



# Pharmacy Interoperability and Emerging Therapeutics Task Force 2023

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# Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Roster

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

# 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

### Short-term

- a. Identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions.
- b. Are there actions ONC can take to enable data exchange in support of public health emergency use cases? For example, Test to Treat and COVID-19 treatment prescribing?

### Long-term

- a. Recommendations to better integrate pharmacy systems and data for public health surveillance, reporting and public health interventions.



# Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Charge (Continued)

## Specific charge:

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.
  - a. How can ONC help facilitate adoption and use of standards to support data exchange for pharmacy-based clinical services?
  - b. Which priority pharmacy-based clinical use cases should ONC focus on in the short-term and long-term?
  - c. What technology gaps exist for pharmacists to participate in value-based care?
  - d. What can ONC do to address drug inventory transparency for prescribers and consumers?
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
4. Identify policy and technology needs and considerations for direct-to-consumer medication services.

# Supporting Public Health

## 1. Public Health, Emergency Use Authorizations, and Prescribing Authorities

### Short-term

- Identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions.
- Are there actions ONC can take to enable data exchange in support of public health emergency use cases? For example, Test to Treat and COVID-19 treatment prescribing?

### Long-term

- Recommendations to better integrate pharmacy systems and data for public health surveillance, reporting and public health interventions.

#### Example of Fact Sheet for Healthcare Providers: Emergency Use Authorization

<p><b>LIMITATIONS OF AUTHORIZED USE</b></p> <ul style="list-style-type: none"> <li>is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.</li> <li>is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.</li> <li>is not authorized for use longer than 5 consecutive days.</li> </ul> <p>may be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs.</p> <p>may also be prescribed for an individual patient by a state-licensed pharmacist under the following conditions:</p> <ul style="list-style-type: none"> <li>Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and</li> <li>Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.</li> </ul>	<p>is not recommended in patients with severe renal impairment (eGFR &lt;30 mL/min). (2.2, 8.6)</p> <p>is not recommend in patients with severe hepatic impairment (Child-Pugh Class C). (2.3, 8.7)</p> <p><b>----- DOSAGE FORMS AND STRENGTHS -----</b></p> <ul style="list-style-type: none"> <li>Tablets: nirmatrelvir 150 mg (3)</li> <li>Tablets: ritonavir 100 mg (3)</li> </ul> <p><b>----- CONTRAINDICATIONS -----</b></p> <ul style="list-style-type: none"> <li>History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components. (4)</li> <li>Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions. (4, 7.3)</li> <li>Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. (4)</li> </ul> <p><b>----- WARNINGS AND PRECAUTIONS -----</b></p> <ul style="list-style-type: none"> <li>The concomitant use of and certain other drugs may result in potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions. (5.1, 7)</li> </ul>
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# Supporting Clinical Pharmacy Services and Coordinated Care

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.

- a. How can ONC help facilitate adoption and use of standards to support data exchange for pharmacy-based clinical services?
- b. Which priority pharmacy-based clinical use cases should ONC focus on in the short-term and long-term?
- c. What technology gaps exist for pharmacists to participate in value-based care?
- d. What can ONC do to address drug inventory transparency for prescribers and consumers?



# Emerging Therapeutics

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

Specialty prescribing mostly fax, portals, limited electronic routing and limited switch connectivity

No standard definition or terminologies for digital therapeutics, yet increasing in use

Expecting 10-20 FDA approvals of new gene therapies through 2025

# Direct to Consumer Medication Services

4. Identify policy and technology needs and considerations for direct-to-consumer medication services







# Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 – Workplan

Key Meeting Dates	Agenda Items
June 21	Task Force Kick-off Meeting
August 17	Task Force Update to HITAC
September 14	Task Force Update to HITAC
October 19	Task Force Update to HITAC
November 9	Task Force Delivers Final Recommendations to HITAC

**Regular Meeting Schedule: Wednesday 10:30 AM – 12 PM ET**

HITAC Calendar: <https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar>

Please contact Mike Berry ([michael.berry@hhs.gov](mailto:michael.berry@hhs.gov)) if additional HITAC members want to participate in this task force



**Questions?**