



Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Meeting #9

Shelly Spiro, Co-Chair

Hans Buitendijk, Co-Chair

August 30, 2023





Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Roster



Name	Organization	Name	Organization
Hans Buitendijk* (Co-Chair)	Oracle Health	Shelly Spiro (Co-Chair)	Pharmacy HIT Collaborative
Pooja Babbrah	Point-of-Care Partners	Deven McGraw*	Invitae Corporation
Chris Blackley	Prescriptive	Ketan Mehta	Micro Merchant Systems
Shila Blend*	North Dakota Health Information Network	Justin Neal	Noble Health Services Dell Medical School, University of Texas at Austin
David Butler	Curatro, LLC	Eliei Oliveira*	CyncHealth
Steven Eichner*	Texas Department of State Health Services	Naresh Sundar Rajan*	Bear Health Tech Consulting
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Scott Robertson	Individual
Adi V. Gundlapalli**	Centers for Disease Control and Prevention	Alexis Snyder*	Yardi Systems, Inc.
Jim Jirjis*	HCA Healthcare	Fillipe Southerland*	Community Pharmacy Owner
Summerpal Kahlon	Rocket Health Care	Christian Tadrus	Elevance Health
Steven Lane*	Health Gorilla	Sheryl Turney*	Walgreens
Meg Marshall**	Department of Veterans Health Affairs	Afton Wagner	
Anna McCollister*	Individual		

Agenda

10:30 AM

Call to Order/Roll Call

- Mike Berry, Designated Federal Officer, ONC

10:35 AM

Opening Remarks

- Mike Berry, Designated Federal Officer, ONC
- Tricia Lee Rolle, Staff Lead, ONC

10:40 AM

Recommendation Drafting Example Discussion

- Hans Buitendijk, Co-Chair

10:55 AM

Task 3 Introduction: Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies

- Shelly Spiro, Co-Chair

11:00 AM

Presentation

- Pooja Babbrah (TF Member), Practice Lead, Pharmacy and PBM Services, Point-of-Care Partners
- Justin Neal (TF Member), Vice President of Patient Support and Data Contract Services Noble Health Services

11:10 AM

Task 3 Discussion

- Shelly Spiro, Co-Chair
- Hans Buitendijk, Co-Chair

11:50 AM

Public Comment

- Mike Berry, Designated Federal Officer, ONC

11:55 AM

Task Force Work Planning

- Shelly Spiro, Co-Chair
- Hans Buitendijk, Co-Chair

12:00 PM

Adjourn



Opening Remarks

Mike Berry, Designated Federal Officer, ONC

Tricia Lee Rolle, Staff Lead, ONC

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Charge

Overarching charge: Identify recommendations to support interoperability between pharmacy constituents, and the exchange of information necessary for medication management, patient safety and consumer engagement.

Recommendations Due: November 9, 2023

Specific charge:

1. Public Health, Emergency Use Authorizations, and Prescribing Authorities
2. Identify opportunities and recommendations to improve interoperability between pharmacy constituents (prescribers, pharmacists, pharmacy benefit managers, dispensers, payers, intermediaries, PDMPs, public health agencies, HIEs, third party service providers, consumers, etc.) for pharmacy-based clinical services and care coordination.
3. Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.
4. Identify policy and technology needs and considerations for direct-to-consumer medication services.

Emerging Therapeutics

TASK 3: August 30- September 27

3. Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.

a. What standards gaps exist for the prescribing and management of:


- i. specialty medications
- ii. digital therapeutics
- iii. gene therapies





Recommendation Drafting Example Discussion

Hans Buitendijk, Co-Chair



Task 3 Introduction: Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies

Shelly Spiro, Co-Chair



Presentation

Pooja Babbrah (TF Member), Practice Lead, Pharmacy and PBM Services,
Point-of-Care Partners

Justin Neal (TF Member), Vice President of Patient Support and Data Contract
Services Noble Health Services



Specialty Medication: Overview of Pain Points

Presentation for ONC HITAC
Pharmacy Interoperability and
Emerging Therapeutics Task Force



How are Specialty Medications Defined?

Criteria	CMS	Pharmacy	Life Sciences	Payers/ PBMs	Health Systems/ Providers
Cost	•			•	•
Complexity of Medication (Delivery, Handling, Administration, Side Effects, etc)		•		•	•
Payer Policies/Plan Sponsor Preferences		•		•	•
Complex Patient Management (eg, patient education, patient management prior to or following administration, care coordination)		•			
FDA Restrictions (eg, REMS)			•		•
Supply Restrictions		•	•		

High Variability in Ownership of Specialty Medication Coverage

Factors that may influence whether a medication or product is covered under pharmacy vs. medical benefit:



Location

- Facilities, ambulatory practices and third-party ancillary centers predominantly contract with payers, not PBMs
- Use of X12 standards and practice management, revenue cycle management vendors that rely on X12



Coverage Complexity

- Cost, disease state and availability of drug alternatives/administration complexity
- Payers will more tightly control utilization management
- Biosimilars, new product introductions or off-label use



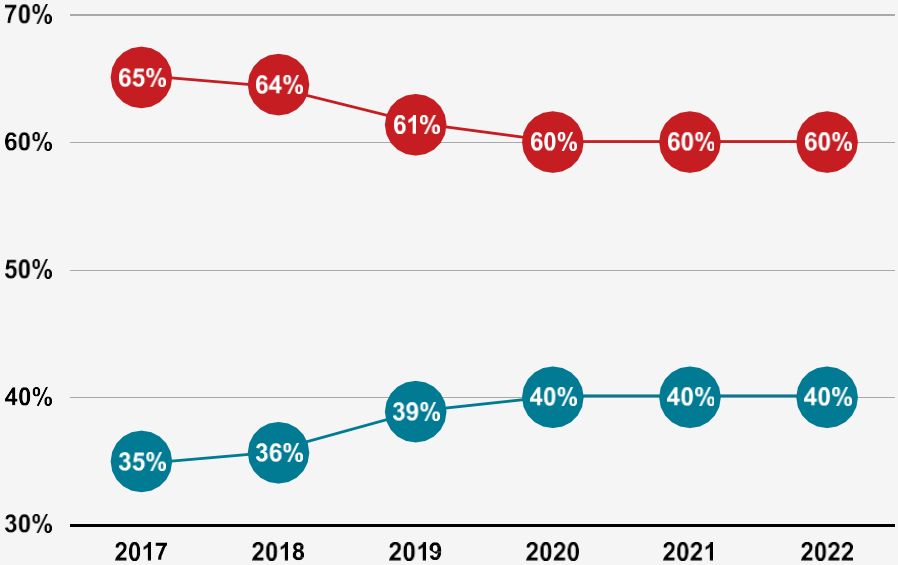
Product Form/ Administration Method

- Pill based medications often remain on pharmacy benefit
- Infusions, injections and products that require skilled administration and additional service billing rely on a facility or provider office, so often remain on medical benefit
- Compounded products can be found on both
- Self-administered medications that can be dispensed at a retail pharmacy or shipped to patient directly are more likely to be covered on pharmacy benefit
- Coverage of non-durable medical equipment and durable medical equipment (DME) that supports a medication may vary by line of business for a payer

The lack of industry standard definition makes the ability to crosswalk patient by patient between medical and pharmacy benefit even more critical.

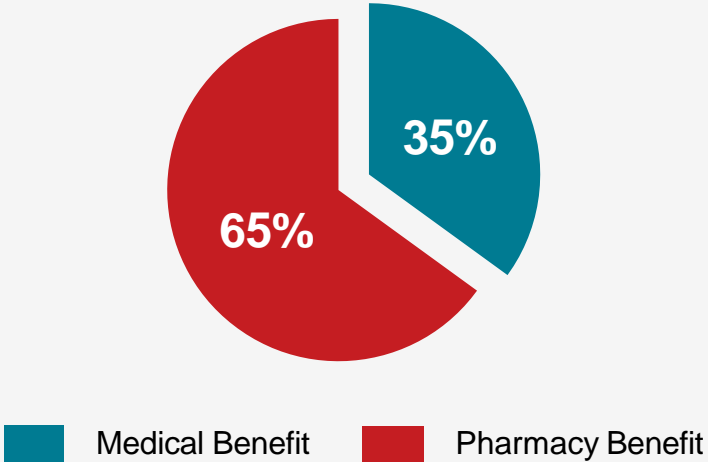
Specialty Prescription Volume by Coverage 2019

**Specialty Pharmacy Coverage Spend
Medical vs. Pharmacy Expected Future Trend 2017-2022**



Specialty pharmacy coverage under medical benefit could go higher than 40% depending on trajectory of new oncology and digital therapeutics. Also, as information technology infrastructure improves for supporting medical benefit, likely to be less pressure to move to pharmacy benefit because of lack of technology.

Specialty Prescription Volume by Coverage 2019



Volume Trend Assumptions and Input

- IQVIA Specialty volume and cost analysis
- CMS Part D and Part B prescription data
- PSG Drug Trend report
- Estimated volume projections using dollars, cost per claim and volume

Sources:
 PSG Drug Trend Report (CY2018, CY2019, CY2020) and POCP Analysis of expected future trends
 POCP Analysis of IQVIA Medicine Use and Spending in the U.S. report, CMS Medicare Part B and Medicare Part D Spending Dashboard and Data, PSG Drug Trend Report, Conversations with IQVIA and CMS
 Point-of-Care Partners | Proprietary and Confidential

Existing Standards Focused on Medications Covered Under Pharmacy Benefit

Content & Function	Standards Available		
	Pharmacy Benefit		
	Formulary & Benefit	Real Time Benefit	ePA
Standard		NCPDP	Yes
Validate Coverage		Surescripts or P2P 270/1	Yes
Patient Specific Coverage		Yes	Specific
Shows Coverage at Product/ Services	Yes	Yes	
Identifies Criteria at Product/ Services		Yes	Partial
Providers Alternatives, Site of Care Restrictions, Pricing	Yes	Yes	
Enables Capture of Patient Clinical Data			Yes
Supports PA Submission			Yes
Support PA Status			

Content & Function	Standards Available					
	Medical Benefit					
	Coverage Requirements Discovery	Documentation Templates & Rules	Prior Authorization Support	Prior Authorization	Attachments	Pre-Adjudicated Claims
Standard						
Validate Coverage	HL7 FHIR					
Patient Specific Coverage				X12N		
Shows Coverage at Product/ Services				or Portal 270/1	Yes	Yes
Identifies Criteria at Product/ Services						Specific
Providers Alternatives, Site of Care Restrictions, Pricing						
Enables Capture of Patient Clinical Data						
Supports PA Submission			Yes	Partial	Yes	
Support PA Status			Yes	Yes		
			Potential	Yes		Yes

Existing standards are focused on medications on pharmacy benefit only, giving providers insight into half of the picture



Patient Scenario

Patient Scenario

- 37-year-old female patient with rheumatoid arthritis (RA)
- After being off all medications due to pregnancy and relatively stable over last few years, patient is experiencing recurring flare ups – altering ability to live life with young children
- Unresponsive to OTC and generic NSAID options
- RA medication options split across patient’s medical and pharmacy benefit plans
- Patient makes an appointment for medication review

Sample RA Medication Options

NSAIDS
Corticosteroids
Humira
Methotrexate
Hydroxychloroquine

Remicade
Rituximab
Cimzia
Enbrel
Simponi
T-cell Costimulatory
Blocking Agents
B-cell Depleting Agents

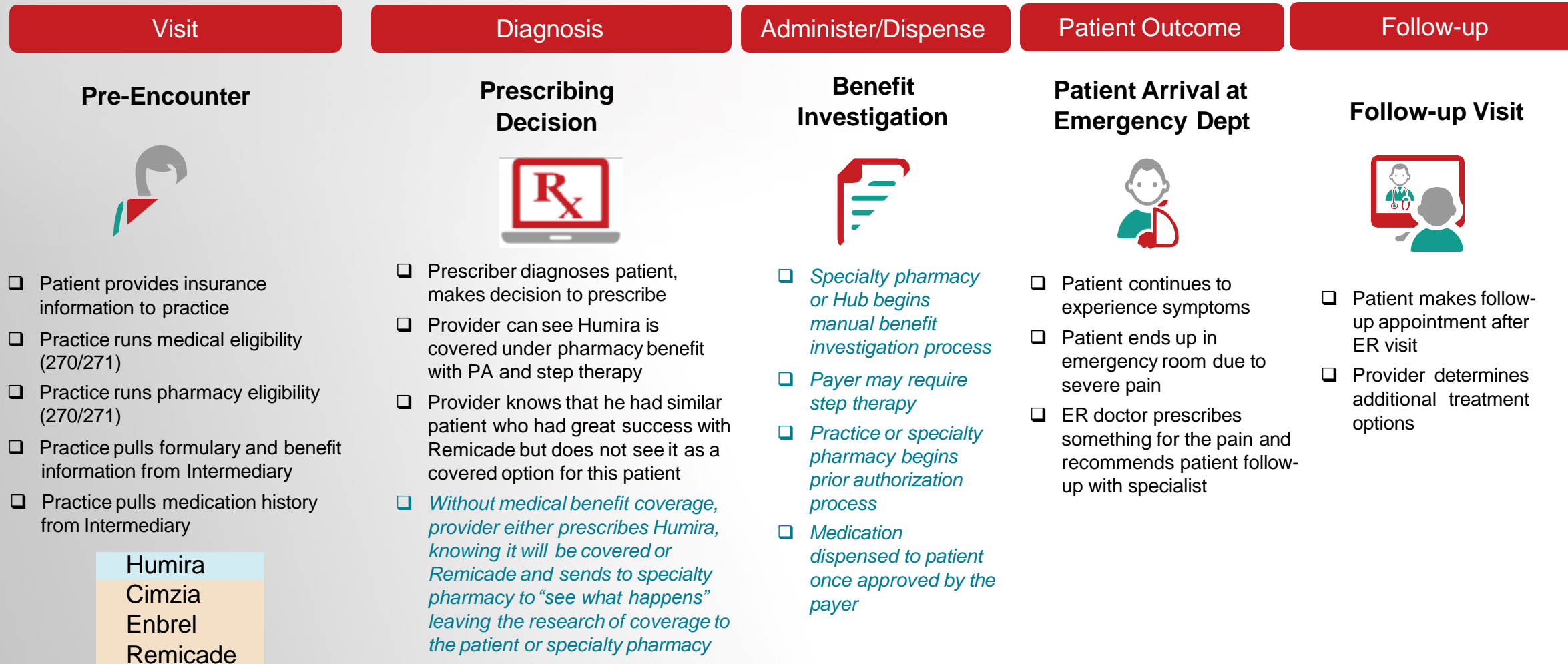
Covered under pharmacy benefit
Covered under medical benefit



Provider and Patient Journey: Prescribing a Specialty Medication: Current State



Covered under pharmacy benefit

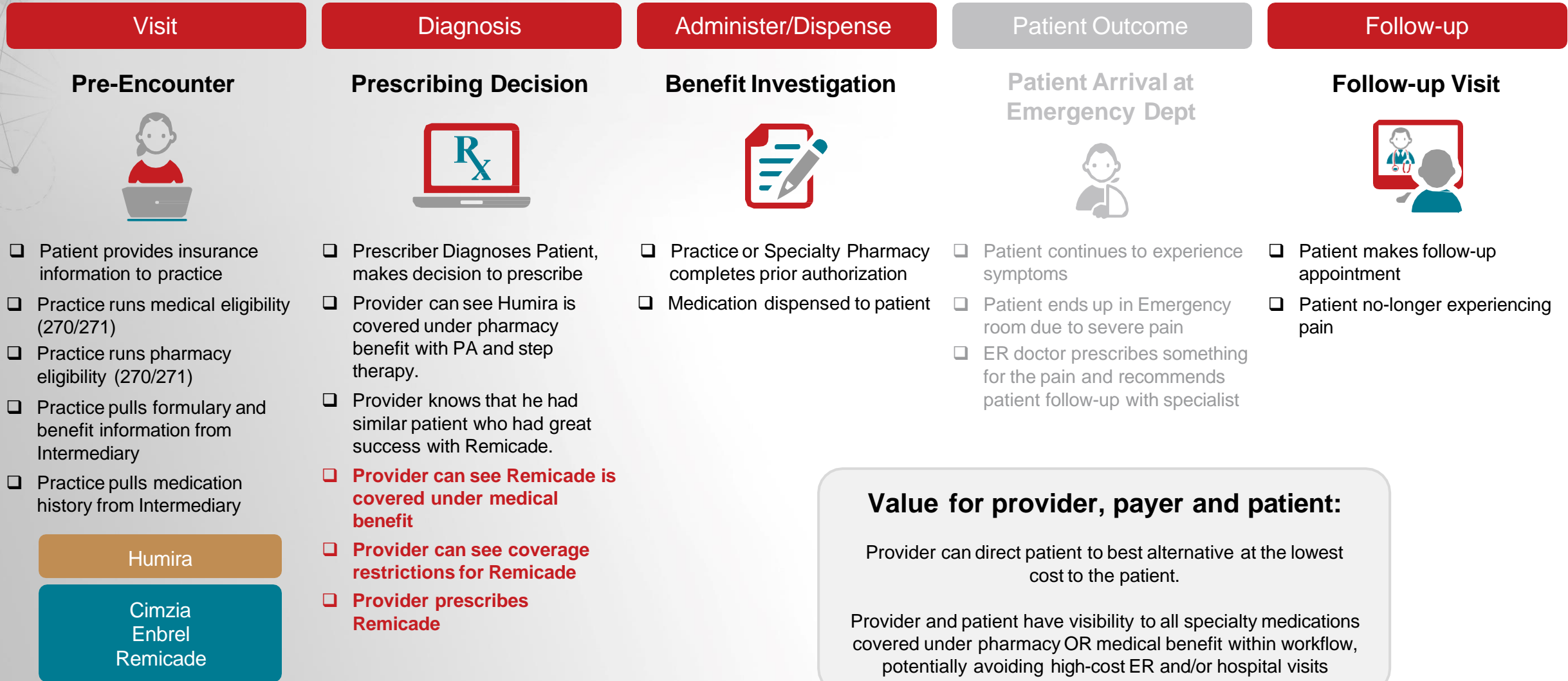
Covered under medical benefit



Note: A hub is a service that allows a manufacturer to have a singular point of contact with patients who utilize their therapies. Services range from benefits investigation, prior auth processing, drug delivery, financial and co-pay assistance, patient education, compliance with REMS, data reporting, and prescription triaging.

Provider and Patient Journey: Prescribing a Specialty Medication: Future State

-  Covered under pharmacy benefit
-  Covered under medical benefit



Value for provider, payer and patient:

Provider can direct patient to best alternative at the lowest cost to the patient.






Provider and patient have visibility to all specialty medications covered under pharmacy OR medical benefit within workflow, potentially avoiding high-cost ER and/or hospital visits

Provider and Patient Journey: Prescribing a Specialty Medication: Workflow and Standards

EVENT

WORKFLOW

STANDARD

	Visit	Diagnosis	Administer/Dispense	Patient Outcome	Follow-up
Event	Pre-Encounter 	Prescribing Decision 	Benefit Investigation 	Patient Arrival at Emergency Dept 	Follow-up Visit 
Workflow	<ol style="list-style-type: none"> 1. Patient or provider system provides patient insurance 2. Provider checks for active coverage across pharmacy and medical benefit 	<ol style="list-style-type: none"> 1. Provider evaluates patient, makes diagnosis and review medication options 2. Patient and provider review patient options 	<ol style="list-style-type: none"> 1. Provider or specialty pharmacy administers and/or dispenses medication 2. Provider or specialty pharmacy submits claim to payer 	<ol style="list-style-type: none"> 1. Patient presents to a new provider, new location 2. Benefit check repeat from step 1 	<ol style="list-style-type: none"> 1. Patient returns for follow up with PCP or specialist 2. If medication under medical, may not appear on medication list
Standard	<ul style="list-style-type: none"> • Eligibility • Formulary & Benefit • Medication History <p> X12N NCPDP HL7 FHIR IGs </p>	<ul style="list-style-type: none"> • Formulary & Benefit • Real-Time Prescription Benefit Check (RTBC) • Coverage Requirements Details • Price Cost Transparency 	<ul style="list-style-type: none"> • Medical Eligibility & Benefits Coverage Requirements Details • Documentation Templates & Requirements • Price Cost Transparency • Prior Authorization Support • Prior Authorization Submission/Status 	<ul style="list-style-type: none"> • Medical Eligibility & Benefits Coverage Requirements Details • Documentation Templates & Requirements • Electronic Prior Authorization • Prior Authorization Support • Prior Authorization Submission/Status 	<ul style="list-style-type: none"> • Medication History • Medical Eligibility & Benefits Coverage Requirements Details • Documentation Templates & Requirements • Electronic Prior Authorization • Prior Authorization Support • Prior Authorization Submission/Status

Thank You

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[Point-of-Care Partners](https://www.linkedin.com/company/point-of-care-partners)



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Specialty Pharmacy Workflow and Interoperability Needs

HITAC TF Presentation: 8/30/2023

THE NEW STANDARD IN SPECIALTY

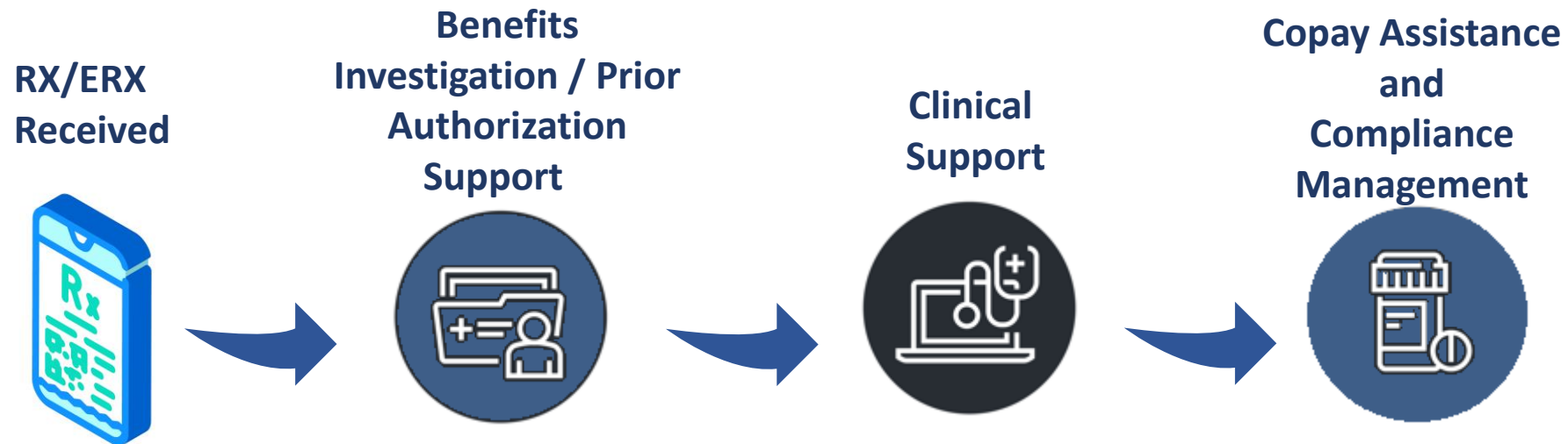
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Overview of Specialty Pharmacy Workflow



Noble Health Services: Mid-range specialty pharmacy, 2 pharmacies licensed and serving patients in all 50 states. Carries 3 specialty pharmacy accreditations (URAC, ACHC, NABP.) Considered an independent specialty pharmacy as opposed to a “vertically integrated” specialty pharmacy owned by a large PBM.



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Role of Specialty Pharmacy



The role of specialty pharmacy is to sit in the middle of various health care and logistics stakeholders to eliminate points of friction, in a system designed around barriers. Due to these being high-cost medications, PBMs and insurance providers build restrictions to limit utilization of those therapies. Simultaneously they set high bars for pharmacies dispensing these medications to maintain and maximize the outcome for patients on those therapies.



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Technology barriers & Interoperability Opportunities



Clinical/Pharmaceutical Care

- Proper dosing evaluation (demographic info)
- Appropriate dx for therapy
- Complete Medication list
- PA Support



Payor Barriers

- Payor Network Reporting Requirements for access
 - ICD-10 for use of medication
 - Utilization Management
 - Compliance Reporting
 - Reasons for discontinuation
 - Turn-around time



Accreditation Barriers

- Payor Barrier of entry & best practices
- Full list of diagnoses and medication list
- Complete DUR
- Outcome tracking (Cure rate, QOL, etc.)
- Turn-around time reporting
 - Prior authorization & chart access



Manufacturer Barriers

- LDD Access and Reporting
- REMS Reporting (ie Pregnancy test)
- Prior Authorization and Turn-around time

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National Footprint, National Needs



Total number of active HIEs in each U.S. state

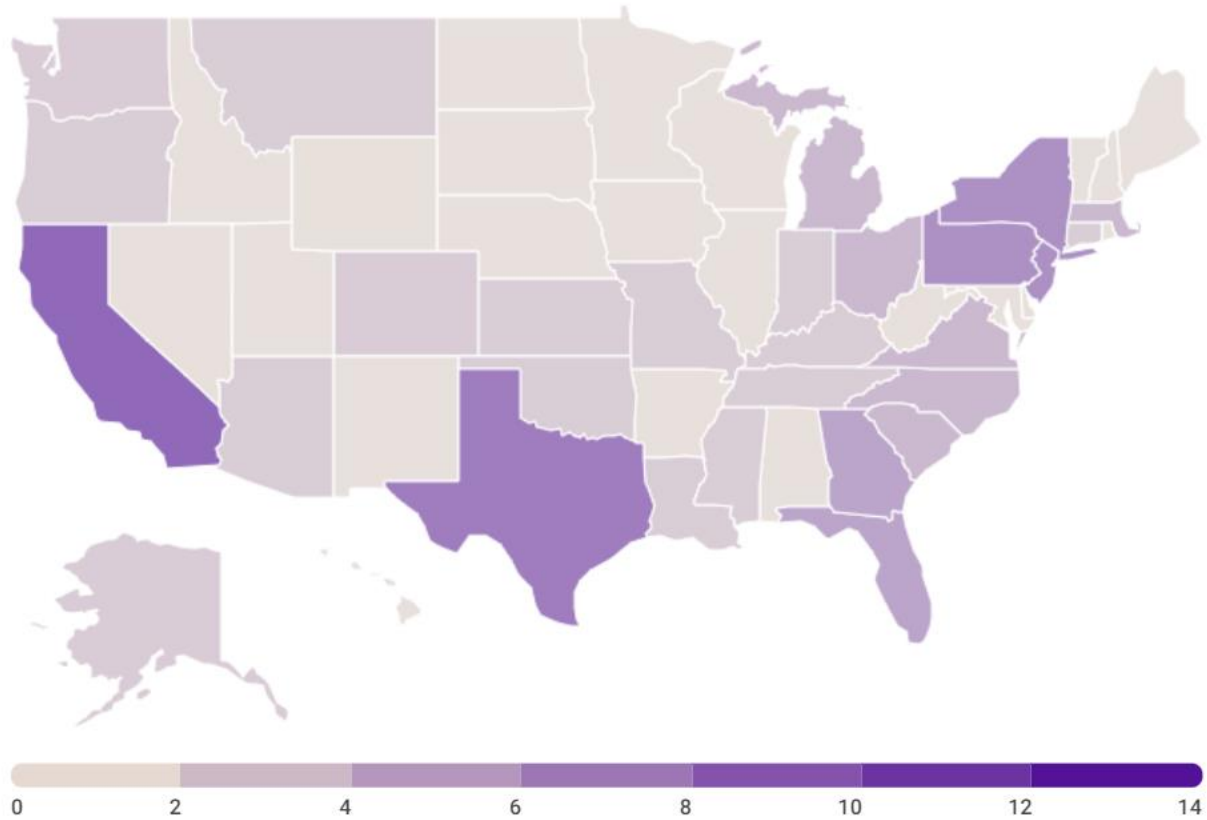


Fig. 1 Data is from the Definitive Healthcare ConnectedCareView product. HIEs are tracked from a variety of sources and updated daily. Data accessed November 2022.

Local prescribing and fulfilment have local integration solutions (HIEs, Health system cooperation.)

As patient footprint in a non-integrated PBM/Health System expands, standardization via tech vendors (Pharmacy Management Systems, Clinical Management Systems, etc.) matter greater to provide the necessary info into the pharmacy workflow.

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Case Sample: Hep-C & Crohn's Patient



Patients prescribed a medication via a commercial insured program with a restricted payor network.

Hep-C Patient



Accreditation & Payor Data Requirements

- Full list of diagnoses and medication list
- Complete DUR
- Lab values relevant to care:
 - Genotype
 - Viral Load
 - Cirrhosis Status
 - Prior treatment status
- SVR-12 after treatment to confirm cure
 - \$1K invoice



Crohn's Patient



Accreditation & Payor Data Requirements

- Full list of diagnoses and medication list
- Complete DUR
- Lab values relevant to care:
 - Negative TB test before start and annually
- # of flare-ups
- Steroid use



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Feedback from Specialty Pharmacies



Information Specialty Pharmacies should be providing back:

- Capturing QOL information about care effectiveness
- Providing fill history/Compliance and discontinuation information
- Identified DRPs



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Thank you!



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Task 3 Discussion

Shelly Spiro, Co-Chair

Hans Buitendijk, Co-Chair

Emerging Therapeutics

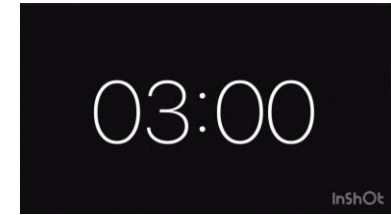
TASK 3: August 30- September 27

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- a. What standards gaps exist for the prescribing and management of:
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Public Comment



To make a comment please
Use the Hand Raise Function

If you are on the phone only, press “*9” to raise your hand

*(Once called upon, press “*6” to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

*Written comments will not be read at this time,
but they will be delivered to members of the task force and made part of the public record*




Task Force Work Planning

Shelly Spiro, Co-Chair

Hans Buitendijk, Co-Chair

Upcoming Meetings



Month	Task Force Meeting Dates	HITAC Meeting Date
September	13, 20, 27	September 14 (TF Update)
October	4, 11, 18, 25	October 19 (TF Update)
November	1	November 9 (Final Recommendation and Vote)



Adjourn