



# Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Recommendations – HITAC Vote

Shelly Spiro, Task Force Co-Chair

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**November 9, 2023**



# Agenda

- Task Force Charge
- Task Force Roster
- Subject Matter Expert Presentations
- Use Cases
- Themes and Topics
- Recommendations
  - General
  - Interoperability Capabilities of Particular Interest
  - Patient Matching and Record Linkage
  - Emerging Therapies
  - Specialized/Focused Certification and Funding
  - Network Participation
  - Quality Measures
- Discussion and HITAC Vote



# 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.

# Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Roster



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



# Subject Matter Expert Presentations

| <u>Meeting Date</u> | <u>Area of Focus</u>   | <u>Invited SMEs</u>  |
|---------------------|--|--|
| June 28             | <u>TF Topic 1: SHORT-TERM Public Health, Emergency Use Authorizations, and Prescribing Authorities</u> | <ul style="list-style-type: none"> <li>• RDML (retired) Pamela Schweitzer, Assistant Surgeon General and 10th Chief Pharmacist USPHS</li> <li>• Lisa Schwartz, Senior Director, Professional Affairs, National Community Pharmacists Association (NCPA)</li> <li>• Darren Townzen, Senior Director Health and Wellness Billing and Reconciliation, Walmart</li> <li>• Chad Worz, Executive Director and CEO, American Society of Consultant Pharmacists (ASCP)</li> <li>• Michael Popovich, CEO and Jason Briscoe, Director of Pharmacy zAOperations, STC Health</li> </ul>  |
| July 12             | <u>TF Topic 1: LONG-TERM Public Health, Emergency Use Authorizations, and Prescribing Authorities</u>  | <ul style="list-style-type: none"> <li>• Tegan K Boehmer, PhD, MPH, CDR, US Public Health Service Acting Chief, Actionable Data Branch (proposed), Inform and Disseminate Division (proposed), Office of Public Health Data, Surveillance, and Technology</li> </ul>   |
| July 19             | <u>TF Topic 1: LONG-TERM Public Health, Emergency Use Authorizations, and Prescribing Authorities</u>  | <ul style="list-style-type: none"> <li>• Laura Conn, MPH, Lead, Electronic Case Reporting (eCR), Public Health Data Transmission Branch (proposed), Detect and Monitor Division (proposed), Office of Public Health Data, Surveillance and Technology, CDC</li> <li>• Lynn Gibbs Scharf, MPH, Chief, Informatics and Data Analytics Branch, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC</li> <li>• Agha (Nabeel) Khan, MD, MPH, MBA, Senior Advisor for Informatics, Office of Informatics, National Center for Immunization &amp; Respiratory Diseases, CDC</li> </ul> |

# Subject Matter Expert Presentations (Continued)

| <u>Meeting Date</u> | <u>Area of Focus</u>   | <u>Invited SMEs</u>  |
|---------------------|--|--|
| July 26             | <u>TF Topic 2: Identify opportunities and recommendations to improve interoperability between pharmacy constituents for pharmacy-based clinical services and care coordination</u> | <ul style="list-style-type: none"> <li>• Kim Boyd, President, Boyd Consulting Group, LLC</li> <li>• Stephen Mullinex, BS Pharm., R.Ph., Senior Vice President, Public Policy &amp; Industry Relations, NCPDP</li> <li>• Richard Sage, Executive Vice President, Innovation &amp; Standards Development, NCPDP</li> <li>• Josh Howland, Pharm.D., MBA, SVP Clinical Strategy &amp; Product, RedSail Technologies</li> </ul> |
| August 9            | <u>TF Topic 2: Identify opportunities and recommendations to improve interoperability between pharmacy constituents for pharmacy-based clinical services and care coordination</u> | <ul style="list-style-type: none"> <li>• Christian Tadrus (TF Member), Community Pharmacy Owner</li> <li>• Jake Galdo, PharmD, MBA, BCPS, BCGP Managing Network Facilitator, CPESN Health Equity and CEO, Seguridad</li> </ul>   |
| August 23           | <u>TF Topic 2: Identify opportunities and recommendations to improve interoperability between pharmacy constituents for pharmacy-based clinical services and care coordination</u> | <ul style="list-style-type: none"> <li>• Phillip Lettrich, RPh, Health Policy and Business Development – Vela</li> </ul>   |



# Subject Matter Expert Presentations (Continued)

## Meeting Date

## Area of Focus

## Invited SMEs

August 30

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

- 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

September 20

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

- Stephanie Garcia, Branch Chief, ONC
- Mark Dunnenberger, Assistant Vice President, Personalized Medicine and Pharmacogenomics, NorthShore University Health System

September 27

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

- Ibrar Ahmed, Software and Enterprise Architecture Manager, ZS





## Use Cases

- **Bi-directional access to Individual patient data supporting testing through treatment process:** Focuses on the sharing of clinical and administrative data between pharmacists and any health care providers
- **Incorporate pharmacist into the care team:** Focuses on coordinated collaboration to manage and implement a patient's care plan across all care team members
- **Consumer Engagement:** Focuses on the pharmacist interactions and data sharing with the patient directly
- **Data-driven medication-related population level interventions:** Focuses on identification of a pharmacist's patient population who qualify for, or are in need of interventions
- **Pharmacy Quality Measures of Clinical Pharmacy Services:** Focuses on capturing data, calculating, and reporting on quality measures that aim to identify clearly defined and actionable levels and opportunities to enhance the provision of pharmacy services, particularly those impacting patients and caregivers, and other providers.





## Use Cases (Continued)

- **VBC Quality Measures Cross Care Team:** Focuses on specific measures that address cross care team coordination, availability of data to the care team, and patient outcomes that are relevant to value based care
- **Public Health:** Focuses on the interactions between pharmacists and public health agencies
- **Patient Safety:** Focuses on capabilities specific to advancing patient safety



## Themes and Topics

- **Standards and Data Exchange:** Gaps in standards and implementation guidance, as well as available infrastructure and networks to advance and scale interoperability with pharmacists and pharmacies.
- **Pharmacist-Other Provider Collaboration and Data Sharing Needs:** Challenges and needs in advancing the interactions between pharmacists and other pharmacists and non-pharmacists who provide care to the patient.
- **Pharmacist - Public Health Collaboration and Data Sharing Needs:** Challenges and needs in advancing the interactions between pharmacists and public health agencies
- **Pharmacist - Special Settings/Populations / Long Term Care Collaboration and Data Sharing Needs:** Challenges and needs for three-way interoperable exchange for settings between multiple providers using different EHR systems (e.g., LTC facility/home care agency-pharmacy- prescriber)
- **Pharmacist Data Capture:** Opportunities to advance data capture by pharmacists not only for their own benefit, but for other care team members, providers, and public health agencies



## Themes and Topics (Continued)

- **Information Sharing/Blocking:** Practices and challenges that impede the ability to share data beyond the technical challenges, e.g., policies, contractual practices, awareness, education.
- **Jurisdictional Variations of Standards and Rules:** Challenges resulting from variations in policies, standards, and rules across jurisdictions (e.g., pharmacists are excluded from some HIEs because pharmacists are not recognized as providers under the Social Security Act).
- **Resources/Funding:** Challenges and needs to invest in the necessary resources, incentive programs and infrastructure to advance interoperability with and among pharmacists.
- **Privacy and Consent:** Considerations with respect to privacy policies and patient consent directives as data could be shared with pharmacists beyond the traditional prescription fulfillment processes.



# **Task Force Recommendations**



# Recommendation Structure

- **Example Recommendation:**

## Recommendation



PhIET-TF-2023\_Recommendation 04: Recommend that ONC identifies the needs and capabilities relevant to the pharmacy vs. the pharmacist as it identifies opportunities for advancing interoperability.

## Rationale



Rationale: The use cases and themes identified yield different dispensing and clinical workflows for the pharmacy, as a business entity, vs. the pharmacist delivering care as a member of the patient's care team. As these themes and use cases are being advanced both the pharmacy and pharmacist perspectives should be considered to ensure a comprehensive approach towards advancing interoperability and integrating data access and sharing into the pharmacists' workflows.

## References

- Question
- Use Cases
- Themes and Topics



### References:

- Questions: Topic 2 (a); Topic 2 (c)
- Use Cases: All
- Themes and Topics: All

# Appendix Structure

- **Appendix A** – Task Force Roster
- **Appendix B** – Abbreviations
- **Appendix C** – Index of Topics/Questions
  - Example :

| Question   | Recommendation Reference   |
|--|--|
| 1. <b>Public Health, Emergency Use Authorizations, and Prescribing Authorities</b>   |  |
| a. <b><u>Short-term</u></b><br><b>Identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions.</b> | PhIET-TF-2023_Recommendation 01<br>PhIET-TF-2023_Recommendation 02<br>PhIET-TF-2023_Recommendation 08<br>PhIET-TF-2023_Recommendation 09<br>PhIET-TF-2023_Recommendation 10<br>PhIET-TF-2023_Recommendation 11<br>PhIET-TF-2023_Recommendation 19<br>PhIET-TF-2023_Recommendation 21<br>PhIET-TF-2023_Recommendation 31<br>PhIET-TF-2023_Recommendation 32 |

Topic  
Number

Sub-Topic

Recommendation  
Number



# General





## General: PhIET-TF-2023\_Recommendation 01

- **Recommend that ONC initiates a collaborative initiative with patients, caregivers, pharmacists, other providers, and public health agencies, including CDC and state, tribal, local, or territorial public health departments (STLT), to prioritize use cases focusing on:**
  - **Bi-directional data sharing and/or exchange among pharmacies, pharmacists, and other providers of relevant patients' medical records held by each entity as within the care team for use in normal operations and under emergency use interventions within established privacy policies and patient consent directives. Patients should have expanded access to disclosure information from what is in practice today, including disclosures for Treatment, Payment, and Operations (TPO) to improve accountability regarding exchange.**
  - **Access by public health agencies, including CDC and STLTs to patient health records maintained by pharmacies and pharmacists, and for pharmacies and pharmacists to access relevant public health data for their patient populations.**
  - **Identifying the appropriate, relevant data sets, such as those captured using the Pharmacist eCare Plan in communications with payers, to ensure that only the appropriate, correct and necessary data is shared for the use case at hand.**



## General: PhIET-TF-2023\_Recommendation 02

- **Recommend that ONC engage the NCPDP and HL7 standards development communities, and include pharmacists, other providers, and public health organizations including STLTs and the CDC, to prioritize the use cases and advance collaboration among pharmacies, pharmacists, other health care providers, and public health, focused on integrated care delivery and public health operations. Recommend that ONC, in collaboration with CMS and other agencies as appropriate, consider enhanced funding to accelerate progress in the availability and use of interoperability capabilities between pharmacy/pharmacist, provider, and public health agencies during both emergency user intervention and normal operations.**



## General: PhIET-TF-2023\_Recommendation 03

- **Recommend that ONC work with other agencies and authorities to clarify the role and associated Health IT capabilities necessary to integrate pharmacies and pharmacists into the public health fabric, including CDC and STLTs, to share critical data more widely between all involved in the test-to-treat process and identify the critical standards to support the pharmacies and pharmacists in their roles and resulting obligations to public health.**



## General: PhIET-TF-2023\_Recommendation 04

- **Recommend that ONC identifies the needs and capabilities relevant to the pharmacy vs. the pharmacist as it identifies opportunities for advancing interoperability.**



## General: PhIET-TF-2023\_Recommendation 05

- **Recommend that ONC identify and address the obstacles, including those beyond technology and standards, to sharing data between pharmacists, other providers (including other pharmacists), and patients/caregivers for patient assessment, treatment, monitoring, care coordination, and other lawful purposes. Furthermore, ONC should consider how it can use its regulatory authority to issue regulations and/or guidance to eliminate obstacles, while encouraging the adoption of already available technology and standards that further harmonizing and advancing interoperability with and among the various pharmacy settings. ONC should provide additional guidance and identify approaches, including considering a focused, modular certification program for pharmacy management systems, to drive advancement of standards-based interoperability as also further described in HITAC’s feedback on the HTI proposed rule “Recommendations on the Health Data technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule” in Recommendation 06.**



## **General: PhIET-TF-2023\_Recommendation 06**

- **Recommend that ONC work with federal policy makers to address gaps where PBMs and payers are not considered covered actors under 21st Century Cures Act Final Rule yet have EHI that is relevant to pharmacists and other providers.**



## General: PhIET-TF-2023\_Recommendation 07

- **Recommend ONC convene stakeholders including pharmacists, other providers, patients and caregivers, online pharmacies, National Association of State Boards of Pharmacies (NABP), and other stakeholders to address the needs for and approach to sharing data captured with and by direct-to-consumer, virtual/telehealth care providers, who include prescribers and pharmacists, as they interact with a patient and/or caregiver and have the same needs to share data with and from the other care team members for that patient.**



## General: PhIET-TF-2023\_Recommendation 08

- **Recommend that ONC work with the pharmacies, pharmacists, and public health agencies including CDC and STLTs to provide education, awareness, and, where needed, further policy guidance to pharmacies and pharmacists regarding submission of case reports, immunization, laboratory results reporting, syndromic surveillance reporting, and other data collected by public health agencies, as well as capabilities already available, opportunities and need for bi-directional exchange between public health agencies, pharmacies, and pharmacists. This should include addressing supporting standards available to report this information to comply with current reporting requirements, and mechanisms and capabilities for pharmacies and pharmacists to access public health information.**





# **Interoperability Capabilities of Particular Interest**



# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 09

- **Recommend that ONC collaborate with CMS, payers, health care providers including but not limited to pharmacists, standards development organizations, Health IT vendors, and other relevant stakeholders to adopt standards for and a Condition of Participation requiring the electronic exchange of data elements necessary for identifying what medications in a formulary require pre-authorization and securing any required pre-authorization/pre-approval which require any informational element that is involved in determining which drugs get covered with/without a prior-authorization and at what cost is captured and accessible to pharmacies, pharmacists, other providers and patients and their caregivers.**



# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 10

- **Recommend that ONC work with CMS, other relevant agencies and industry to advance full interoperability between EHRs and PBMs - and other TPAs - that ensure that information about drug, device, medical supplies, and services coverage terms of an insurer are available in real time to patients, practitioners, and appropriate personnel affected by that change, including providing full awareness of the therapeutic- and cost-impact of that formulary change, beginning at the start of any open enrollment period through the end of a patient's coverage period.**



# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 11

- **Recommend that ONC work with other federal policy makers and the pharmacy community to advance the ability for patient facing pharmacy apps/portals to facilitate two-way communication between a pharmacy/pharmacist and the patient or caregiver in order to improve patient care through greater pharmacist-patient-caregiver interaction for such needs as sharing fill status with reason/issue(s), and interactive messaging patient or their caregiver and the pharmacist.**



# Interoperability Capabilities of Particular Interest: PhIET-TF-2023\_Recommendation 12

- **Recommend that ONC, in collaboration with FDA, CDC and STLTs further review FDA's Sentinel surveillance program and how pharmacy data sharing would be important for their surveillance during emergencies.**



# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 13

- **Recommend that ONC, in collaboration with the FDA, provide guidelines to further advance transparency as part of the proposed Decision Support Intervention certification criterion in the proposed HTI-1 rule that are needed to ensure greater clarity on authority, delegation of authority, responsibility, reviewing procedures regarding future machine learning (ML) software-hardware-dataset combinations that achieve artificial intelligence (AI) levels capable of self-initiative, self-management, and self-control within practice settings overseen by local and state regulatory authorities.**



# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 14

- **Recommend that ONC collaborates with the pharmacies and other providers community, including their Health IT vendors, to establish appropriate reporting mechanisms directly from the pharmacy to the care team members and vice versa, i.e., enable bi-directional push messaging rather than solely relying on respective queries for information. For example, ADT messages upon discharge, results availability, administration of a drug, and/or fill status on a prescription when filled.**



# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 15

- **Recommend that ONC collaborate with the pharmacy community, patients, and caregivers to develop guidance on best practices for data capture from patients by pharmacists and pharmacies.**





# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 16

- **Recommend that ONC further explore the potential of an interoperable privacy policy and consent infrastructure for helping to assure appropriate sharing of health information, including but not limited to clinical data and medication fill administration, consistent with applicable law and patient preferences. In exploring this infrastructure, ONC should collaborate with other relevant organizations, workgroups, and similar industry efforts (e.g., HITAC, HL7, National Interoperability Collaborative (NIC), Shift, The Sequoia Project, WEDI, etc.) for this capability. Any such infrastructure should support a broad spectrum of entities who are or should be engaged in health information exchange to improve individual and population health, including (but not limited to) pharmacies and pharmacists, other providers, payers, PBMs, and HIT vendors.**



# Interoperability Capabilities of Particular Interest: PhIET-TF-2023\_Recommendation 17

- **Recommend that ONC considers inclusion of the more specific prescription status change interactions, e.g., RxChange, CancelRx and RxFill status, as required interactions for both prescribers and pharmacies into United States Core Data for Interoperability (USCDI) and ONC's certification program. Consideration should be given to appropriate inclusion of the patient and caregiver for relevant notifications and awareness.**



# Interoperability Capabilities of Particular Interest: PhIET-TF-2023\_Recommendation 18

- **Recommend that ONC explores the need and readiness for standards-based, secure instant messaging capabilities in addition to the current messaging capabilities that use Direct Messaging and a variety of message paradigms through HL7 (v2, HL7 FHIR) and NCPDP (SCRIPT).**



# Interoperability Capabilities of Particular Interest:

## PhIET-TF-2023\_Recommendation 19

- **Recommend that ONC includes event notification capabilities with pharmacies and pharmacists as part of a focused, modular certification approach.**



# Patient Matching and Record Linkage



# **Patient Matching and Record Linkage: PhIET-TF-2023\_Recommendation 20**

- **Recommend that ONC include the pharmacy community in the advancement of patient matching discussions, including record location services, such as those within the Trusted Exchange Framework (TEF), advancing pharmacies' ability to link patients to the right records to provide pharmacists the necessary information for improving patient care.**



# Patient Matching and Record Linkage: PhIET-TF-2023\_Recommendation 21

- **Recommend that ONC establish a learning collaborative across pharmacies, pharmacists, other providers, patients, jurisdictions and government agencies to explore methods such as tokenization and Privacy Protecting Record Linkage (PPRL) in combination with relevant standards as well as record locator services' patient linking knowledge for further advancement in linking the patient's data across multiple sources to the same, de-identified person record to establish a more complete person record for analytics that can fully and accurately incorporate pharmacy/pharmacists sourced data, and how this can be implemented and leveraged across surveillance, research, and other national and state priorities.**



# Emerging Therapies





## Emerging Therapies: PhIET-TF-2023\_Recommendation 22

- **Recommend that ONC work with laboratories, device manufacturers, NLM, LOINC, SNOMED, and industry organizations to address the mapping of pharmacogenomic lab test and values from the test device to industry standard encoding used in the test reporting, akin to the HL7 LIVD mapping initiatives under FDA's SHIELD for general laboratory testing. Additionally, alignment should be pursued on common terminology for relevant gene therapies that would be indicated based on the test results.**



## **Specialized/Focused Certification and Funding**



# Specialized/Focused Certification and Funding: PhIET-TF-2023\_Recommendation 23

- Recommend that ONC pursues a set of standards, technologies, and frameworks to advance interoperability with and among pharmacies and pharmacists that is common with the provider community that is being deployed through ONC's certification program as also further described in HITAC's feedback on the HTI-1 proposed rule "Recommendations on the Health Data technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule" in recommendations 04 and 06.



# Specialized/Focused Certification and Funding: PhIET-TF-2023\_Recommendation 24

- **Recommend that ONC initiates the development of a certification approach in collaboration with critical industry organizations such as NCPDP, HL7, and NABP, for key functionality for pharmacy-based interoperability across practice settings (e.g., community, clinicals, specialty pharmacies, LTPAC, etc.) to encourage adoption of the necessary standards and technologies by pharmacies and pharmacists to interact with providers throughout the test-to-treatment processes during emergent or normal operations. Such a program should focus on the following use cases as outlined in the introduction to the recommendations:**
  - **Bi-directional access to Individual patient data supporting testing through treatment process**
  - **Incorporate pharmacist into the care team**
  - **Consumer engagement**
  - **Data-driven medication-related population level interventions**



# Specialized/Focused Certification and Funding: PhIET-TF-2023\_Recommendation 24 (Continued)

- Pharmacy Quality Measures of Clinical Pharmacy Services
- VBC Quality Measures Cross Care Team
- Public health
- Patient Safety

These should utilize the same standards used in ONC's current certification program, particularly, HL7 v2/CDA C-CDA/FHIR based implementation guides, SMART, NCPDP Script, Direct Messaging, and IHE Document Exchange. Consideration should be given to specialty certification and consider bi-directional certification of eRx transactions and standards encouraging the use of additional transactions to support clinical data exchange, including consideration for the use of the Pharmacist eCare Plan.



# Specialized/Focused Certification and Funding:

## PhIET-TF-2023\_Recommendation 25

- **Recommend that ONC collaborates with pharmacists, other providers, IIS and other relevant clinical data registries, and public health agencies, including the CDC and STLTs, to identify a minimum data set within the USCDI standard that pharmacists must be able to exchange with relevant clinical data registries, EHRs, and possibly other pharmacy information systems, considering the various roles that pharmacists may have in the test-to-treat process. The scope should consider not only prescription related data, but also any non-prescription related data where the pharmacist provides test-to-treat services, such as assessments, tests, treatment and/or advice rendered.**



## **Specialized/Focused Certification and Funding: PhIET-TF-2023\_Recommendation 26**

- **Recommend that ONC consider including the ability to capture and exchange race and ethnicity as part of ePrescribing certification and point to USCDI V4 that references the CDC Race and Ethnicity Code Set Version 1.2 where alternative paths of sharing the data with public health agencies are not available or policies and measures require the sharing as part of ePrescribing.**



## **Specialized/Focused Certification and Funding: PhIET-TF-2023\_Recommendation 27**

- **Recommend that ONC work with HHS enabling receipt of incentives to develop and adopt certified Health IT under ONC's HIT Certification Program, e.g., through full recognition of pharmacists as providers.**





## **Specialized/Focused Certification and Funding: PhIET-TF-2023\_Recommendation 28**

- **Recommend that ONC include different pharmacy settings, specialty pharmacies, and PMS vendors in any requirements related to certification of PMSs. ONC should ensure that these vendor types are called out specifically in any potential regulation.**



# Network Participation



## Network Participation: PhIET-TF-2023\_Recommendation 29

- **Recommend that ONC recognize interactions between pharmacist and other providers as a critical component of TEF treatment exchange purpose and address the barriers and encourage education for pharmacies and pharmacists to join the TEF as it is operationalized. This should address both the ability for pharmacists to query other providers, as well as other providers to query pharmacies for patient data.**



## **Network Participation: PhIET-TF-2023\_Recommendation 30**

- **Recommend that ONC recognizes the pharmacist with public health interactions and reporting as a critical component of TEF's public health exchange purpose and address the barriers to consistent, standardized data elements and formats across the public health community, including CDC and STLTs considering reporting frameworks such as APHL's case reporting approach. This not only applies to pharmacy interoperability, but all reporting to public health by all providers.**



# Quality Measures



## Quality Measures: PhIET-TF-2023\_Recommendation 31

- **Recommend that ONC work with CMS, STLTs, and other relevant agencies to develop a value-based incentive structure using quality measures so that prescribing providers and patients and their caregivers can be timely and accurately informed at the point of e-prescribing regarding where they can fill all prescriptions, routine to urgent, in a manner that optimizes patient care and convenience. Such incentive structure should address availability of information whether a prescribed/recommended medication/intervention is available or may be in a defined timeframe at the pharmacy selected by the patient to which the patient or prescribed medication or service has been or is being considered to be sent/referred.**



# Quality Measures: PhIET-TF-2023\_Recommendation 31 (Continued)

- **This should include data on the status of drug supplies, on the expected time of medication availability and detailed tracking data on shipments for medications with all actors in the process, including pharmacists, pharmacies, ordering providers, patients, caregivers, and public health emergency systems. We suggest that a cross-sectional workshop, with a focus on the patients and caregivers, ordering providers, pharmacists, and pharmacies, go through a use case model to further inform existing standards, the necessary capabilities and gaps, including those identified in the HITAC Intersection of Clinical and Administrative Data (ICAD) Taskforce Report "A Path Toward Further Clinical and Administrative Data Integration" regarding transparency to patients as they apply to the pharmacy setting as well.**



## Quality Measures: PhIET-TF-2023\_Recommendation 32

- **Recommend that ONC work with CDC, ASPR, and STLTs in particular to identify a shared super set of key operational measures critical to situational awareness during declared emergencies across different data sources such as hospitals, clinics, pharmacies, etc. Include support for that set, which covers pharmacies as data sources as well, into the HELIOS Aggregate Data initiative to ensure implementation guidance covers these measures.**





## Quality Measures: PhIET-TF-2023\_Recommendation 33

- **Recommend that ONC work with the public health organizations, including CDC and STLTs, to create a set of metrics, measurement systems, and outcome measures specifically addressing identification of gaps and advances in exchange of critical data between pharmacists' capturing clinical data related to immunizations, medications treatments prescribed-dispensed-administered (e.g. antibiotic, antivirals, and related public health medications), and case reporting identified during the pharmacists' encounters. The measures should align with the principles of measurement science, specifically around feasibility - the ability to readily capture data appropriate to the level of analysis. Additionally, the measures should improve the quintuple aim (safety, outcomes, cost, health equity, burnout) and with the focus on the measured entity (pharmacy, health plan, hospital, etc.) have the ability to improve the measure.**



## Quality Measures: PhIET-TF-2023\_Recommendation 34

- **Recommend that ONC work with CMS to establish quality measures as part of a performance program, aligned with an ONC defined certification approach, focusing on measures that advance the adoption of interoperability. Example measures for consideration would be: (1) how many times did a patient need to call a pharmacy, how many people did they need to speak with, (2) how much time did the patient spend communicating with pharmacy and/or payor and/or provider to coordinate care, (3) how many bi-directional interactions were involved to finalize a prescription (see PhIET-TF-2023\_Recommendation 17 for examples), (4) how much time did it take from writing a prescription to it being filled for a patient, or (5) other best-outcomes focused measures such as medication adherence rates; pharmacist detection and prevention of potential adverse drug events; patient counseling time, activities, and outcomes; physician consulting time, activities, and outcomes and disease management impact.**



# Parking Lot Considerations



## Parking Lot Considerations

The following topic was considered out of scope of the charge but should be considered by HITAC whether this may be an appropriate topic for future consideration.

- The interactions with, and usability of, technologies by users yield concerns regarding whether more can or should be done to support consistent use and interactions of such technologies. Some of the variations can lead to user errors that in turn impact patient safety, while others lead to inconsistent data across providers that challenge analytics. ONC's HIT Certification Program includes criteria on the use of appropriate design guidelines in the development process (§ 170.315(g)(3) - Safety Enhanced Design) and consumer focused portals (§ 170.315(e)(1) - View, download, and transmit to 3rd party). The Task Force suggests that ONC and HITAC should further explore opportunities to align Health IT in terms of common terminology, surveys, questions, and assessments that can further advance consistency and data quality, particularly between pharmacists and other providers, while maintaining flexibility to advance new and alternative approaches.



**Discussion**

**HITAC Vote**