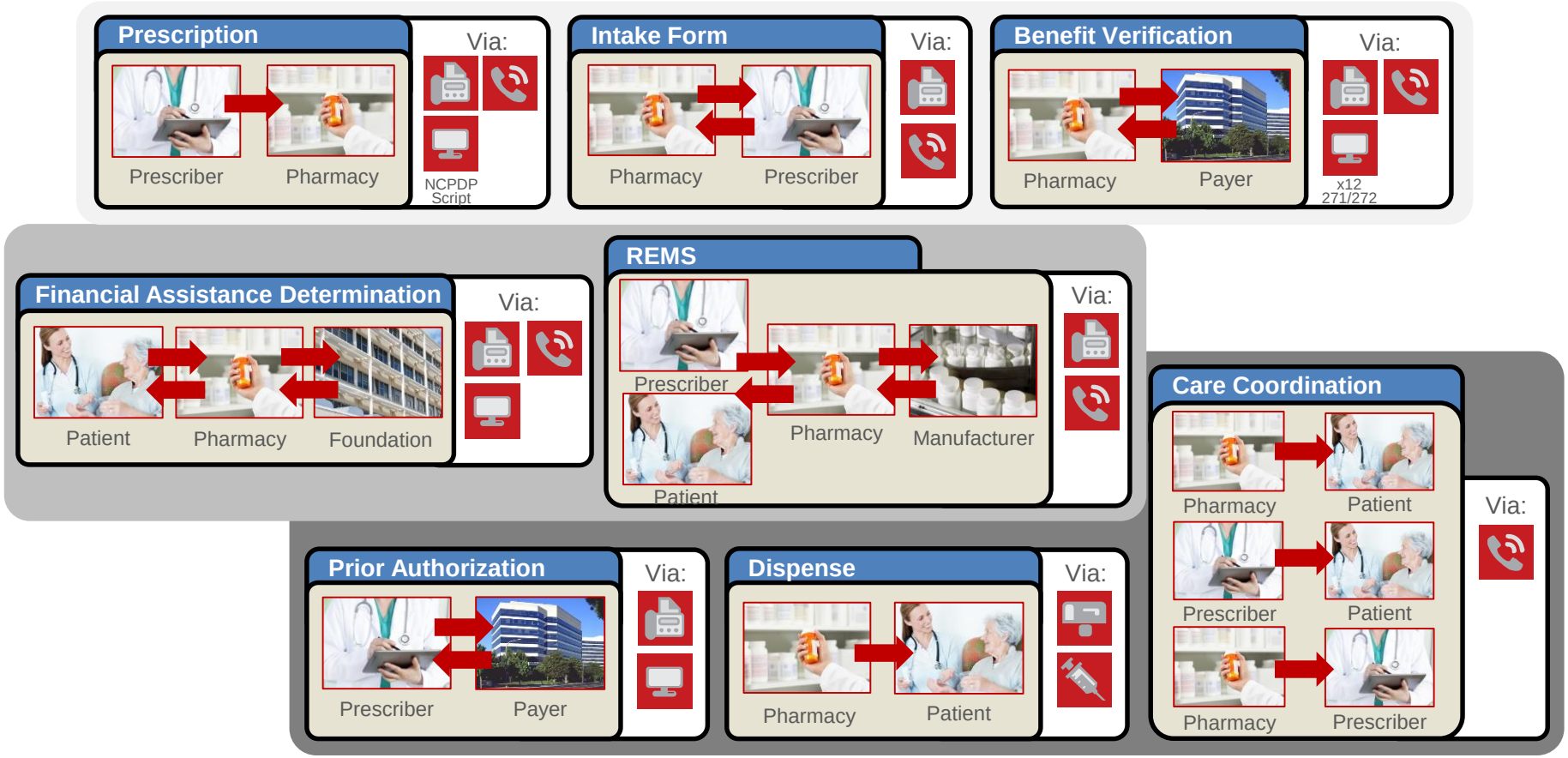
Specialty Med Spending: **67%** growth end 2015

Specialty Drugs as % of Total Drug Spend



Source: Prime Therapeutics

Types of Specialty Prescription Transactions



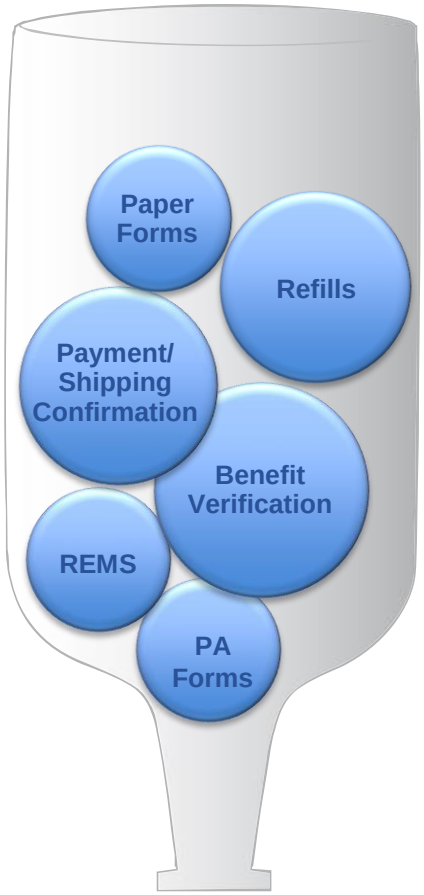
Source: Point-of-Care Partners

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 Pharmacy

NCPDP™

ePrescribing uptake

- Physician adoption increasing drastically from 68 million scripts in 2008 to 1 billion in 2014
- 80% of physicians utilize
- Standard route for prescriptions in retail
- ***Fax is still the standard in specialty***
    - < 5% e-prescriptions
    - >40% require call back to physician

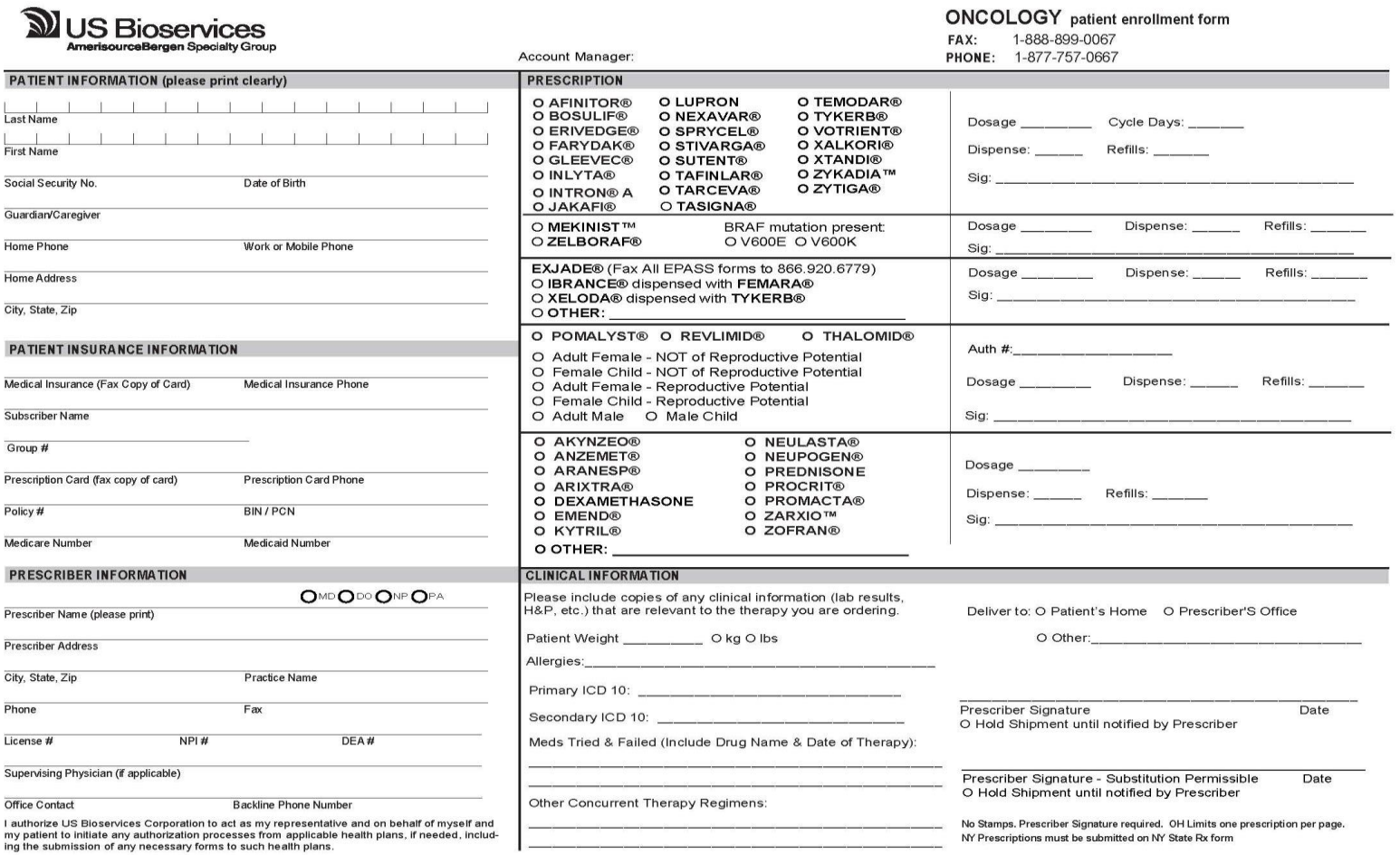
Source: ESI Network Pharmacy Weekly September 17, 2015

Points of entry for specialty prescriptions

- Prescriber
  - Fax, Portal, e-prescription
- Hub
  - Data Feeds
  - REMS requirements
- Other specialty pharmacies
  - LD requirements
- Retail pharmacies
  - Partnerships
- Health Systems
  - 340b

NCPDP

Referral Forms



US Bioservices
AmerisourceBergen Specialty Group

Account Manager:

ONCOLOGY patient enrollment form
FAX: 1-888-899-0067
PHONE: 1-877-757-0667

PATIENT INFORMATION (please print clearly)

Last Name
First Name
Social Security No. | Date of Birth
Guardian/Caregiver
Home Phone | Work or Mobile Phone
Home Address
City, State, Zip

PATIENT INSURANCE INFORMATION

Medical Insurance (Fax Copy of Card) | Medical Insurance Phone
Subscriber Name
Group #
Prescription Card (fax copy of card) | Prescription Card Phone
Policy # | BIN / PCN
Medicare Number | Medicaid Number

PRESCRIBER INFORMATION

O MD O DO O NP O PA
Prescriber Name (please print)
Prescriber Address
City, State, Zip | Practice Name
Phone | Fax
License # | NPI # | DEA #
Supervising Physician (if applicable)
Office Contact | Backline Phone Number

I authorize US Bioservices Corporation to act as my representative and on behalf of myself and my patient to initiate any authorization processes from applicable health plans, if needed, including the submission of any necessary forms to such health plans.

PRESCRIPTION

O AFINITOR® O BOSULIF® O ERIVEDGE® O FARYDAK® O GLEEVEC® O INLYTA® O INTRON® A O JAKAFI® O LUPRON O NEXAVAR® O SPRYCEL® O STIVARGA® O SUTENT® O TAFINLAR® O TARCEVA® O TASIGNA® O TEMODAR® O TYKERB® O VOTRIENT® O XALKORI® O XTANDI® O ZYKADIA™ O ZYTIGA®

Dosage _____ Cycle Days: _____
Dispense: _____ Refills: _____
Sig: _____

O MEKINIST™ O ZELBORAF® BRAF mutation present: O V600E O V600K

Dosage _____ Dispense: _____ Refills: _____
Sig: _____

EXJADE® (Fax All EPASS forms to 866.920.6779)
O IBRANCE® dispensed with FEMARA®
O XELODA® dispensed with TYKERB®
O OTHER: _____

Dosage _____ Dispense: _____ Refills: _____
Sig: _____

O POMALYST® O REVLIMID® O THALOMID®
O Adult Female - NOT of Reproductive Potential
O Female Child - NOT of Reproductive Potential
O Adult Female - Reproductive Potential
O Female Child - Reproductive Potential
O Adult Male O Male Child

Auth #: _____
Dosage _____ Dispense: _____ Refills: _____
Sig: _____

O AKYNZEO® O ANZEMET® O ARANESP® O ARIXTRA® O DEXAMETHASONE O EMEND® O KYTRIL® O NEULASTA® O NEUPOGEN® O PREDNISONE O PROCRIT® O PROMACTA® O ZARXIO™ O ZOFRAN®
O OTHER: _____

Dosage _____
Dispense: _____ Refills: _____
Sig: _____

CLINICAL INFORMATION

Please include copies of any clinical information (lab results, H&P, etc.) that are relevant to the therapy you are ordering.

Patient Weight _____ O kg O lbs
Allergies: _____
Primary ICD 10: _____
Secondary ICD 10: _____
Meds Tried & Failed (Include Drug Name & Date of Therapy):
_____
_____
Other Concurrent Therapy Regimens:
_____
_____

Deliver to: O Patient's Home O Prescriber'S Office
O Other: _____

_____
Prescriber Signature Date
O Hold Shipment until notified by Prescriber

_____
Prescriber Signature - Substitution Permissible Date
O Hold Shipment until notified by Prescriber

No Stamps. Prescriber Signature required. OH Limits one prescription per page.
NY Prescriptions must be submitted on NY State Rx form

NCPDP™

Referral Forms

Pathpoint HCV
a US Bioservices program

FAX: 1-888-418-7246
PHONE: 1-866-223-7914

Account Manager:

US Bioservices
AmerisourceBergen Specialty Group

PATIENT INFORMATION (please print clearly)

Last Name

First Name

Social Security No. | Date of Birth

Guardian/Caregiver

Home Phone | Work or Mobile Phone

Home Address

City, State, Zip

PATIENT INSURANCE INFORMATION

Medical Insurance (Fax Copy of Card) | Medical Insurance Phone

Subscriber Name

Policy # | Group #

Prescription Card (fax copy of card) | Prescription Card Phone

Policy # | BIN / PCN

Medicare Number | Medicaid Number

PRESCRIBER INFORMATION

O MD O DO O NP O PA

Prescriber Name (please print)

Prescriber Address

City, State, Zip | Practice Name

Phone | Fax

License # | NPI # | DEA #

Supervising Physician (if applicable)

Office Contact | Backline Phone Number

I authorize US Bioservices Corporation to act as my representative and on behalf of myself and my patient to initiate any authorization processes from applicable health plans, if needed, includ-ing the submission of any necessary forms to such health plans.

PRESCRIPTION

Direct Acting Antiviral Agents

- O **HARVONI (ledipasvir 90mg/sofosbuvir 400mg) Tab** — 28 days supply ____ refills
  OTake one tab PO once daily with/without food. o Other: _____
- O **VIEKIRA PAK (ombitasvir 12.5 mg / paritaprevir 75 mg/ ritonavir 50 mg, dasabuvir 250mg)** — 28 days supply ____ refills
  o Take two ombitasvir, paritaprevir, ritonavir tabs (pink) PO once daily (in the morning) and one dabsabuvir tab (beige) twice daily (morning and evening). Take Viekira Pak with a meal.
  o Other: _____
- O **SOVALDI (sofosbuvir) 400mg Tab** o Take one 400mg tab PO once daily with/without food. 28 days supply ____ refills
  o Other: _____
- O **OLYSIO (simeprevir) 150mg Cap** Take one capsule PO once daily with food. 28 days supply ____refills
  Screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline is strongly recommended. Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.
- O **DAKLINZA (daclatasvir) o 30 mg o 60mg Tab with SOVALDI** — 28 days supply ____ refills
  OTake one tab PO once daily with/without food.
  Decrease dose to 30mg daily when given with strong CYP3A inhibitors; increase to 90mg daily when given with moderate CYP3A inducers.
- O **TECHNIVIE (ombitasvir 12.5mg, paritaprevir 75mg, ritonavir 50mg) with RIBAVIRIN** — 28 days supply ____ refills
  OTake two tablets PO once daily in the morning with a meal.

Ribavirin

- O **RIBAPAK (ribavirin)** O **MODERIBA (ribavirin, USP) Dose Pack** — 28 days supply ____ refills
  o 200mg am/400mg pm (600mg/day - 56 Tab/pak) o 600mg am/400mg pm (1000mg/day - 56 Tab/pak)
  o 400mg am/400mg pm (800mg/day - 56 Tab/pak) o 600mg am/600mg pm (1200mg/day - 56 Tab/pak)
  o Add RIBASPHERE (ribavirin) 200mg o Tab o Cap _____mg PO once daily for a total dose of _____mg/day
  o Add MODERIBA (ribavirin, USP) 200mg Tab _____mg PO once daily for a total dose of _____mg/day
  o Other: _____
- O **RIBASPHERE (ribavirin) 200mg** o Tab o Cap O **MODERIBA (ribavirin) 200mg Tab** — 28 days supply ____ refills
  o Take _____mg PO AM and _____mg PM o Other: _____

- O **Other**: _____ — 28 days supply ____refills
  Sig: _____

REQUIRED CLINICAL INFORMATION

Total duration of therapy: _____**Weeks**
Patient Weight: _____ **O kg O lbs Date:**_____
Allergies: _____
Primary ICD-10 Code:_____
Secondary ICD-10 Code:_____

Fibroscan Score: _____ **Fibrosure Score:** _____
Biopsy Score: _____ **O Metavir O Knodell O Ishak**
Genotype (include subtype): _____
O Compensated Liver Disease O Cirrhosis
Co-infected: O HIV O HBV O Transplant Patient

PREVIOUS TREATMENT HISTORY AND DELIVERY

O Naive to treatment O Non-responder O Null responder
O Partial responder O Relapser
Meds Tried and Failed _____Date(s):_____
_____ Date(s):_____
Deliver to: O Patient's Home O Prescriber Office
O Other:_____
O Hold Shipment until notified by prescriber

LABWORK* and NURSING

HCV RNA: _____ Date:_____ PLT:_____
ALT:____ AST:____Date:_____ Hgb:_____
NS Q80K Polymorphism: _____ Other:_____
*please include a hard copy of all labwork
O Patient opts out of telephonic nurse counseling

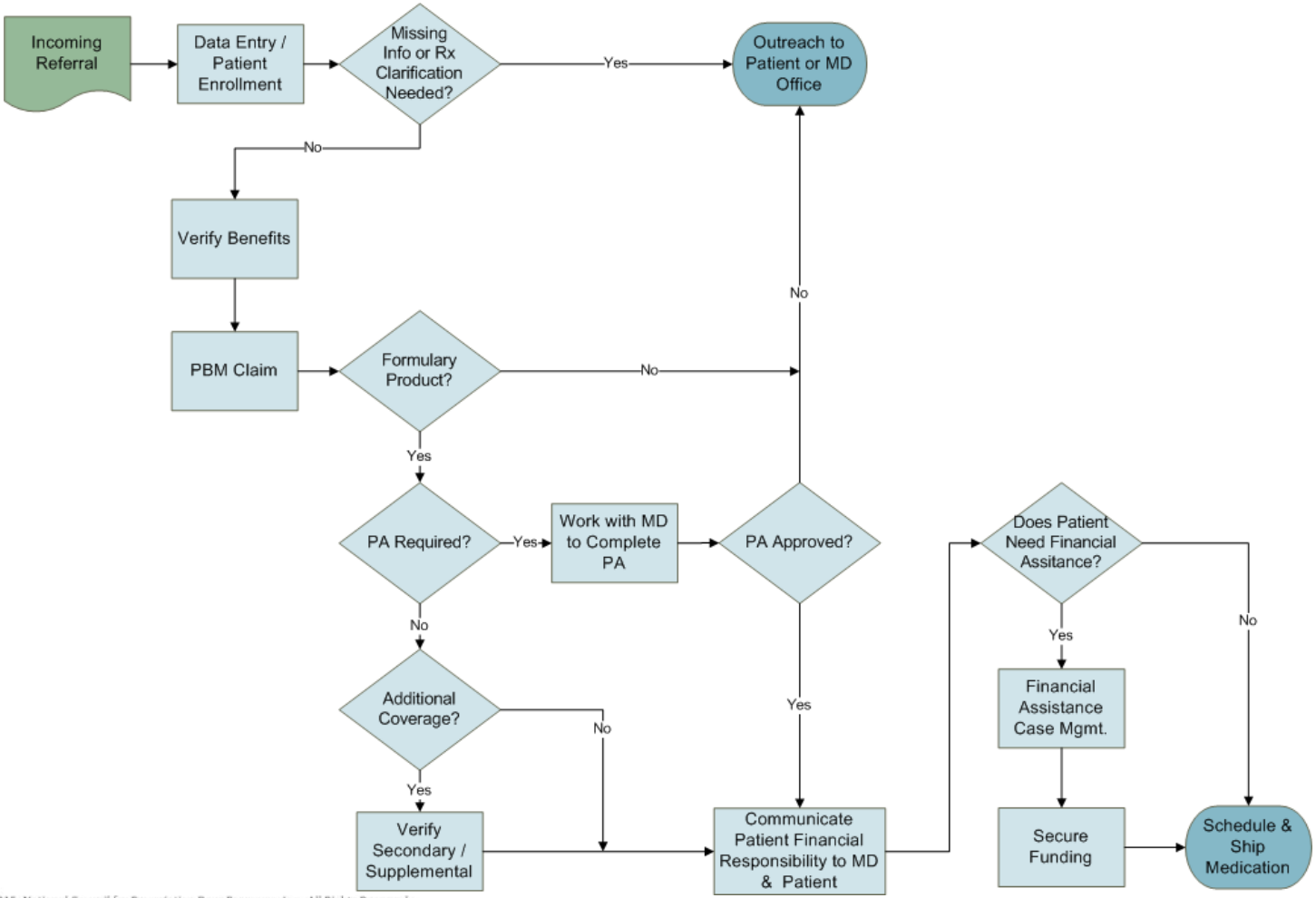
PRESCRIBER SIGNATURE

_____ _____
Prescriber Signature - Dispense as Written Date | **Prescriber Signature-Substitution Permissible Date**

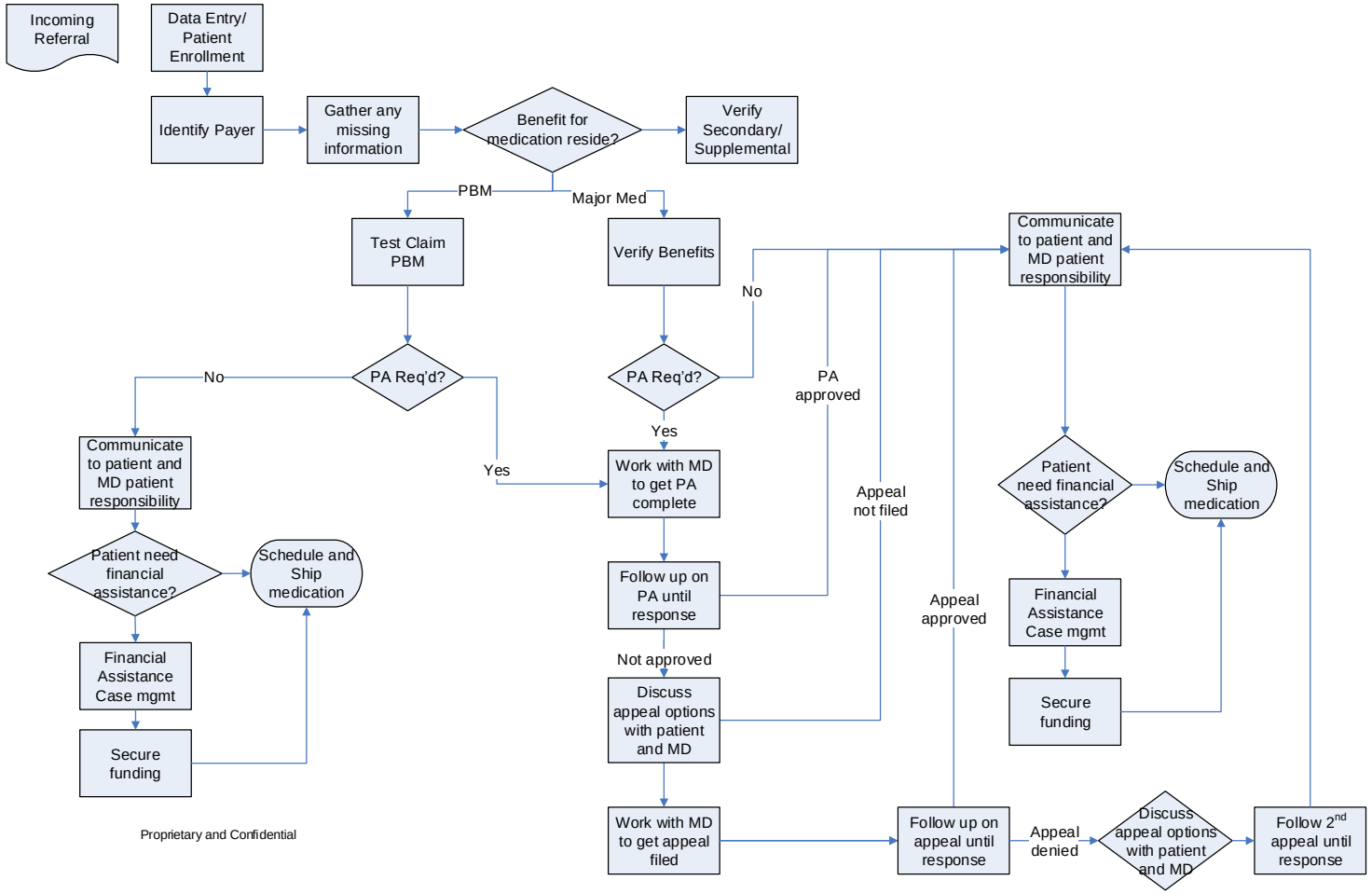
No Stamps. Signature and date must be completed by Prescriber. NY Prescriptions must be submitted on NY State Rx form. OH Limits one prescription per page.

NCPDP

Specialty Pharmacy Process Flow



Prior Authorization Process



Hub Services

- Receive referrals for specific manufacturer programs
- Educate offices on program offering
- Services include:
  - Eligibility Request
  - Product Benefit Verification
  - Prior Authorization Support
  - Copay Support
  - SP Triage
  - Nurse Support
  - Ongoing program communication
  - Data transfer from SP and to program sponsor

NCPDP

US Bioservices Case Study

Friday, September 25th

- Received eRx for abiraterone acetate and prednisone from MD
- Prednisone Rx written for #30 1 BID; sent to exception que for follow up with MD
- Ran test claim for abiraterone acetate and determined PA needed
- Contacted patient to notify a PA was needed
- Contacted insurance company to request that PA forms be faxed to MD
- MD office closed; faxed office to notify that insurance company would be faxing PA forms

Monday, September 28th

- Left voice mail with MD to clarify quantity on prednisone Rx

Tuesday, September 29th

- MD office sent new eRx for prednisone #60 1BID
- Called insurance company and confirmed PA was approved
- Adjudicated claims and sent to fulfillment

Wednesday, September 30th

- Contacted patient and scheduled delivery for Friday, October 2nd.

E-Rx challenges in specialty

- Multiple, evolving prescription data elements needed based on new treatments
- e-PA needs to occur in conjunction with eRx
- Prescriber education, training and office resources
- Limited distribution networks
- Unique REMS requirements

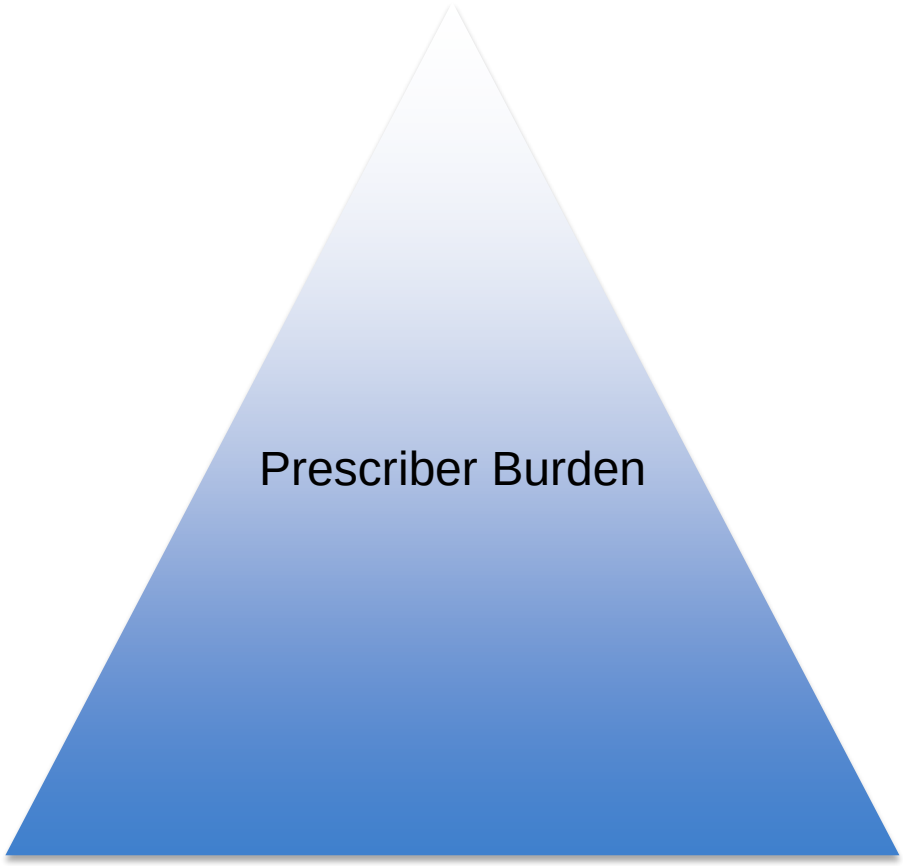
E-Rx advantages in specialty

- More efficient work flow
- Reduced overhead
- Improve quality
- Less prescriber outreach
- Speed to therapy

Addressing Prescriber Needs

NCPDP™

New Prescriber Workflow



ERX

ePA

Financial Assistance

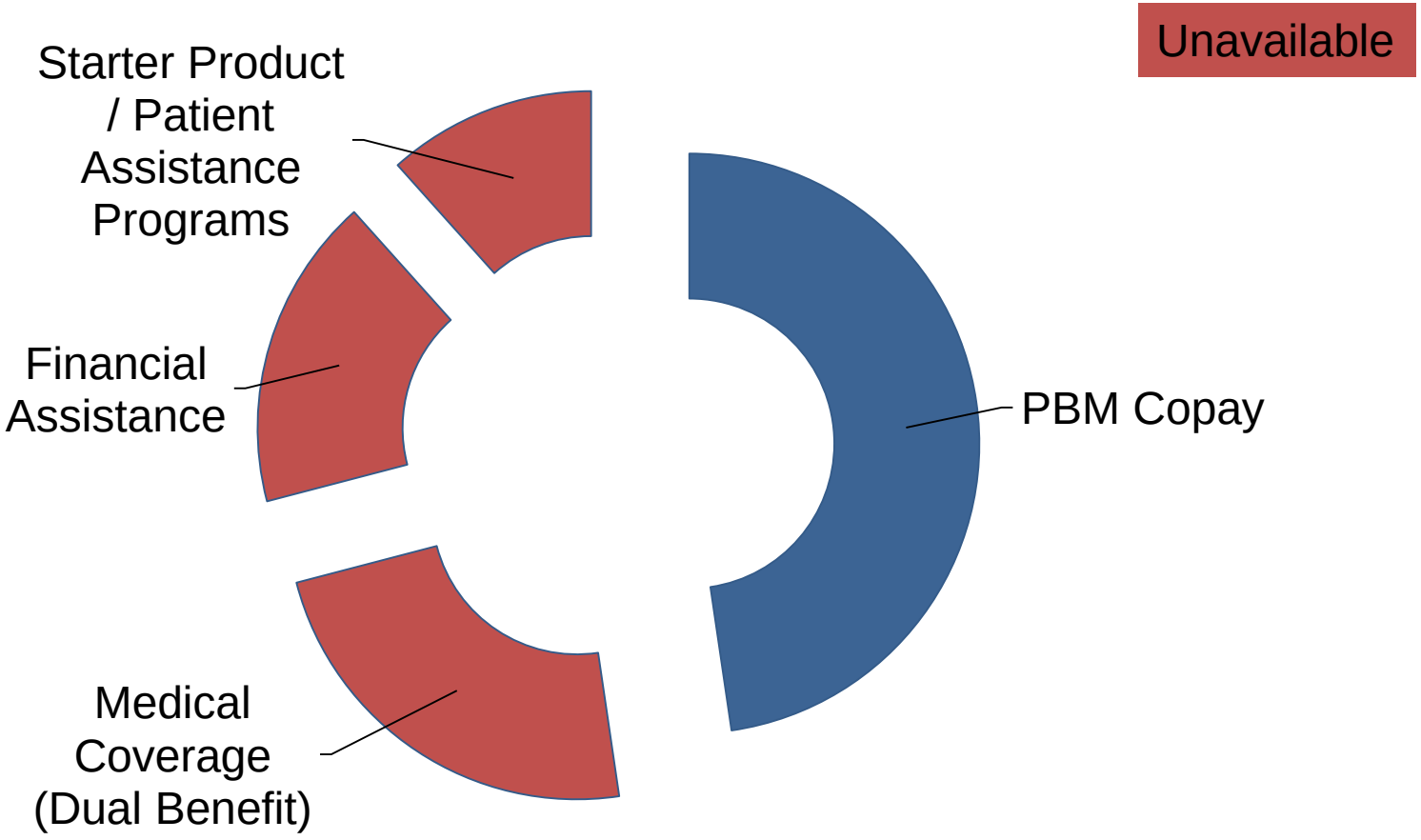
Nurse Training

Starter Product / Kits

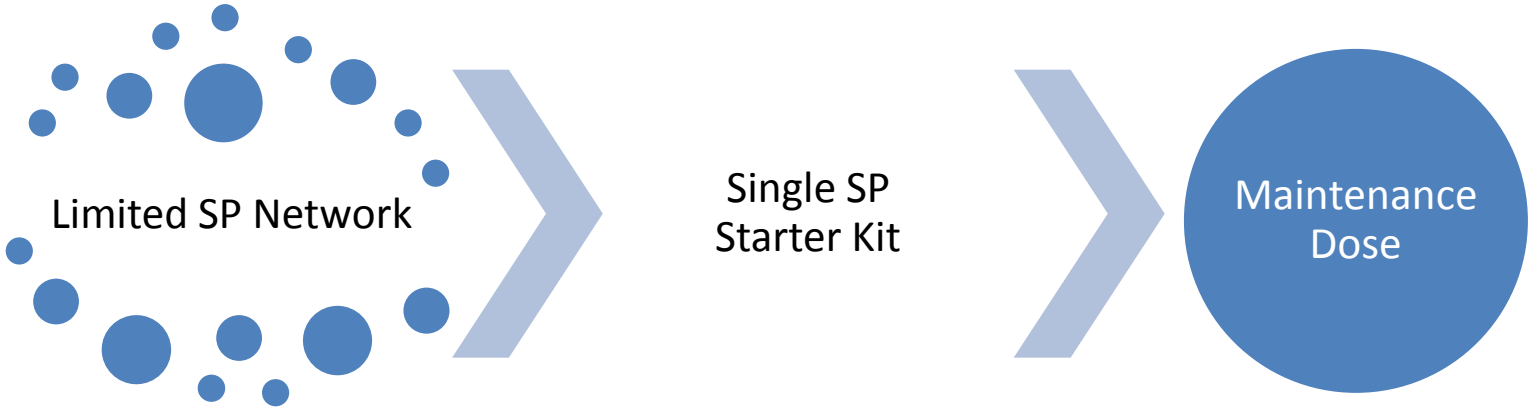
REMS / Assessments

NCPDP

Gaps in PBM Benefit



Distribution Model



- Injection Center
- REMS
- Assessments

NCPDP Efforts

NCPDP™

NCPDP Standard for Electronic Prior Authorization (ePA) Transactions

Officially approved in July 2013 as a major advancement for e-prescribing

Physician/EHR

Reducing administrative burden

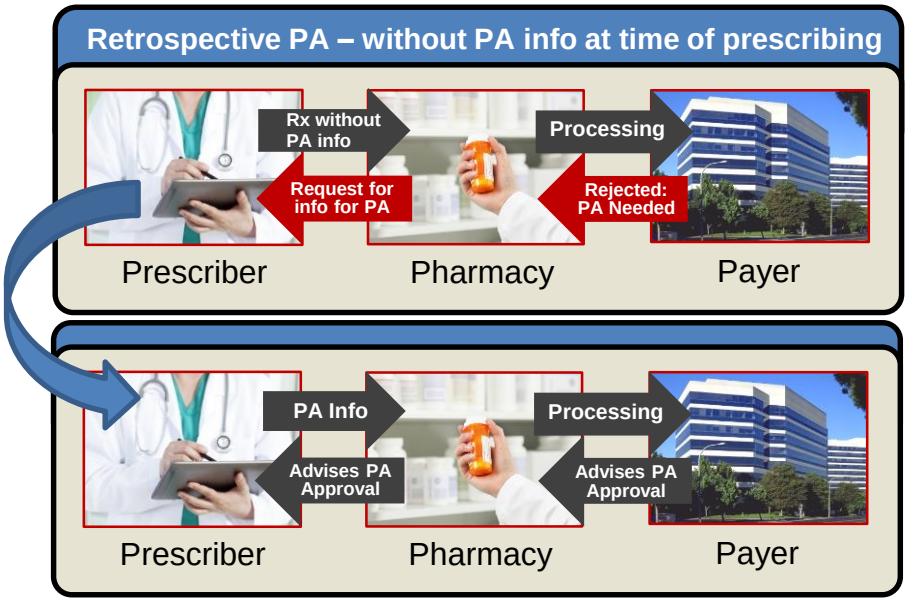
PBM/Payers

Increasing workflow efficiency

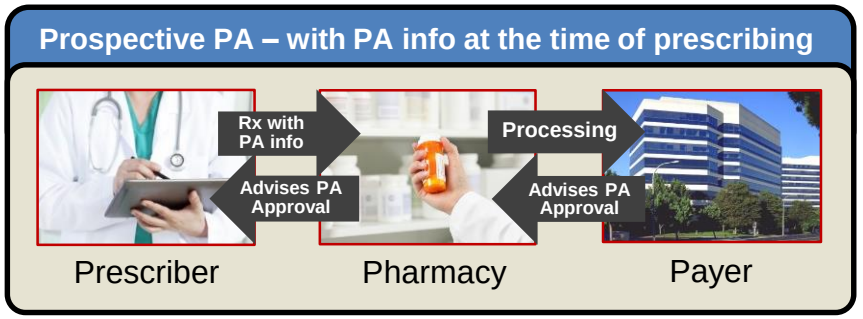
New Standard Enables Multiple Workflows

Retrospective vs. Prospective

Two-Step Process



Single-Step Process



NCPDP

Electronic Prior Authorization Milestones

When the Federal government imposed ePA on the marketplace, adoption was minimal. Then the industry decided what it wanted to implement, and progress began to be made.

1996 — HIPAA
- X12 278 named prior authorization standard
- Telecom Standard named for retail pharmacy

2004 — Multi-SDO ePA Task Group Formed
- Promotes standardized automated PA using X12 278, HL7 PA Attachment and NCPDP Formulary & Benefit

2006 — MMA ePrescribing Pilots
- Determined that the X12 278 + HL7 PA Attachment was suboptimal for ePA

2006 — CMS/AHRQ Pushes Forward
- Resolution of where standard should reside
- Value model created

2009 — NCPDP Facilitates Creation of New Transactions
- Based on NCPDP SCRIPT standard

2010 — Renewed Interest
- Pilots conceived
- State legislative interest begins
- CMS's OESS apprised

2012 — NCPDP Revises Transactions
- Pilot results incorporated into revised standard
- Ballot
- Educational Sessions
- CMS's OESS Apprised

2013 — NCPDP SCRIPT 2013 Published
- Education Sessions
- Implementations Begin

2014 — Implementation
- With intermediaries leading the way, stakeholders start implementation

NCPDP™

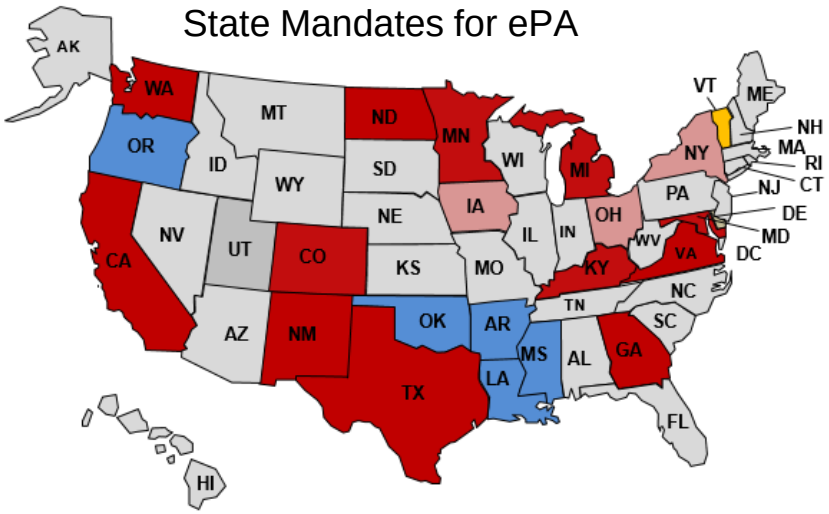
ePA Being Implemented Nationally

ePA standard currently being implemented nationally

- Task Group DERFs all about clarifying standard and adding new, unanticipated data elements
- Payers/PBMs required to be able to support ePA or a universal PA form in 14 states by July 2015
- Turn-around times for forms return improving
- Retrospective is most used means of ePA, though adoption is sub-optimal
- Adoption of prospective dependent on PA flag in formulary or RTBI and is consequently sub-optimal

For ePA to reach wide adoption, HCPs need integration within the EHR workflow, and auto-completion of ePA request with existing EHR data

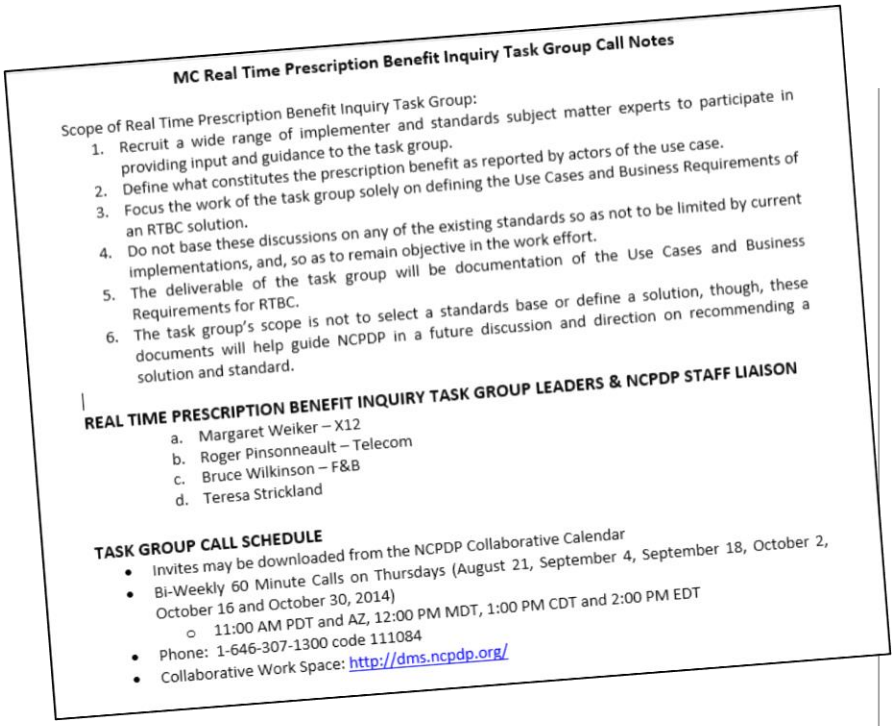
State Mandates for ePA



- Require support some type of ePA submission, some states pending deadlines
- Require electronically available PA forms
- Law mandates electronic transaction, not being enforced
- Legislation proposed or rules in development

Map SOURCE: Point-of-Care Partners, www.pocp.com, Revised 7/15/2015
Copyright © 2015 Point-of-Care Partners

Benefits Verification



MC Real Time Prescription Benefit Inquiry Task Group Call Notes

Scope of Real Time Prescription Benefit Inquiry Task Group:

1. Recruit a wide range of implementer and standards subject matter experts to participate in providing input and guidance to the task group.
2. Define what constitutes the prescription benefit as reported by actors of the use case.
3. Focus the work of the task group solely on defining the Use Cases and Business Requirements of an RTBC solution.
4. Do not base these discussions on any of the existing standards so as not to be limited by current implementations, and, so as to remain objective in the work effort.
5. The deliverable of the task group will be documentation of the Use Cases and Business Requirements for RTBC.
6. The task group's scope is not to select a standards base or define a solution, though, these documents will help guide NCPDP in a future discussion and direction on recommending a solution and standard.

REAL TIME PRESCRIPTION BENEFIT INQUIRY TASK GROUP LEADERS & NCPDP STAFF LIAISON

a. Margaret Weiker – X12
b. Roger Pinsonneault – Telecom
c. Bruce Wilkinson – F&B
d. Teresa Strickland

TASK GROUP CALL SCHEDULE

- Invites may be downloaded from the NCPDP Collaborative Calendar
- Bi-Weekly 60 Minute Calls on Thursdays (August 21, September 4, September 18, October 2, October 16 and October 30, 2014)
  - 11:00 AM PDT and AZ, 12:00 PM MDT, 1:00 PM CDT and 2:00 PM EDT
- Phone: 1-646-307-1300 code 111084
- Collaborative Work Space: http://dms.ncpdp.org/

- 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

Real Time Benefit Inquiry Milestones

The ONC Notice of Proposed Rule Making (NPRM) released in Feb 2014 was the catalyst for NCPDP efforts around RTBI

Feb 2014

ONC NPRM

- ONC Solicits comments on NCPDP Telecom and Formulary and Benefit Standard to support expanded use cases such as real-time benefit checks

June 2014

NCPDP Task Group Created

- NCPDP Task Group created under maintenance and control workgroup

Sept 2014

HITSC Meeting

- NCPDP presents at Health IT Standards Committee meeting.
- Requests for additional demonstration projects are made

Apr 2015

NCPDP Use Case Development

- NCPDP Task Group focused on development of 4 use cases to present at November Workgroup Meeting

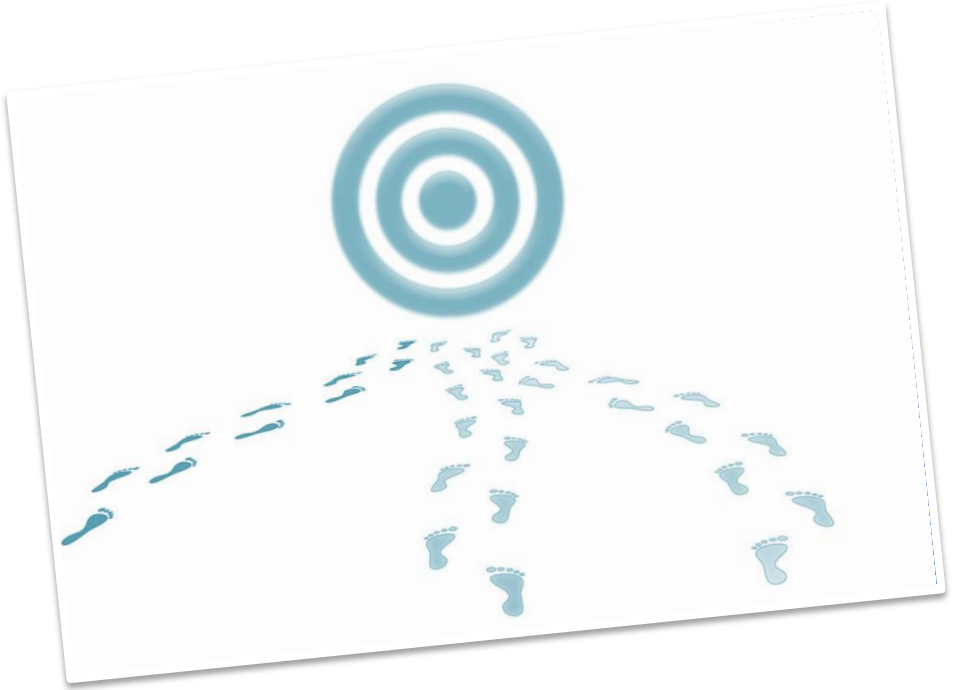
Sept 2015

NCPDP Consensus Building

- Task Group holding bi-weekly calls to solicit input from all stakeholders on use cases

NCPDP

Real Time Benefit Inquiry Today



One Target, but currently **many paths…**

- NCPDP workgroup efforts
  - Use Case Development
- Industry Stakeholder Pilots
  - Modification of D.0 Telecommunications standard
  - Modification of SCRIPT standard
  - Proprietary connection
- ONC and CMS requests for pilots

Risk Evaluation and Mitigation Strategy (REMS)

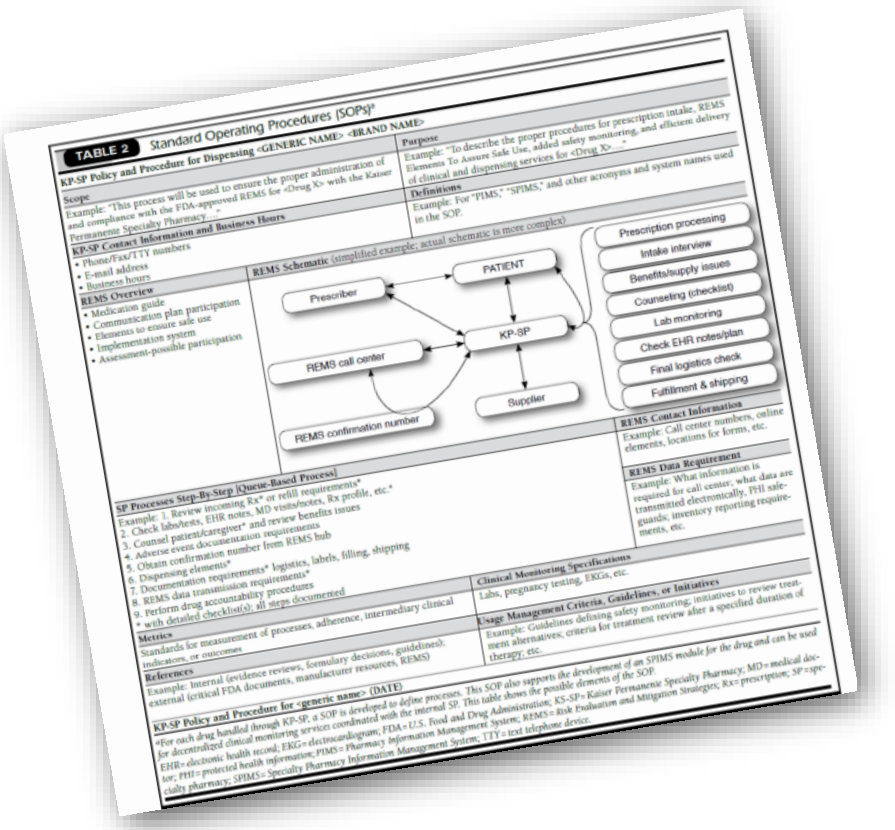


TABLE 2 Standard Operating Procedures (SOPs)[a]

KP-SP Policy and Procedure for Dispensing <GENERIC NAME> <BRAND NAME>

Scope
Example: "This process will be used to ensure the proper administration of and compliance with the FDA-approved REMS for <Drug X> with the Kaiser Permanente Specialty Pharmacy ..."

Purpose
Example: "To describe the proper procedures for prescription intake, REMS Elements To Assure Safe Use, added safety monitoring, and efficient delivery of clinical and dispensing services for <Drug X> ..."

KP-SP Contact Information and Business Hours
• Phone/Fax/TTY numbers
• E-mail address
• Business hours

Definitions
Example: For "PIMS," "SPIMS," and other acronyms and system names used in the SOP.

REMS Overview
• Medication guide
• Communication plan participation
• Elements to ensure safe use
• Implementation system
• Assessment-possible participation

REMS Schematic (simplified example; actual schematic is more complex)

SP Processes Step-By-Step [Queue-Based Process]
Example: 1. Review incoming Rx* or refill requirements*
2. Check labs/tests, EHR notes, MD visits/notes, Rx profile, etc.*
3. Counsel patient/caregiver* and review benefits issues
4. Adverse events documentation requirements
5. Obtain confirmation number from REMS hub
6. Dispensing elements*
7. Documentation requirements*
8. REMS data transmission requirements*
9. Perform drug accountability procedures
* with detailed checklist(s); all steps documented

REMS Contact Information
Example: Call center numbers, online elements, locations for forms, etc.

REMS Data Requirement
Example: What information is required for call center; what data are transmitted electronically, PHI safeguards; inventory reporting requirements, etc.

Metrics
Standards for measurement of processes, adherence, intermediary clinical indicators, or outcomes

Clinical Monitoring Specifications
Labs, pregnancy testing, EKGs, etc.

References
Example: Internal (evidence reviews, formulary decisions, guidelines); external (critical FDA documents, manufacturer resources, REMS)

Usage Management Criteria, Guidelines, or Initiatives
Example: Guidelines defining safety monitoring, initiatives to review treatment alternatives; criteria for treatment review after a specified duration of therapy, etc.

KP-SP Policy and Procedure for <generic name> (DATE)

[a]For each drug handled through KP-SP, a SOP is developed to define processes. This SOP also supports the development of an SPIMS module for the drug and can be used for decentralized clinical monitoring services coordinated with the internal SP. This table shows the possible elements of the SOP.
EHR= electronic health record; EKG= electrocardiogram; FDA= U.S. Food and Drug Administration; KS-SP= Kaiser Permanente Specialty Pharmacy; MD= medical doctor; PHI= protected health information; PIMS= Pharmacy Information Management System; REMS= Risk Evaluation and Mitigation Strategies; Rx= prescription; SP=specialty pharmacy; SPIMS= Specialty Pharmacy Information Management System; TTY= text telephone device.

- REMS are **required plans** that use **risk minimization strategies** to ensure that the benefits of certain prescriptions drugs outweigh the risks
  - As of May 2015, there are 73 individual product REMS; 6 shared system REMS
- **Structured REMS data** can be used to provide additional information and "triggers" for pharmacies, health system and EHRs who wish to integrate REMS into their processes

REMS Timeline

The Food and Drug Administration Amendments Act (FDAAA) of 2007 granted authority to enforce REMS

Sept 2007

Food and Drug Administration Amendments Act

- FDAAA passed which granted FDA authority to enforce REMS through Manufacturers

Nov 2010

NCPDP REMS Guide Released

- NCPDP REMS Reference Guide released to encourage transaction-based REMS solution

May 2011

FDA and NCPDP Task Groups Created

- FDA creates REMS Integration Initiative to focus on REMS standardization and assessment
- NCPDP creates REMS related Task Groups under WG1, WG2 and WG11

Nov 2013

REMS Transaction approved by NCPDP

- NCPDP approves “in workflow” REMS solution for pharmacies using Telecommunications Std. D.0

Sept 2014

FDA Federal Register Notice Released

- FDA agrees to measure the effectiveness of REMS and to continue to develop techniques to standardize REMS

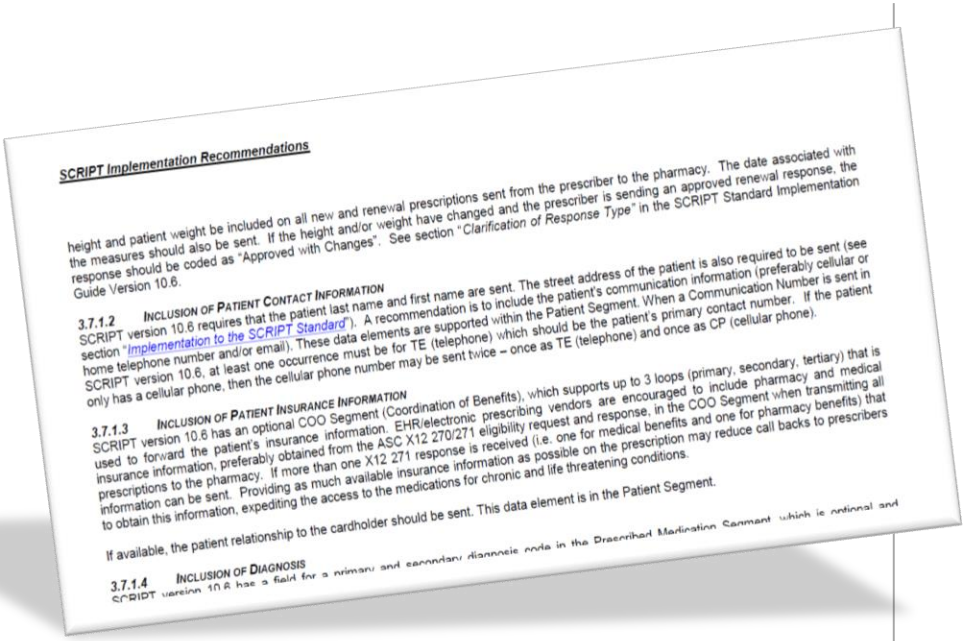
Oct 2015

Proposed SCRIPT modifications for REMS transactions

- NCPDP presentation to FDA for standard REMS transactions for SCRIPT standard

NCPDP

Specialty ePrescribing



SCRIPT Implementation Recommendations

height and patient weight be included on all new and renewal prescriptions sent from the prescriber to the pharmacy. The date associated with the measures should also be sent. If the height and/or weight have changed and the prescriber is sending an approved renewal response, the response should be coded as "Approved with Changes". See section "*Clarification of Response Type*" in the SCRIPT Standard Implementation Guide Version 10.6.

3.7.1.2 INCLUSION OF PATIENT CONTACT INFORMATION

SCRIPT version 10.6 requires that the patient last name and first name are sent. The street address of the patient is also required to be sent (see section "*Implementation to the SCRIPT Standard*"). A recommendation is to include the patient's communication information (preferably cellular or home telephone number and/or email). These data elements are supported within the Patient Segment. When a Communication Number is sent in SCRIPT version 10.6, at least one occurrence must be for TE (telephone) which should be the patient's primary contact number. If the patient only has a cellular phone, then the cellular phone number may be sent twice – once as TE (telephone) and once as CP (cellular phone).

3.7.1.3 INCLUSION OF PATIENT INSURANCE INFORMATION

SCRIPT version 10.6 has an optional COO Segment (Coordination of Benefits), which supports up to 3 loops (primary, secondary, tertiary) that is used to forward the patient's insurance information. EHR/electronic prescribing vendors are encouraged to include pharmacy and medical insurance information, preferably obtained from the ASC X12 270/271 eligibility request and response, in the COO Segment when transmitting all prescriptions to the pharmacy. If more than one X12 271 response is received (i.e. one for medical benefits and one for pharmacy benefits) that information can be sent. Providing as much available insurance information as possible on the prescription may reduce call backs to prescribers to obtain this information, expediting the access to the medications for chronic and life threatening conditions.

If available, the patient relationship to the cardholder should be sent. This data element is in the Patient Segment.

3.7.1.4 INCLUSION OF DIAGNOSIS

SCRIPT version 10.6 has a field for a primary and secondary diagnosis code in the Prescribed Medication Segment, which is optional and

- Task Group formed during Fall 2013 Workgroup Meeting
- Co-lead by Laura Topor and Tony Schueth
- Initial goal was to include data elements needed by specialty pharmacy in the original prescription
- Also working on wound care
- Recently formed sub-task group on compounding

NCPDP SCRIPT: Data Elements to Support Specialty ePrescribing

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 PA request** to facilitate the billing and delivery of the specialty medication.

NCPDP

Post-Test

NCPDP™

Post-Test Question #1

1. Which of the following is not currently a challenge with e-prescribing for specialty medications?
    a) Prescriber education, training and office resources
    b) Limited Distribution networks
    c) EMR's are not capable of sending e-prescriptions for specialty drugs
    d) Unique REMS requirements

NCPDP

Post-Test Answer #1

1. Which of the following is not currently a challenge with e-prescribing for specialty medications?
    a) Prescriber education, training and office resources
    b) Limited Distribution networks
    c) EMR's are not capable of sending e-prescriptions for specialty drugs
    d) Unique REMS requirements

NCPDP

Post-Test Question #2

2. Advantages to e-prescriptions in specialty pharmacy include all of the following except:
    a) More efficient workflow
    b) Reduced overhead
    c) Improved quality
    d) Eliminates the need for Prior Authorizations

NCPDP

Post-Test Answer #2

2. Advantages to e-prescriptions in specialty pharmacy include all of the following except:
    a) More efficient workflow
    b) Reduced overhead
    c) Improved quality
    d) Eliminates the need for Prior Authorizations

NCPDP

Post-Test Question #3

3. True or False: It is common for prescribers to send prescriptions for specialty medications to Hubs.
    a) True
    b) False

Post-Test Answer #3

3. True or False: It is common for prescribers to send prescriptions for specialty medications to Hubs.
   a) True
   b) False

Post-Test Question #4

4. Which of the following are currently provided in the PBM Benefit for specialty medications?
    a) Starter product/patient assistance programs
    b) Financial assistance
    c) Medical coverage (dual benefit)
    d) PBM copay

NCPDP

Post-Test Answer #4

4. Which of the following are currently provided in the PBM Benefit for specialty medications?
    a) Starter product/patient assistance programs
    b) Financial assistance
    c) Medical coverage (dual benefit)
    d) PBM copay

NCPDP

Post-Test Question #5

5. Which of the following NCPDP SCRIPT data elements support specialty ePrescribing?
    a) Diagnosis
    b) Patient contact information
    c) Insurance policy number
    d) Status of a PA request
    e) All of the above

NCPDP

Post-Test Answer #5

5. Which of the following NCPDP SCRIPT data elements support specialty ePrescribing?
    a) Diagnosis
    b) Patient contact information
    c) Insurance policy number
    d) Status of a PA request
    e) All of the above

NCPDP

Questions?

Kevin James, R.Ph., MBA
VP, Payer Strategy| US Bioservices
Kevin.James@usbioservices.com

Jeff Spafford
President and CEO | AssistRx
Jeff.Spafford@Assistrx.com

Tony Schueth, M.S.
CEO & Managing Partner | Point-of-Care Partners
tonys@pocp.com