

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023

Recommendations to support interoperability between pharmacy constituents, and the exchange of information necessary for medication management, patient safety and consumer engagement.

Report to the Health Information Technology Advisory Committee (HITAC)

November 9, 2023



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Background

The rise of electronic prescribing is recognized as an example of successfully meeting an interoperability challenge through standards development and implementation. Despite the large success of electronic prescribing, little progress has been made to support interoperable data exchange between all pharmacy constituents involved in managing an individual's care and medication therapy. Of note, the increase in availability of pharmacy-based and pharmacist-delivered clinical services (i.e., immunization, medication therapy management, genetic testing, state-specific prescribing authorities, etc.) necessitates improved coordination between pharmacists and prescribers. Recent public health emergencies have highlighted the need to ensure that pharmacists can provide needed services without technology- or interoperability-induced delays. Innovations in medication therapies have opened a new frontier with new challenges to the prescribing and management of emerging therapies. Additionally, use of virtual care providers has exposed new data gaps in prescription services rendered that an individual's care team may not have knowledge of. For these reasons, ONC has asked the HITAC to provide a series of recommendations to support interoperability between pharmacy constituents, and the exchange of information necessary for medication management, patient safety and consumer engagement. We believe this Task Force's diverse panel of experts will be instrumental in informing possible actions ONC can take to improve interoperability for pharmacy constituents.

ONC 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.

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.
- #### 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.¹

ADDITIONAL BACKGROUND INFORMATION

The Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 (Task Force) includes an engaged group of subject matter experts representing various stakeholder groups including direct patient care providers, public health, patient and caregiver advocates, health IT developers, standards development organizations, and others. The roster included in Appendix A to this document reflects the workgroup's membership at the time these recommendations were finalized.

To assist in the development of these recommendations, the Task Force invited several external subject matter experts to give testimony regarding their areas of expertise, interest, and work. These presenters also responded to questions from Task Force members to inform their deliberations and recommendations. These included:

- On June 28, 2023, RDML (retired) Pamela Schweitzer, Assistant Surgeon General and 10th Chief Pharmacist USPHS; Lisa Schwartz, Senior Director, Professional Affairs, National Community Pharmacists Association (NCPA); Darren Townzen, Senior Director Health and Wellness Billing and Reconciliation; Walmart, Chad Worz, Executive Director and CEO, American Society of Consultant Pharmacists (ASCP); Michael Popovich, CEO and Jason Briscoe, Director of Pharmacy Operations, STC Health were invited to discuss recommendations related to SHORT-TERM Public Health, Emergency Use Authorizations, and Prescribing Authorities
- On July 12, 2023, 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 was invited to discuss Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities

¹ The task force discussed direct to consumer prescription services in which a patient receives prescription medications from a virtual care provider who is not a member of their primary care team.

- On July 19, 2023, 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; Lynn Gibbs Scharf, MPH, Chief, Informatics and Data Analytics Branch, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC; Agha (Nabeel) Khan, MD, MPH, MBA, Senior Advisor for Informatics, Office of Informatics, National Center for Immunization & Respiratory Diseases, CDC were invited to discuss Long Term Recommendation for Public Health, Emergency Use Authorizations, and Prescribing Authorities
- On July 26, 2023, Kim Boyd, President, Boyd Consulting Group, LLC; Stephen Mullinex, BS Pharm., R.Ph., Senior Vice President, Public Policy & Industry Relations, NCPDP; Richard Sage, Executive Vice President, Innovation & Standards Development, NCPDP; Josh Howland, Pharm.D., MBA, SVP Clinical Strategy & Product, RedSail Technologies were invited to discuss identify opportunities and recommendations to improve interoperability between pharmacy constituents for pharmacy-based clinical services and care coordination
- On August 9, 2023, Christian Tadrus (TF Member), Community Pharmacy Owner, and Jake Galdo, PharmD, MBA, BCPS, BCGP Managing Network Facilitator, CPESN Health Equity and CEO, Seguridad were invited to discuss identify opportunities and recommendations to improve interoperability between pharmacy constituents for pharmacy-based clinical services and care coordination
- On August 23, 2023, Phillip Lettrich, RPh, Health Policy and Business Development – Vela was invited to discuss identifying opportunities and recommendations to improve interoperability between pharmacy constituents for pharmacy-based clinical services and care coordination
- On August 30, Pooja Babbrah (TF Member), Practice Lead, Pharmacy and PBM Services, Point-of-Care Partners, and Justin Neal (TF Member), Vice President of Patient Support and Data Contract Services Noble Health Services were invited to discuss identifying standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies
- On September 20, Stephanie Garcia, Branch Chief, ONC and Mark Dunnenberger, Assistant Vice President, Personalized Medicine and Pharmacogenomics, NorthShore University Health System were invited to discuss identifying standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.
- On September 27, Ibrar Ahmed, Software and Enterprise Architecture Manager, ZS, was invited to discuss identifying standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.

Recommendations

INTRODUCTION

The focus of the Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 work was to support interoperability between pharmacy constituents, and the exchange of information necessary for medication management, patient safety and consumer engagement. The recommendations represent the views of the Task Force.

During the discussions it became clear that consistent definitions for purposes of the recommendation are critical as terms such as pharmacy, pharmacist, and providers have varying regulatory interpretations.

These terms are used as follows:

- Provider – Per 42 USC 300jj and as referenced by ONC in the 21st Century Cures Act Final Rule, the term “health care provider” includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 450 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title, an ambulatory surgical center described in section 1395l(i) of this title, a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.
- Pharmacist – A provider who is licensed and authorized to fill prescriptions and may provide other clinical services as well under a jurisdictional and/or licensed authority, e.g., initiate or modify drug and device therapies, perform tests, administer drugs, provide consults.
- Pharmacy – The organization or business entity that provides the pharmacy services that a pharmacist on staff is licensed and authorized to deliver. As many businesses referenced as “pharmacies” sell many other products and services as well, the focus here is on the organizational unit, either a department or the entire organization that operates under the authority of a pharmacist. This includes licensed pharmacy technicians and other staff working under the authority of a pharmacist.
- Other Provider – Any other provider but the pharmacist applicable to the recommendation, which may include other pharmacists.

As the task force reviewed and discussed the Charge questions, it identified the following use cases and themes plus topics that the recommendations address. These are referenced in the applicable

recommendations where the recommendation addresses one or more of these use cases, themes and topics:

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 such as:

- Prescribing (indication/diagnosis, fill status, change, cancel)
- Prior authorization, real-time formulary, benefit, and price transparency information
- Immunizations
- Public health electronic case reporting
- Medication lists, including Over-the-Counter (OTC) medications, vitamins, herbals, supplements, discontinued medications, and the reasons for discontinuation
- Recommendations for medication use, dispensing, and availability of prescriptions including inventory availability
- Pharmacogenomics (PGx) laboratory results and recommendations for changing medications
- Laboratory and point of care test results
- Demographics and social determinants of health data
- Diagnoses and/or indication for medication use
- Patient Encounter Disease Management
- Other data relevant to medication optimization
- Patient Education, Counseling, and Adherence data
- Access to clinical trial opportunities

Incorporate Pharmacist into the Care Team

Focuses on coordinated collaboration to manage and implement a patient's care plan across all care team members such as:

- Care Planning / Care Gaps / Care Coordination (Pharmacist eCare Plan)
- Event Notification (ADT, fill status, public health issues, immunizations, etc.)
- Transitions of Care (ToC) including medication reconciliation (MR) and medication-related data (e.g., cognitive and function status, patient preferences, language, SDOH, including housing, transportation, disease state dietary restriction, etc.) with a Standardized Medication Profile (SMP)

Consumer Engagement

Focuses on the pharmacist interactions and data sharing with the patient directly such as:

- Full transparency to the patient and their caregivers when data is used and shared/disclosed with other providers or parties
- Information on whether the product is on hand and information on the quantity available to fill a prescription

- Coordination where/how patient can obtain prescriptions when unavailable at 1st pharmacy and/or next steps if drug is unavailable anywhere due to drug shortages/supply issues
- Comprehensive privacy policies and consent directives management to maximize data sharing where authorized

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 such as:

- Identifying patients whose active medication lists are not optimized
- Medication prior authorization workflow related to population bias (e.g., pediatrics, geriatrics, disease management, etc.)
- Immunization reconciliation

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. This includes measures such as:

- Clinical outcomes: Assessment of renal function in older adults; Assessment of weights in pediatrics; Pain management safety; Improving diabetes safety; Known allergy status; Medication indication; Understanding of social determinants of health
- Process: Point of care testing structure; Electronic care plan accessibility; Prescription order to fill efficiency and challenges, e.g., coordination and communication between pharmacist, prescriber, and payer; Ability to capture clinical and medication data to query and or push to HIEs/QHINs
- Staffing: Employee vaccination rate; Advanced pharmacy technicians on staff

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 such as:

- Medication reconciliation across care team members
- Access to complete medical record by all care team members
- Outcomes measures for medication management of disease states such as diabetes, hypertension, and asthma

Public Health

Focuses on the interactions between pharmacists and public health agencies such as:

- Public health reporting (e.g., immunization reporting, electronic laboratory reporting (ELR), eCR, syndromic surveillance, registry reporting)
- Public health Insights

- Public health emergency data access (e.g., problems, allergies, meds, vitals, labs, vaccines, drug recalls, etc.)

Patient Safety

Focuses on capabilities specific to advancing patient safety such as:

- Reporting adverse drug events and medication errors
- Population bias in clinical decision support (CDS) tools especially with artificial intelligence (AI) and or machine learning (ML) algorithms
- Patient safety reporting with digital therapeutic (DTx) applications

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

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.

LIST OF SPECIFIC RECOMMENDATIONS

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.

Rationale: Pharmacists increasingly participate in the test-to-treatment process beyond the pharmacist's historical role of dispensing medications. Pharmacists need access to patients' complete and pertinent medication list, diagnoses, and/or relevant laboratory results enabling appropriate testing and treatment decisions. This is complicated because the prescribing physician's EHR does not necessarily contain all patients' medication information, or other relevant clinical data, thus the pharmacist needs access to other providers' EHRs that have relevant data on the patients. At the same time other providers need access to the patient's medical record established by the pharmacist as they document their observations, guidance, and procedures when interacting with the patient. Public health requires access to conduct health activities and investigations. Without respective access to patient records, it's difficult to ensure appropriate clinical decisions based on all known data and/or implement potential public health/emergency interventions. This also ties into health equity initiatives as there may be areas (rural, etc.) where the only available "clinician" or "provider" is a pharmacist. Pharmacies already use the Pharmacist eCare Plan developed by NCPDP and HL7(R) (using HL7 CDA(R) and HL7 FHIR(R)) with payers, while adoption of sharing that data with providers is limited. At the same time, privacy policies and patient consent directives must be consistently honored across all providers and other data holders. Patients may have different concerns about sharing data with different care team members – they may want some care team members to have access to all information (e.g., physicians having full access), while other members (e.g., nursing, pharmacists) may have limited access. As with all healthcare data and across all providers, patients should have transparency on who is accessing and sharing their data, as well as on their rights to consent or not to access and sharing of their data; where such consent rights exist, they must be honored. Pharmacy entities should be held accountable for providing transparency and honoring consent rights.

References:

- *Questions:* Topic 1 – Short Term (a); Topic 1 – Long Term (a)
- *Use Cases:*
- *Themes and Topics:* Standards and Data Exchange; Pharmacist-Other Provider Collaboration and Clinical Data Sharing



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.

Rationale: The ability for pharmacists and providers to easily communicate not only during normal operations, but also during emergency use interventions is critical. As demonstrated in the recent Public Health Emergency, pharmacists can be a vital component of test-to-treat and public health processes. That means not only advancing the prescription and medications specific interactions, but also expanding access to clinical data relevant to treatment decisions by both the provider and pharmacist as either may be the original source for that data. I.e., it is not limited anymore to the data necessary for filling the prescriptions as pharmacists may prescribe medications (as permitted by state regulation). Pharmacy information can be used in public health surveillance (medication use as an indicator of population health), public immunization status (pharmacy-administered immunizations), and product and service availability. Standards such as NCPDP's SCRIPT, TELECOM, Pharmacist eCare Plan, and HL7's CDA C-CDA and FHIR standards are either already available or rapidly emerging for the various interactions of interest. Adoption and participation in the necessary network arrangements and having the necessary pharmacy management system (PMS) capabilities to connect must be areas of focus. As public health is not universally a component of pharmacy operations, dedicated funding would facilitate the development of the pharmacy/pharmacist interaction with public health. As the participation of pharmacies and pharmacists in the test-to-treat processes is not limited anymore to emergency use interventions but increasingly during normal operations as well. This focus can have a substantial impact on the quality of care and decision making that can ultimately benefit the patient and their care.

References:

- *Questions:* Topic 1 – Short Term (a); Topic 1 – Short Term (b)
- *Use Cases:* All
- *Themes and Topics:* Standards and Data Exchange; Pharmacist-Other Provider Collaboration and Data Sharing Needs; Pharmacist Data Capture

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.

Rationale: Policy and awareness considerations beyond ONC's scope are essential to advance sharing across pharmacies, pharmacists and public health organizations and realize the benefits of the task force's/HITAC recommendations. Particularly the task force notes that:

- While advancing adoption and operationalizing interoperable PMSs with other Health IT, particularly EHRs, and reporting critical data to public health organizations, including CDC and STLTs, clarity on pharmacists' authorities and roles in the patient care process beyond filling prescriptions is essential. Clarity through policies and data sharing agreements, particularly but not limited to national networks, streamlines the ability for interoperable Health IT to actually share data based on trust and authority.

- Statewide protocols or standing orders are more functional and less burdensome than collaborative practice agreements, particularly during emergency use interventions. Such protocols provide a broad, typically non-patient specific approach and are focused on public health. They can support pharmacies receiving reimbursement without complicated and time-consuming credentialing processes. This would reduce the significant cost burdens to payers and speed access to care, particularly of interest during emergency use interventions. Such adoption is beyond the scope of ONC, but where adopted the recommendations above further enable the use and deployment of statewide protocols that include pharmacists' authorizations for point of care testing, test-to-treat, ordering of Labs and prescribing of countermeasures to help address immediate authorized public health interventions.

References:

- *Questions:* Topic 1 – Short Term (b); Topic 1 – Long Term (a)
- *Use Cases:* Public Health
- *Themes and Topics:* Standards and Data Exchange

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: 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:

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

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.

Rationale: Several technologies and standards have been deployed and adopted by the provider community with the aid of a variety of incentives that has led to a substantial increase in data sharing. It is imperative for patient safety and care coordination that pharmacists are part of this national data sharing infrastructure and be held to the same standards of documentation, access, exchange and use as other clinicians providing similar services. Pharmacies and pharmacists are also considered actors under the 21st Century Cures Act information blocking provisions. Thus, any contractual provisions among exchange partners that include restrictions on the exchange of critical electronic health information could be considered a form of information blocking when done with intent to restrict access to electronic health information as defined in the 21st Century Cures Act. Fulfilling the obligations for data sharing under the 21st Century Cures Act information blocking provisions should not lead to a multitude of proprietary and varied solutions, rather be

fully integrated and build on the same standards being deployed for the provider community as another critical goal is to advance standards-based interoperability without special effort.

References:

- *Questions:* Topic 2 (a); Topic 2 (b)
- *Use Cases:* All
- *Themes and Topics:* Information Sharing/Blocking

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.

Rationale: As both PBMs and payers hold clinical data for value-based payment models and electronic clinical quality measures, such data should be accessible to providers as well to support a quality measure reporting under such models.

References:

- *Questions:* Topic 2 (a); Topic 2 (c);
- *Use Cases:* VBC Quality Measures Cross Care Team
- *Themes and Topics:* Technology and Data Exchange

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.

Rationale: Sharing the prescription information as well as any associated assessment notes and documentation captured during virtual/ telehealth providers' interactions with patients, including prescription services, is not only relevant to the other members of the patient's care team, but from a patient safety and care coordination perspective, critical to the appropriate delivery of care for all care team members, including those providers in the care team who are not yet connected. While the patient may not authorize such sharing, with full understanding of the potential impacts, the capability should be available and use interoperability standards consistent with those used for similar interactions in other pharmacy settings, e.g., NCPDP SCRIPT, HL7 v2/CDA/FHIR. When this data is not shared, this may lead to inaccurate medication lists, drug-drug interactions problems, and medication errors.

References:

- *Questions:* Topic 4
- *Use Cases:* Bi-Directional Access to Individual Patient Data Supporting Testing Through Treatment Process; Incorporate Pharmacist into the Care Team; Patient Safety
- *Themes and Topics:* Standards and Data Exchange; Pharmacist-Other Provider Collaboration and Data Sharing Needs; Privacy and Consent

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.

Rationale: During emergency use intervention, but also during normal operations, the inclusion of pharmacies and pharmacists in the test-to-treatment processes beyond filling prescriptions expanded the relevant data that pharmacies and providers capture that is also relevant to public health. There is a need for pharmacists and pharmacies to understand reporting requirements and available methods. Methods and standards available to other providers should be made available for use by pharmacies as well establishing a consistent reporting process across all members of the care teams. Alternative data sources, such as claims where available (e.g., Medicare claims for CDC), may not be adequate as these may not cover all the data of interest while other methods, e.g., case reporting and electronic laboratory reporting would. Timely communication of relevant, complete, accurate, clinical data from pharmacies and pharmacists is critical to further inform public health agencies.

References:

- *Questions:* Topic 1 – Short Term (a); Topic 1 – Short Term (b); Topic 1 – Long Term (a)
- *Use Cases:* Public Health
- *Themes and Topics:* Standards and Data Exchange; Pharmacist - Public Health Collaboration and Data Sharing Needs; Pharmacist Data Capture; Pharmacist-Other Provider Collaboration and Clinical Data Sharing

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.

Rationale: Payers' rules regarding which prescription medications require prior authorization change over time and vary by payer. Prescribing providers, pharmacists, patients, and caregivers need to understand what medications may require pre-authorization and what data is necessary for payers to review pre-authorization requests. If payers communicate whether a particular medication requires prior authorization at the point of care, it will be easier to ensure timely provision of relevant information.

References:

- *Questions:* Topic 1 - Short Term (a); Topic 1 – Short Term (b)
- *Use Cases:* Consumer Engagement; Bi-Directional Access to Individual Patient Data Supporting Testing Through Treatment Process
- *Themes and Topics:* Pharmacist-Other Provider Collaboration and Data Sharing; Standards and Data Exchange

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.

Rationale: Currently there is no warning that a formulary is/has changed until a refill is requested and the patient is told it's not covered or requires a prior authorization. As well, patient's selecting an insurer during CMS open enrollment periods have only limited access to the potential costs covered by a PBM. In addition, this is limited to only drugs, with no information on devices available for coverage, nor does it attempt to provide a patient with information of the impact of a selected drug on other care costs and outcomes. This puts a significant burden on patients and their caregivers to contact the insurer, inquire about /learn about the formulary change, contact the doctor to provide the doctor with the type of information the health plan needs to approve the medication, coordinate the process with the doctor's office and the insurance company, etc. The administrative burden is unexpected and substantial. The time required to manage is significant, and communications between the insurance company and doctor's office are not always as efficiently managed as needed. Often this means the patient goes without a medication they have needed/relied upon for their health/disease management - for weeks and in some cases months. The disruption to health status is significant, can be dangerous and completely unavoidable and the unnecessary burden placed on patients who are already ill.

References:

- *Questions:* Topic 1 – Short Term (a); Topic 1 – Short Term (b)
- *Use Cases:* Consumer Engagement
- *Themes and Topics:* Standards and Data Exchange; Pharmacist-Other Provider Collaboration and Data Sharing

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.

Rationale: Typically, a pharmacy app/portal only indicates that there's "an insurance issue" or "more information is needed from your provider" but there is no detail on what the issue is or what information is needed. Since the patient or their caregiver is typically forced to manage the process and be the go between the pharmacy, physician and insurance company, they must have the detailed information about the issue to be able to act. This information is available in structured fields at the pharmacy, but it is not shared with the patient or their caregiver. To figure out the problem, one must call or visit the pharmacy, wait on hold/in line and get a printout of the needed information from the pharmacists' portal. This can be a very lengthy process in which patients and their caregivers may wait on hold for hours or need to go to the pharmacy and wait in line there. To further facilitate communications, having messaging capabilities to query for, follow-up on, or communicate about a status or issue, can further enable patients or their caregivers to be informed and progress the completion of their prescription.

References:

- *Questions:* Topic 1 - Short Term (a)
- *Use Cases:* Consumer Engagement
- *Themes and Topics:* Standards and Data Exchange

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.

Rationale: As pharmacies are increasingly engaged in the test and treatment processes, particularly during emergency use interventions, data on FDA-regulated medical products, including drugs, vaccines, biologics, and medical devices would extend beyond prescriptions filled, and include vaccines, testing, and use of medical devices of interest. Thus, inclusion into the surveillance process can further advance the critical insights needed during emergencies as well.

References:

- *Questions:* Topic 1 – Long Term (a)

- *Use Cases:* Public Health
- *Themes and Topics:* Pharmacist – Public Health Collaboration and data Sharing

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.

Rationale: As ML and AI advance, ONC should work closely with the FDA on how to manage software-hardware-dataset technologies that can self-teach, self-manage, and initiate decisions and actions on patient care cases. For example, the FDA might require ongoing clinical trials, where self-learning technology will be included in a comparative, randomized clinical trial with humans for each area of specialty and receive an FDA-approved indication much like a board certification for the indicated practice type (e.g., diagnosis, therapeutics, nursing care, etc.) Once FDA-approved, the "software-hardware combination" will be "licensed" to practice in a healthcare specialty and will have to undergo periodic board recertification in order to continue to practice (i.e., be utilized) in a patient care setting.

References:

- *Questions:* Topic 1 – Long Term (a)
- *Use Cases:* Patient Safety
- *Themes and Topics:* Standards and Data Exchange

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.

Rationale: While various networks provide query capabilities enabling gathering relevant data from multiple data sources where the patient may have records, there is still a need to directly inform the patient's care team members with any point of care testing and documentation.

References:

- *Questions:* Topic 1 – Short Term (b)
- *Use Cases:* Bi-Directional Access to Individual Patient Data Supporting Testing Through Treatment Process; Incorporate Pharmacist into the Care Team; Patient Safety
- *Themes and Topics:* Pharmacist-Other Provider Collaboration and Data Sharing Needs

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.

Rationale: If some information (demographic, other) is not known or available through other data sources, pharmacies are an ideal in-person patient contact point to solicit (or confirm) such information. Developing a suggested method/format for engaging patients during this contact would benefit the entire healthcare system by enabling sharing a more complete patient record.

References:

- *Questions:* Topic 1 – Long Term (a)
- *Use Cases:* Incorporate Pharmacist into the Care Team
- *Themes and Topics:* Pharmacist Data Capture



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.

Rationale: Increasingly more data is being shared electronically automatically, yet current tools and data tagging capabilities are insufficient to support effective and efficient sharing of all the data that one is authorized to access. The reality is that consent information is stored in multiple systems and in non-computable formats, further complicating the issue. Data is shared when it should not or is not shared where it should. There is strong interest in exploring whether an automated mechanism that is 1) based on the most current, computable policies and that 2) can be leveraged for any transaction that needs to be pushed or is provided in response to a query, is an achievable and effective solution for helping to ensure all eligible data authorized to share is actually shared and that data that is not authorized to be shared is not shared. As data can be shared through a variety of methods and channels it is imperative that all methods and channels, including those between payers, PBMs, and pharmacies, are considered as part of the larger privacy policy and patient consent management and validation approaches and considerations across all data sharing participants.

References:

- *Questions:* Topic 1 – Long Term (a); Topic 2 (b)
- *Use Cases:* Bi-Directional Access to Individual Patient Data Supporting Testing; Through Treatment Process; Consumer Engagement; Patient Safety
- *Themes and Topics:* Privacy and Consent

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.

Rationale: USCDI includes data elements for fill status, but there is no required interaction between pharmacists and prescribers to inform the prescriber about the fill status. Similarly, to improve care coordination, timely awareness of changes to the prescription is essential. Patients and their caregivers should have insight in such updates, as well as awareness who is receiving their data particularly if additional clinical information on the patient is included.

References:

- *Questions:* Topic 2 (a); Topic 2 (b)
- *Use Cases:* Bi-Directional Access to Individual Patient Data Supporting Testing Through Treatment Process; Incorporate Pharmacist into the Care Team; Consumer Engagement; VBC Quality Measures Cross Care Team; Pharmacy Quality Measures for Clinical Pharmacy Services
- *Themes and Topics:* Standards and Data Exchange; Pharmacist-Other Provider Collaboration and Data Sharing Needs

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).

Rationale: There is no agreed upon secure instant messaging capability enabling direct, interactive exchange of PHI between pharmacists and other providers and care team members, e.g., to follow-up on certain prescriptions or other aspects of the patient's care. Current message

capabilities are asynchronous or not considered sufficiently secure to include PHI. Having a standards-based capability would enable a more immediate and security method of addressing a patient's care needs.

References:

- *Questions:* Topic 2 (a); Topic 2 (b)
- *Use Cases:* Incorporate Pharmacist into the Care Team
- *Themes and Topics:* Standards and Data Exchange

PHIET-TF-2023 Recommendation 19: Recommend that ONC includes event notification capabilities with pharmacies and pharmacists as part of a focused, modular certification approach.

Rationale: As pharmacies and pharmacists are further integrated into the care delivery process relevant notifications, e.g., suspend automatic refills based on an inpatient admission, scheduling, as well as other events such as awareness of an emergency with associated notices during such an even, are made available to the pharmacies and pharmacists as well.

References:

- *Questions:* Topic 1 – Short Term (a); Topic 2 (a); Topic 2 (b)
- *Use Cases:* Incorporate Pharmacist into the Care Team
- *Themes and Topics:* Standards and Data Exchange; Pharmacist-Other Provider Collaboration and Data Sharing Needs

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.

Rationale: Patient matching and record linkage is a universal challenge, not unique to pharmacies. As advances are made, the pharmacy community should be fully involved to consistently and widely support any advances made.

References:

- *Questions:* Topic 2 (a); Topic 2 (b)
- *Use Cases:* All
- *Themes and Topics:* Standards and Exchange

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.

Rationale: In the absence of a unique patient identifier, patient matching quality remains a challenge. As data is de-identified for certain analytics and research the ability to link data from disparate sources to the same person is lost as the identifying information has been removed. Tokenization and PPRL, with relevant standards and infrastructure, shows promise in advancing the ability to establish a more complete patient record that is worthy of further pursuit in a collaborative approach while limiting the risk of compromising the patient's identity. Less than complete records, i.e., data not all being connected to the same person, impacts certain analytics and research where such context is critical. At the same time, we recognize that tokenization across diverse data sources remains challenging to connect a patient record across those sources. Use of network level record locator services ability to link patient records should also be considered in these approaches.

References:

- *Questions:* Topic 1 – Short Term (a); Topic 1 – Long Term (a)
- *Use Cases:* Public Health
- *Themes and Topics:* Standards and Data Exchange; Pharmacist-Other Provider Collaboration and Clinical Data Sharing

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.

Rationale: For emerging therapies such as pharmacogenomics, sharing of laboratory results using consistent terminologies require translations from device specific nomenclature to industry standard vocabulary. It is important that, as results are provided back to the clinician, that relevant and appropriate industry standard vocabulary is available. This is needed to enable consistent interpretations across clinicians and the potential for analytics and clinical decision support.

References:

- *Questions:* Topic 3 (a)(iii)
- *Use Cases:* Bi-Directional Access to Individual Patient Data Supporting Testing Through Treatment Process
- *Themes and Topics:* Standards and Data Exchange

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.

Rationale: Advancing and acceleration of data sharing on a common standards framework has the ability to drive economies of scale, consistency, and improved data quality by reducing the variations and translations that need to be maintained. Such an approach will further advance the ability to access and use minimum necessary data following USCDI consistent with other providers. Without a clear path to a standard approach, further supported through a certification program and a related set of incentives, can reduce the progression of proprietary solutions.

References:

- *Questions:* Topic 2 (a)
- *Use Cases:* Bi-Directional Access to Individual Patient Data Supporting Testing Through Treatment Process, Incorporate Pharmacist into the Care Team, Consumer Engagement
- *Themes and Topics:* Standards and Data Exchange

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
- 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.

Rationale: Introducing a certification approach enables a common, predictable data sharing approach among providers and including pharmacies expands on the ability for providers and pharmacists to share and access a more complete patient record as they care for the patient. Consideration should be given to specialty certification and consider bi-directional certification of eRx transactions, e.g., RxChange, RxFill, and CancelRx, as well as clinical data through standards encouraging the use of additional transactions to support clinical data exchange. Absent a certification approach there is insufficient clarity on how pharmacy management systems can enable consistent interoperability without special effort to reduce the risks of information blocking, while continuing use of proprietary solutions. We do note regarding the Pharmacist eCare Plan that various updates are in progress that would be considered important to be addressed before including the Pharmacist eCare Plan into a certification program.

References:

- *Questions:* Topic 1 – Short Term (b); Topic 1 – Long Term (a)
- *Use Cases:* All
- *Themes and Topics:* Standards and Data Exchange; Pharmacist Data Capture

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.

Rationale: Pharmacists need the ability to access health records w/ labs, meds, and other clinical information, particularly during emergencies when their role in the test-to-treat process can be expanded, but also where such data is relevant during normal operations. At the same time, the patient's primary care physician and other care team members need health records w/ labs, meds, and other clinical information, particularly during emergencies when the pharmacist role in the test-to-treat process can be expanded, but also where pharmacists already provide those services during normal operations.

References:

- *Questions:* Topic 1 – Long Term (a)
- *Use Cases:* All
- *Themes and Topics:* Pharmacist-Other Provider Collaboration and Data Sharing Needs



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.

Rationale: Demographic data is not always made available through fundamental reporting such as case reporting to public health organizations that can contain all relevant context information, including demographics, for a patient. Either the case report is not required for the analysis at hand, it is directed to another public health department and not shared, the source does not support case reporting, or any other reason that one cannot rely on case reporting having provided the relevant data. Yet, the ability to perform analytics requires that all data feeds include all relevant race and ethnicity, and other key demographic data for such analytics. Thus, various prescribing and laboratory results reporting capabilities need to be able to support sharing of the relevant when an alternative source is not consistently available. While it is important to share no more than needed, where there is a need and the data is not otherwise available, e-prescribing transactions should be able to convey that data while minimizing impact on receiving systems that otherwise may not have any need for that data. While the pharmacy is in a number of these situations the originating source, inclusion is not a challenge, but where the data has to come from another source through pharmacy that may be a challenge as the original source may not have that data either.

References:

- *Questions:* Topic 1 - Short Term (b)
- *Use Cases:* Public Health
- *Themes and Topics:* Pharmacist Data Capture

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.

Rationale: Under the Social Security Act pharmacists are not recognized as providers, thus cannot be paid by Medicare for therapy management and patient consultation services. Yet during emergency use interventions such as the COVID pandemic as well as expanded participation in the test-to-treat processes, clear benefits have been demonstrated to fully enable pharmacists in those expanded roles. Until this is fully recognized, incentives for pharmacies/pharmacists to adopt Health IT that manages and supports those roles, particularly to enable data sharing with providers as part of an integrated care team, will slow down adoption. Reimbursement limited to emergency use interventions does not provide sufficient incentives to advance essential adoption of the necessary Health IT to ensure full access to the necessary data for all care team members.

References:

- *Questions:* Topic 1 – Long Term (a)
- *Use Cases:* All
- *Themes and Topics:* Standards and Data Exchange; Resources 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.

Rationale: As ONC has substantially engaged with the provider focused Health IT vendors, particularly EHR vendors, including pharmacy management systems vendors and other relevant pharmacy focused Health IT developers to identify practical certification criteria will be equally important, while maintaining consistency across the larger Health IT systems that the overall certification program is relevant to.

References:

- *Questions:* Topic 3 (a)(i)
- *Use Cases:* All

- *Themes and Topics:* Standards and Data Exchange; Information Sharing/Blocking

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.

Rationale: The advancing and emerging networks should not be limited to the inpatient and outpatient provider community, but rather all care settings should be able to easily connect including pharmacies and pharmacists. Additionally, pharmacies and pharmacists are providers under the 21st Century Cures Act information blocking provisions. Pharmacists and other providers both have the right and responsibility to (a) access clinical data via available means to inform treatment decisions, and (b) make available upon valid request all EHI generated when providing care related to emergency use interventions and normal operations where they are part of the test-to-treat process.

References:

- *Questions:* Topic 1 – Short Term (b)
- *Use Cases:* Bi-Directional Access to Individual Patient Data Supporting Testing Through Treatment Process; Incorporate Pharmacist into the Care Team; Consumer Engagement; Patient Safety
- *Themes and Topics:* Pharmacist – Other Provider Collaboration and Clinical Data Sharing; Information Sharing/Blocking

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.

Rationale: Ensuring that pharmacists and providers have access to the latest patient records, within their authorities based on law, privacy policies, and patient consent directives, TEF enables all those involved in the treatment process to access and share the patient's records. Thus, adoption by both providers and pharmacists will enable consistent access to the relevant data through a common platform, rather than pharmacists and providers separately developing a combination of point-to-point capabilities with different data sharing agreements. TEF has the opportunity to have a data sharing agreement established once that all parties can agree to.

References:

- *Questions:* Topic 1 – Short Term (b)
- *Use Cases:* Public Health,
- *Themes and Topics:* Information Sharing/Blocking; Standards and Data Exchange; Pharmacist – Other Provider Collaboration and Data Sharing

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. 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.

Rationale: Currently there is no way to inform the prescribing provider or the patient if a pharmacy, drug distributor (and sometimes the manufacturer) has the prescribed drug in supply. Often, lack of communication between the pharmacy, prescriber and patient can lead to lack of visibility as to the status or availability of medications. This lack of communication and or visibility may result in substantial delays in patients receiving medications hours, days, and at times, even weeks later as one is trying to find the pharmacy with the appropriate supply on hand. Prescriptions may need to be transferred and re-routed multiple times due to insurance or other restrictions and factors when attempting to fill and often may not be filled at all due to limited distribution scenarios or supply shortages. Delays are not only time consuming and burdensome for patients and other stakeholders, but importantly may also result in poor health outcomes.

Having better information about the pharmacy, or pharmacies that best meets the patient's needs as stated by the patient or their caregiver.

References:

- *Questions:* Topic 1 – Short Term (a); Topic 2 (b); Topic 2 (d)
- *Use Cases:* Consumer Engagement
- *Themes and Topics:* Standards and Data Exchange; Information Sharing/Blocking

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.

Rationale: Pharmacies and pharmacists provided an important, expanded role/authority during the pandemic in the test-to-treat process, while during normal operations their role/authority in the test-to-treat process may remain expanded or further expand. As such it is important that pharmacy reporting is consistent with reporting across all relevant data sources for the same data they have available. Thus, definition of relevant measures and inclusion in the rollout of the HELIOS Aggregate Data capabilities should encompass pharmacies and pharmacists as a critical data source as well.

References:

- *Questions:* Topic 1 – Short Term (a)
- *Use Cases:* Public Health
- *Themes and Topics:* Pharmacist – Public Health Collaboration and Data Sharing

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.

Rationale: Currently, measures are captured based on IIS registries to track individual's immunization and program performance overall, but do not identify pharmacy/pharmacist specific contributions to the advancement, completeness, and quality of both data sharing with and from public health entities at local, state, and federal levels.

References:

- *Questions:* Topic 1 – Long Term (a)
- *Use Cases:* Pharmacy Quality Measures of Clinical Pharmacy Services; Public Health
- *Themes and Topics:* Standards and Data Exchange

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.

Rationale: Outcomes-based measures can be positively impacted by advanced use of interoperability, transparency and access to data by the ordering provider and patient. Use of outcomes-based measures can also enable use of well-defined incentives that can drive the adoption of the necessary PMS functionality to connect pharmacies and pharmacists to the relevant networks integrating pharmacies, pharmacists, and other providers across the entire care team.

References:

- *Questions:* Topic 2 (a); Topic 2 (c)
- *Use Cases:* Pharmacy Quality Measures of Clinical Pharmacy Services
- *Themes and Topics:*

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.



Appendix A

TASK FORCE ROSTER

Name	Organization
Shelly Spiro ^{***} (Co-Chair)	Pharmacy HIT Collaborative
Hans Buitendijk* (Co-Chair)	Oracle Health
Pooja Babbrah ^{***}	Point-of-Care Partners
Chris Blackley ^{***}	Prescriptive
Shila Blend*	North Dakota Health Information Network
David Butler ^{***}	Curatro, LLC
Steven Eichner*	Texas Department of State Health Services
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network
Adi V. Gundlapalli ^{**}	Centers for Disease Control and Prevention
Jim Jirjis ^{**}	Centers for Disease Control and Prevention
Summer Kahlon ^{***}	Rocket Health Care
Steve Lane*	Health Gorilla
Meg Marshall ^{**}	Department of Veterans Health Affairs
Anna McCollister*	Individual



Deven McGraw*	Invitae Corporation
Ketan Mehta***	Micro Merchant Systems
Justin Neal***	Noble Health Services
Eliel Oliveira*	Harvard Medical School & Harvard Pilgrim Health Care Institute
Naresh Sundar Rajan*	CyncHealth
Scott Robertson***	Bear Health Tech Consulting
Alexis Snyder*	Individual
Fillipe Southerland*	Yardi Systems, Inc.
Christian Tadrus***	Sam's Health Mart Pharmacies
Sheryl Turney*	Elevance Health
Afton Wagner***	Walgreen Co.

* HITAC MEMBER **FEDERAL REPRESENTATIVE *** EXTERNAL SME

Appendix B

ABBREVIATIONS

ADT - Admission, Discharge, and Transfer

APHL - Association of Public Health Laboratories

ASPR - Administration for Strategic Preparedness and Response

CDA - Clinical Document Architecture - An HL7 document standard

C-CDA - Consolidated Clinical Document Architecture - AN HL7 document implementation guide based on CDA.

CDC - Centers for Disease Control and Prevention

CMS - Centers for Medicare and Medicaid Services

eCQM – Electronic Clinical Quality Measures

eCR - Electronic Case Reporting

ELR - Electronic Laboratory Reporting

FHIR - Fast Healthcare Interoperability Resources - An HL7 standard

HL7 - Health Level 7 - A standards development organization for the v2, CDA, FHIR and other standards

HIT - Health Information Technology

HITAC - Health Information Technology Advisory Committee

HTI-1 - Health Data, Technology, and Interoperability - An ONC (proposed) rule to advance interoperability, algorithm transparency, and information sharing

IIS - Immunization Information System

IT - Information Technology

LIVD - LOINC - IVD Test Code Mapping - An HL7 FHIR based implementation guide

LOINC - Logical Observation Identifiers Names and Codes

LTPAC - Long Term Post Acute Care

MR - Medication Reconciliation

NABP - National Association of Boards of Pharmacy

NCPDP - National Council for Prescription Drug Programs - A standards development organization of the SCRIPT and other standards.

NLM - National Library of Medicine

ONC - Office of the National Coordinator

OTC - Over the Counter

PGx - Pharmacogenomics

PMS - Pharmacy Management System

SDOH - Social Determinants of Health

SMP - Standardized Medication Profile

SNOMED - Systematized Nomenclature for Medicine - A standards development organization

STLT - State, Tribal, Local, or Territorial public health departments

TEF - Trusted Exchange Framework - An ONC national network initiative under the 21st Century Cures Act

ToC - Transition of Care

USCDI - UNITED STATES CORE DATA FOR INTEROPERABILITY



Appendix C

INDEX OF TOPICS/QUESTIONS

Question	Recommendation Reference
1. Public Health, Emergency Use Authorizations, and Prescribing Authorities	
<u>Short-term</u>	
a. Identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions.	PhIET-TF-2023_Recommendation 01 PhIET-TF-2023_Recommendation 02 PhIET-TF-2023_Recommendation 08 PhIET-TF-2023_Recommendation 09 PhIET-TF-2023_Recommendation 10 PhIET-TF-2023_Recommendation 11 PhIET-TF-2023_Recommendation 19 PhIET-TF-2023_Recommendation 21 PhIET-TF-2023_Recommendation 31 PhIET-TF-2023_Recommendation 32
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?	PhIET-TF-2023_Recommendation 02 PhIET-TF-2023_Recommendation 03 PhIET-TF-2023_Recommendation 08 PhIET-TF-2023_Recommendation 09 PhIET-TF-2023_Recommendation 10 PhIET-TF-2023_Recommendation 14 PhIET-TF-2023_Recommendation 24 PhIET-TF-2023_Recommendation 26 PhIET-TF-2023_Recommendation 29 PhIET-TF-2023_Recommendation 30
<u>Long-term</u>	
a. Recommendations to better integrate pharmacy systems and data for public health surveillance, reporting and public health interventions.	PhIET-TF-2023_Recommendation 01 PhIET-TF-2023_Recommendation 03 PhIET-TF-2023_Recommendation 08 PhIET-TF-2023_Recommendation 12 PhIET-TF-2023_Recommendation 13 PhIET-TF-2023_Recommendation 15 PhIET-TF-2023_Recommendation 16 PhIET-TF-2023_Recommendation 21 PhIET-TF-2023_Recommendation 24 PhIET-TF-2023_Recommendation 25 PhIET-TF-2023_Recommendation 27 PhIET-TF-2023_Recommendation 33
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?	PhIET-TF-2023_Recommendation 04 PhIET-TF-2023_Recommendation 05 PhIET-TF-2023_Recommendation 06 PhIET-TF-2023_Recommendation 17 PhIET-TF-2023_Recommendation 18 PhIET-TF-2023_Recommendation 19



	PhIET-TF-2023_Recommendation 20 PhIET-TF-2023_Recommendation 23 PhIET-TF-2023_Recommendation 34
b. Which priority pharmacy-based clinical use cases should ONC focus on in the short-term and long-term?	PhIET-TF-2023_Recommendation 05 PhIET-TF-2023_Recommendation 16 PhIET-TF-2023_Recommendation 17 PhIET-TF-2023_Recommendation 18 PhIET-TF-2023_Recommendation 19 PhIET-TF-2023_Recommendation 20 PhIET-TF-2023_Recommendation 31
c. What technology gaps exist for pharmacists to participate in value-based care?	PhIET-TF-2023_Recommendation 04 PhIET-TF-2023_Recommendation 06 PhIET-TF-2023_Recommendation 34
d. What can ONC do to address drug inventory transparency for prescribers and consumers?	PhIET-TF-2023_Recommendation 31
3. Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.	
I. specialty medications II. digital therapeutics III. gene therapies	PhIET-TF-2023_Recommendation 22 PhIET-TF-2023_Recommendation 28
4. Identify policy and technology needs and considerations for direct-to-consumer medication services.	PhIET-TF-2023_Recommendation 07