The CARIN Alliance

Real-Time Pharmacy Benefit Check Work Group Kick-Off Meeting
Antitrust Statement

Please remember that this meeting may include representative of companies that compete with one another in the marketplace. Discussions, plans, consensus, arrangements, agreements, strategies, etc., may be unlawful if they relate to any of the following topics:

- Current or future prices or bidding information
- Limits on production of product lines
- Allocating customers and territories
- Individual company marketing strategies, projections, and assessments
- Establishing a practice of dealing with customers or suppliers
# Agenda

<table>
<thead>
<tr>
<th>Welcome, Introductions, and Anti-trust Reminder</th>
<th>9:30am – 9:40am</th>
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<tbody>
<tr>
<td>Ryan Howells, Leavitt Partners</td>
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<thead>
<tr>
<th>Leadership Perspective</th>
<th>9:40am – 9:45am</th>
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<tr>
<td>Aneesh Chopra, CareJourney</td>
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<tr>
<th>CARIN’s Objectives and the goal of consumer-directed exchange</th>
<th>9:45am – 9:55am</th>
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<td>Ryan Howells, Leavitt Partners</td>
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<tr>
<th>Legislative and Regulatory Landscape and Opportunities</th>
<th>9:55am – 10:05am</th>
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<tr>
<td>Dave Lee and Anne-Marie Polak, Leavitt Partners</td>
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<tr>
<th>What is Real-Time Pharmacy Benefit Check and how is it being used today?</th>
<th>10:05am – 10:45am</th>
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<td>Tony Scheuth, Point of Care Partners</td>
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<th>BREAK</th>
<th>10:45am – 11:00am</th>
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<tr>
<th>What are the opportunities to develop a RTPBC for consumers?</th>
<th>11:00am – 12:15pm</th>
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<td>Group Discussion</td>
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<th>Next Steps</th>
<th>12:15pm – 12:30pm</th>
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<td>Ryan Howells and Anne Marie-Polak, Leavitt Partners</td>
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| Adjourn                                                      | 12:30pm           |
CARIN’s Objectives and the Goal of CDEx

RYAN HOWELLS
What is Consumer-Directed Exchange?

HIPAA

Covered Entity

Consumer API

Covered Entity

FTC

“Must” Share vs. “May” Share

No Legal Agreements Needed

A consumer can share their data with anyone
January 4th, 2018
Penick Medical Center

- **Allergies**
  - Recorded

- **Peanut Allergy**
  - Recorded

- **Medications**
  - Albuterol HFA 90mcg
    - Ordered

- **Immunizations**
  - Influenza
    - Recorded

- **Lab Results**
  - HDL cholesterol
    - Recorded
    - 53.5 mg/dL
Our Vision

Creating Access to Real-time Information Now through Consumer-Directed Exchange

www.carinalliance.com
@carinalliance

Consumer-focused FHIR Implementation Guides

Clinical Data
(Argonaut CCDA, Notes)

Payment Data
(CARIN CPCDS)

Pharmacy Data
(CARIN RTPBC)

LTC Assessments
(CARIN TBD)

Trust Framework
(Policy, Technology and Governance)

ID and Authentication
(OAuth, OIDC, FIDO)

Outside CARIN’s Scope

In Flight Projects

Proposed

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Legislative and Regulatory Landscape
DAVE LEE AND ANNE-MARIE POLAK
Current Methods of Exchange

- EHR
- Payer Tools
- Pharmacy
Public Policy Interests

Drug Pricing
- Transparency
- Therapeutic Equivalence
- Formulary Placement
- Rebates

Consumer Engagement in Health Care
- HSAs
- DTC Advertising

Insurance Practices
- Surprise Billing
- Step Therapy
- Prior Authorization
What is RTPBC and how is it being used today?

TONY SCHUETH, POINT OF CARE PARTNERS
The merger of RxHub and Surescripts was a major catalyst in connecting patient identities with a specific formulary. NCPDP developed a standard format in which PBMS/payers should send formulary data to EHRs. Government regulations helped to push along mandatory use of electronic formulary data by physician practices. ONC NPRM released in Feb 2014 was the catalyst for NCPDP efforts around RTBI and subsequent demonstration projects.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>RxHub/Surescripts Merger*</td>
<td>July 2008</td>
</tr>
<tr>
<td>Merger of RxHub and Surescripts Announced</td>
<td>Jan 2009</td>
</tr>
<tr>
<td>NCPDP F&amp;B V 1.0</td>
<td>April 2009</td>
</tr>
<tr>
<td>NCPDP Formulary and Benefit v1.0 adopted</td>
<td>August 2012</td>
</tr>
<tr>
<td>CMS MU Stage 2 Final Rule</td>
<td>Feb 2014</td>
</tr>
<tr>
<td>Requires at least 50% of all permissible prescriptions are queried for drug formulary</td>
<td>March 2015</td>
</tr>
<tr>
<td>NCPDP F&amp;B V 3.0</td>
<td>April 2015- March 2018</td>
</tr>
<tr>
<td>NCPDP Formulary and Benefit v3.0 adopted</td>
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Timeline:
- **RxHub/Surescripts Merger**: July 2008
- **NCPDP F&B V 1.0**: April 2009
- **CMS MU Stage 2 Final Rule**: Aug 2012
- **NCPDP F&B V 3.0**: Mar 2015
- **RTBC Standards Development & Pilots**: Apr 2015 - Mar 2018

**Notes:**
1. The merger of RxHub and Surescripts was a major catalyst in connecting patient identities with a specific formulary.
2. NCPDP developed a standard format in which PBMS/payers should send formulary data to EHRs.
3. Government regulations helped to push along mandatory use of electronic formulary data by physician practices.
4. ONC NPRM released in Feb 2014 was the catalyst for NCPDP efforts around RTBI and subsequent demonstration projects.
Addresses Deficiencies in Current Formulary & Benefits

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

- Formulary data is based on “Plan-” or “Group”-level; not patient specific
- Prior Authorization flag often missing or inaccurate
- Formulary tier/preferred level often not accurately displayed for HCP
- Issue is payer providing the data, not the standard

Eligibility Request
- First Name
- Last Name
- Gender

Eligibility Response
- Formulary List ID
- Coverage List ID
- Co-pay List ID
- Alternatives List ID

Formulary & Benefit Data Plan Membership
RTPBC Provides Patient Specific Benefit Information

Real-Time Pharmacy Benefit Check (RTPBC) provides patient specific benefit information, improving transparency and ensuring accurate display of tier/preferred information to health care professionals (HCPs)

<table>
<thead>
<tr>
<th>Formulary status</th>
<th>Tier or Preferred Level</th>
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<tr>
<td>Coverage alerts</td>
<td>Age &amp; Quantity Limits, Prior Authorization (PA), Step Therapy</td>
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<tr>
<td>Channel options</td>
<td>Retail, Mail Order, Specialty</td>
</tr>
<tr>
<td>Member Price</td>
<td>Member Copay and Cost Sharing Details</td>
</tr>
<tr>
<td>Alternative drugs</td>
<td>Preferred Formulary/ Lower Cost Options</td>
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Real-Time Pharmacy Benefit Check (RTPBC) – Why, How, When

• RTPBC solves data issues surrounding formulary and benefit information including:
  ‒ Inaccurate display of preferred status and tier level
  ‒ PA indicator missing or incorrect
  ‒ Benefit information at plan, not patient level

• RTPBC data pulled in real-time and direct from payer
  ‒ Provides for more detailed benefit information at patient level

• Formulary and Benefit files will not be replaced
  ‒ Provides “directional” guidance during the initial prescription decision
    ‒ On/Off Formulary -> Formulary Status
    ‒ Tier Level -> Copay Tier, Dollar or Percentage Co-pay
    ‒ PA required

• Can help determine if a RTPBC is even necessary
RTPBC Response Data Elements

Initiate RTPBC Request → Intermediary → RTPBC Response → PBM/Payer

Prescription covered by benefit:
- Patient financial responsibility

Prescription not covered by benefits:
- Reason for Denial
- Alternatives
- Coverage Limits
- PA required
- Step therapy
- Drug Utilization Review (DUR) alert
With a Direct Connection, prescription benefit information comes directly from the PBM/Payer to the EHR or RTPBC Service Provider. The EHR/RTBC Service Vendor needs to connect directly to multiple PBMs.

Assumption: Vendor checks patient eligibility to confirm where to send RTPBC transaction.
Intermediaries already have connections to PBMs/Payers for formulary information. The existing connections are used to send and receive an RTPBC transaction.
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.

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

**BENEFIT DISTRIBUTION**

- Pharmacy Benefit: 39%
- Medical Benefit: 61%

**MEDICAL BENEFIT**

Distribution by Site of Care

- Physician Office: 35%
- Home: 21%
- Outpatient Hospital: 37%
- Other: 6%

Source: 14th Edition, EMD Serono Specialty Digest
Specialty Medication Stakeholders

- Manufacturers
- Hub & Hub Services
- Providers
- Patient
- EHRs
- Pharmacies
- Medical Payers
The Complexity of Specialty Drug Dispensing

There is a significant amount of complexity involved with dispensing specialty medications and a number of areas to focus on in regards to standards and moving processes electronic.
The Patient Burden

- Patient out-of-pocket costs vary widely between medical and pharmacy benefit and between dispensing sites.
- The patient may not be aware of co-pay assistance programs and may abandon therapy if co-pay is too high, particularly if the medication falls under the medical benefit.
- Patients are forced to be their own advocates.
- Employer benefit changes are particularly challenging for patients and cause therapy delays that negatively impact outcomes.

Abandonment Rates for Branded Medicines:
- Almost 1 in 4 Prescriptions Are Abandoned By Patients During Their Deductible Phase

Source: Amundsen Consulting (a division of QuintilesIMS) analysis for PhRMA; IMS FIA; Rx Benefit Design, 2015
Addressing Barriers: Da Vinci Project Coverage Requirements

Discovery

• Providers need to easily discover which payer covered services or devices have
  – Specific documentation requirements or guidance,
  – Rules for determining need for specific treatments/services
  – Requirement for Prior Authorization (PA) or other approvals

• FHIR based API enables providers to discover payer-specific coverage requirements in **real-time**
  – Answer to discovery request
  – A list of services, templates, documents, rules
  – URL to retrieve specific items (e.g. template)
Considerations, Drivers, Future

• Innovators/Early Adopters will help determine the value and lessons learned/best practices
• There are costs to both the payers/PBMs and EHRs
• Formulary and Benefit (F&B) will not go away with introduction of RTBC; there’s debate but both are likely needed
• What will drive wide-spread adoption of RTBC?
  • Regulations
  • Business model
What are the opportunities for a consumer-facing RTPBC?

GROUP DISCUSSION
Questions for Consideration

• Would this group be interested in creating an implementation guide for consumer-facing RTPBC?

  At a minimum, the Implementation Guide would include:
  • Listing the required and situational data elements (What)
  • Defining the manner in which the fields and data elements should be displayed (How)
  • Developing reference implementations
  • Collaboration with SDOs (NCPDP, HL7)

• Should we limit the scope to how RTPBC is currently defined or should we re-examine from a consumer perspective?

• Who else needs to be around the table?
Next Steps
RYAN HOWELLS AND ANNE-MARIE POLAK