PRIORITY USES OF HEALTH INFORMATION TECHNOLOGY

RECOMMENDED STANDARDS & IMPLEMENTATION SPECIFICATIONS

Report of the Health Information Technology Advisory Committee's Interoperability Standards Priorities Task Force to the National Coordinator for Health Information Technology

Abstract

This report summarizes the findings of the Interoperability Standards Priorities Task Force and makes specific recommendations regarding standards and implementations specifications supporting identified priority uses of health information technology as called for by the 21st Century Cures Act.

I. Executive Summary

The 21st Century Cures Act (Cures Act) requires the Health Information Technology Advisory Committee (HITAC), in collaboration with the National Institute for Standards and Technology (NIST), to annually and through the use of public input, review and publish priorities for the use of health information technology (HIT) as well as the standards and implementation specifications to support those priorities. This report meets that directive by summarizing the activities of the Interoperability Standards Priorities Task Force (ISPTF) between Fall 2018 and Fall 2019, describing priorities, recommendations and suggested policy actions for ONC consideration.

II. Overview

The HITAC standards adoption priorities were identified under section 3003 of the 21st Century Cures Act as implementation of the incentive program for the Meaningful Use of Certified EHR Technology (CEHRT), the Merit-based Incentive Payment System (MIPS), Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary of Health and Human Services (HHS). More specifically, the priorities are related to quality of patient care, public health, clinical research, privacy and security of electronic health information, innovation in the field of health information technology, patient safety, usability of health information technology, access to electronic health information and other priorities determined to be appropriate by the Secretary.

In identifying such standards and implementation specifications stated above, the HITAC was charged to prioritize the selected standards and implementation specifications developed by consensus-based standards development organizations.

As stated in the Cures Act, beginning 5 years after the date of enactment of the Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to maintain or phase out the use of such standards and implementation specifications.

The HITAC, in collaboration with the National Institute of Standards and Technology (NIST), shall review and publish priorities annually through the use of public input, regarding health information technology, standards, and implementation specifications.

III. Overarching Task Force Charge

As indicated in section 3003 of the Public Health Service Act, the ISPTF was established by the HITAC and charged to identify priority uses of health information technology consistent with the Cures Act's identified priorities, standards and specifications that best support or may need to be developed for each identified priority, and subsequent steps for industry and government action.

In the identification of priority standards and implementation specifications, the Cures Act specifies that the standards that were developed by the consensus-based methods used by standards development organizations should be of highest priority. During the initial meetings, the Task Force reviewed the mission/charge, and the members identified high priority uses of health IT (HIT) and rank-ordered them through a voting process. Following this ranking and group discussion of the results, the Task Force decided, by consensus, to focus on the three uses below. If given more time, the Task Force could explore and make recommendations regarding the additional uses in future deliberation. The Task Force was charged to publish a report on its findings and make recommendations to the larger HITAC.

<u>Priority Uses of Health IT Addressed in this Report:</u>

1. Orders & Results

2. Closed Loop Referrals & Care Coordination

3. Medication & Pharmacy Data

<u>Additional Priority Uses Recommended for Future Consideration:</u>

4. Evidence-Based Care for Common Chronic Conditions

5. Social Determinants of Health

6. Cost Transparency (note: this topic was a central focus for the Medication use above)

IV. Task Force Membership

The membership of the ISPTF is shown below. The Task Force included a wide range of stakeholders, including healthcare providers, EHR and other HIT vendors, payers, governmental organizations, and a patient advocate.

Ken Kawamoto, Co-Chair, University of Utah Health	**Steven Lane, Co-Chair, Sutter Health**
Ricky Bloomfield, Public Member, Apple	Tina Esposito, HITAC Member, Advocate Aurora Health
Tamer Fakhouri, Public Member, Livongo Health	Cynthia A. Fisher, HITAC Member, WaterRev, LLC
Valerie Grey, HITAC Member, New York eHealth Collaborative	Edward Juhn, Public Member, Blue Shield of California
Anil K. Jain, HITAC Member, IBM Watson Health	Victor Lee, Public Member, Clinical Architecture
Leslie Lenert, HITAC Member, Medical University of South Carolina	Arien Malec, HITAC Member, Change Healthcare
David McCallie, Jr., Public Member, Individual	Clem McDonald, HITAC Member, National Library of Medicine
Terrence O'Malley, HITAC Member, Massachusetts General Hospital	Ming Jack Po, Public Member, Google
Raj Ratwani, HITAC Member, MedStar Health	Ram Sriram, HITAC Member, National Institute of Standards and Technology
Sasha TerMaat, HITAC Member, Epic	Andrew Truscott, HITAC Member, Accenture
Sheryl Turney, HITAC Member, Anthem Blue Cross Blue Shield	Scott Weingarten, Public Member, Cedars-Sinai Health System
Mark Roche, Federal Representative, Centers for Medicare and Medicaid (retired)	

V. Task Force Recommendations Development

The following recommendations were proposed by the ISP Task Force and endorsed by the full HITAC following review, discussion, and modification.

For each area, the task force:

- Invited subject matter experts to provide input and consultation
- Identified issues that could be improved upon through better use of health IT
- Formulated recommendations to address the issues, as well as potential policy levers
- Iteratively refined the recommendations through feedback from the task force, members of the public, and the larger HITAC

For each area, this report provides:

- A patient story that illustrates how the recommendations, if adopted, could improve health and health care
- Tier 1 issues, along with observations, recommendations and potential policy levers. These are the top priority issues the HITAC recommends addressing.
- Tier 2 issues, along with observations, recommendations and potential policy levers. These are also important issues in the view of the HITAC, but with less urgency compared to the Tier 1 issues

In addition, overarching recommendations are first provided for issues that cross multiple priority use domains.

VI. HITAC Recommendations [pending HITAC review/edit/approval]

A. Cross-Domain Recommendations

Public availability of health IT standards (including code sets and terminologies) required by federal programs

Observations:

Some health IT standards required by federal programs, including standard code sets and terminologies, are not publicly available.

- There is significant benefit in public availability of health IT standards required by federal programs including EHR certification, to ensure public review and compliance.
- Not all code sets are maintained by certified standards development organizations.
- Organizations that develop and maintain standards and code sets depend on a sustainable business model in order to carry out their work with the level of quality that is appropriate to standards required by federal programs.

Recommendations:

- Support public availability of all health IT standards required by EHR certification criteria.

Policy Levers / Responsibilities:

- ONC: Potentially in partnership with federal organizations such as the Centers for Medicare and Medicaid Services (CMS) or National Library of Medicine (NLM), consider paying for a U.S. license to standards required by EHR certification criteria, similar to how the U.S. government currently pays for a national Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT) license.
- To avoid perverse incentives (e.g., penalizing those standards development organizations that have already opted to make their standards openly available at no cost), support both:
    - Standards that are not currently publicly available, assuming they make them publicly available
    - Standards that are publicly available now, but whose future availability and maintenance could be jeopardized without such support

Price Transparency

Observations:

Healthcare costs are a major challenge facing many U.S. consumers and households. Price transparency was a key component of the recommendations provided around medications/pharmacy data below, but it affects many other domains, including imaging, procedures, durable medical equipment, and hospitalizations.

- Consumers have an interest in understanding the total prices of individual products and services as provided by various sources or vendors, as well as the net out-of-pocket cost that they would have to or will pay based on their individual circumstances, including coverage, deductibles, discounts, negotiated rates, etc.
- Price transparency supports competition and choice for healthcare consumers.
- Price transparency was one of the priority areas identified by the ISPTF, but which the ISPTF did not have sufficient time to tackle.

Recommendations:

- Advance price transparency in all aspects of clinical care.
- Health IT standards should include mechanisms for conveying price data, including both the cash price and the net out-of-pocket costs to individuals to the extent possible.

Policy Levers / Responsibilities:

- ONC: Advance standards for price transparency. Charge a task force, which could be a continuation of the ISPTF, to further assess and provide recommendations in this area.
- CMS: Encourage or require the use of such standards for enabling price transparency.

Multiple competing standards

Observations:

There are often multiple, sometimes competing, standards that may need to be maintained as the industry moves toward single standards where appropriate and as new technologies, such as FHIR, are integrated into workflow. At the same time, a clear single best approach may not be available. There is a need for a process to “retire” standards that have been supplanted by subsequent versions, possibly as part of advancement of the Interoperability Standards Advisory (ISA).

Recommendations:

- Actively seek out and identify opportunities to consolidate and simplify the health IT interoperability landscape.
- ONC should avoid "picking winners" prematurely (e.g., Direct Messaging vs. Fast Healthcare Interoperability Resources (FHIR)-based referral; Consolidated Clinical Document Architecture (C-CDA) vs. FHIR-based care record interchange) and remain open to potential alternative approaches, such as those that are in widespread use for

the specific use case or for other related use cases. A standard should not be "picked as a winner" prior to sufficient validation, ideally in real-world use, leveraging standard maturity assessments as discussed in other ONC work efforts such as the ISA and the U.S. Core Data for Interoperability (USCDI).

Policy Levers / Responsibilities:

- ONC
    - Where appropriate (such as in the case of failure of the industry to reach consensus on its own), commission/support effort(s) to identify functional overlap between standards and opportunities for consolidation and/or harmonization.
    - For individual ONC-funded projects, consider including required and/or optional tasks for exploring such cross-use-case harmonization and de-duplication in the project scope.
    - Convene practicing clinicians, HL7, the Argonaut Project, EHR vendors, and other relevant stakeholders to identify specific use cases that would warrant a standards evolution path to allow applicable functionalities to potentially also function in FHIR.
    - Develop certification criteria and associated CMS programmatic changes to allow a flexible transition to the appropriate use of the FHIR standard where this technology is deemed superior for a given clinical use case.

Patient Access to Data

Observations:

Patients' access to their own data is important for patient-centered, patient-engaged care. A detailed discussion with recommendations is provided in the Orders & Results section below, but this issue affects more than orders & results.

Recommendations:

- Support patients' access to their data, in realms beyond orders & results (e.g., clinical notes, goals, care plans, histories, and vital signs).

B. Orders & Results

Illustrative Story of what Recommendations will Enable:

After getting your annual laboratory tests completed, you receive an email notification the next day that your results are available in your personal health record (PHR) associated with your EHR. You open the results on your smartphone PHR application, and can see all the results, including normal ranges, with a note that the data were provided to you as soon as they were available, and that your doctor may not yet have reviewed the results. Because all laboratory tests are now encoded using a standard known as Logical Observation Identifiers Names and Codes (LOINC), there are standard, patient-friendly test names and information resources that have been linked to them. For example, for your slightly low calcium level, there is a link to a MEDLINEPlus patient resource (e.g., https://medlineplus.gov/ency/article/003477.htm) that explains the significance of this minor abnormality. By the afternoon, your doctor has added a note, of which you are notified, to not worry about the slightly low calcium as it is likely due to your kidney disease, is unchanged from your previous result, and will be checked again later. Your doctor is easily able to trend your lab result data on a graph, including data obtained from your other care providers, because each laboratory result is LOINC-encoded, enabling similar lab tests obtained from across the healthcare systems to be displayed, compared, and trended together – something that was not possible until recently through a public-private partnership.

Tier 1 Issues and Recommendations:

Need for consistent encoding of tests and their result values

Observation:

Laboratory and other tests and their results are not consistently encoded with appropriate standard codes, limiting the ability to exchange actionable results between HIT systems, also known as “semantic interoperability.” In this report, “tests” (Observation Identifiers) refer to the *test performed* (e.g., hemoglobin A1c test [LOINC code 4548-4], systolic blood pressure, bacteria identified in blood by culture), whereas “results” or “values” (Observation Values) refer to the *value* of those tests (e.g., 7.4%, 140 mm Hg, Neisseria meningitidis [SNOMED CT code 17872004]).

Recommendations:

- Require and enforce the use of an information model standard (e.g., that a laboratory result should include a code, value, reference range, etc.) and associated terminology standard (e.g., that a laboratory code should use LOINC) for all test

orders and results. Terminology standards are inadequate on their own to meet semantic interoperability needs; standard information models are also needed.

- Resulting organizations, (e.g., labs, imaging centers, providers), should provide LOINC codes to identify all clinical tests, and send these LOINC codes with the results when reporting or exchanging this data via messages, documents, application programming interfaces (APIs), or other future transport mechanisms.
- When result observation values are coded (as opposed to free text, as in the "bacteria identified in blood by culture" example above), resulting organizations should use SNOMED CT concepts to encode the observation value.
    - An ONC resource about where to use LOINC vs. SNOMED when reporting observations is the 2019 ONC ISA guidance section II: (https://www.healthit.gov/isa/sites/isa/files/inline-files/2019ISAReferenceEdition.pdf).
    - The International Health Terminology Standards Development Organisation (IHTSDO), which is the owner of SNOMED CT, has also published "Using LOINC with SNOMED CT": (https://confluence.ihtsdotools.org/display/DOCLOINC/Using+LOINC+with+SNOMED+CT).
- Assure that there is a well-managed and appropriately resourced process to develop and deliver additional LOINC codes when needed for new tests or needed variations of existing tests. This could take the form of more formal support for the current process to submit, review, and if appropriate approve new LOINC codes.
- Prioritize complete and accurate coding at the data source (e.g., laboratory/laboratory information system [LIS]) and instrument vendors rather than trying to code, or correct the coding of, externally sourced data downstream. Attempting to assign a LOINC code in an EHR (after the LIS has generated the result) is always going to be riskier and harder to maintain than ensuring the LOINC code is assigned accurately at the point of origin of the test.
- EHRs, LISs and radiology information systems (RISs) should be required to provide a mechanism that allows clients/users to map internally generated results and result codes (including observations and values) to standard vocabularies in cases where coding is not done at the source.
- Implement mechanisms to support and ensure proper LOINC and SNOMED CT encoding by resulting agencies, such as auditing and/or certification by the Clinical Laboratory Improvement Amendments (CLIA).

Policy Levers / Responsibilities:

- ONC

- Use available EHR data sources to assess current compliance with Laboratory Results Interface (LRI) specifications and LOINC and SNOMED encoding to identify areas for additional focus.
- Work with Health Level 7 International (HL7) and industry stakeholders to create a LRI companion guide for HL7 Medical Document Management (MDM) and associated content and terminology standards to allow standards-based exchange of textual reports. While introducing more structured data in reports vs. free text may be useful, the intent is not to forbid or inhibit the use of free text where appropriate.
- As necessary, support the work of LOINC and others to address problems that are currently encountered when new tests, observations, methodologies, and instruments are introduced. Potential areas to consider for prioritization include:
    i. EHRs and other health IT systems should support the use of local codes and/or standard codes other than LOINC when a LOINC code would otherwise be most appropriate to use but an appropriate LOINC code is not yet available for use. Note that the FHIR specification supports such an approach, and that what may be needed is EHR and health IT system support for such an approach. This type of an approach should still ensure that there is motivation to submit proposed codes to LOINC where needed.
    ii. Accelerate existing LOINC work to represent hierarchical relationships with respect to how granular/specific the LOINC codes are (e.g., have a general code for a test, have more specific codes capturing test + methodology combinations along the lines of the “Group” tables being developed by LOINC)
    iii. Explore how to deal with time lags between requests for new lab test codes required by new test observation methodologies and instruments. Potential approaches include the addition of resources to speed up the process, the accelerated delivery of processed requests (e.g., through LOINC pre-release content, https://loinc.org/prerelease/), and perhaps making pre-pre-release content available for well-documented new requests.
- Continue to work with CMS, the Centers for Disease Control and Prevention (CDC) and associated industry stakeholders to harmonize information models and terminology standards to Electronic Clinical Quality Measure (eCQM) definitions and reportable disease requirements.
- Continue coordination with Food & Drug Administration (FDA), CLIA, and NLM to establish mappings between the outputs of analyte devices and LOINC terms.

- FDA
    - Continue to promote the use of LOINC in diagnostic device approval and oversight and in the delivery of clinical trial results.
- CMS

    - Establish safe harbors or fast lanes for achieving CLIA quality obligations through delivery of HHS-endorsed standard-based results (e.g., LRI with LOINC encoding) electronically to certified EHRs.
    - Require certification under CLIA to HHS-endorsed standard-based results (e.g., LRI with LOINC encoding).
    - Work with NIST to develop and provide a testing program to assure compliance.
    - Should the above steps be insufficient to promote consistent standards-based interoperability, require certification as a condition of participation and/or payment for laboratories.
    - LOINC-based coding of tests and SNOMED CT-based coding of coded test values should be enforced by CLIA regulations. If this enforcement is ineffective in assuring that coded data are delivered consistently, use of codes for these data should be made a condition of payment by CMS. There should be exceptions, as is done in the case of US Core FHIR profiles, where an appropriate LOINC code does not exist to identify an observation, or where a required value cannot or should not be represented using a SNOMED CT code.

The level of granularity of standard codes differ according to use, causing challenges

Observations:

There are several issues with regard to the granularity of standard codes. In some cases, they may be too specific for certain uses (e.g., a clinical user generally would not care about the specific laboratory mechanism used to obtain a patient's low-density lipoprotein [LDL] cholesterol level). In other cases, the available LOINC codes, or the ones selected/assigned to a test, may be insufficiently granular (e.g., for quality reporting purposes). Moreover, the level of granularity that is appropriate may differ according to use case (e.g., need to be as specific as possible for a lab, vs. a common desire to have the "same" lab trended together for a clinical user).

Recommendations:

- Where standard codes do not exist at the required level of granularity, either create such a code or a code grouper (e.g., LOINC rollups/equivalence classes) at the desired level of granularity.
- Where standard codes do exist but their usage is suboptimal or problematically inconsistent in terms of the level of granularity, consider seeking industry consensus on the appropriate approach.

Policy Levers / Responsibilities:

- ONC:
    - Facilitate the addition of codes with sufficient granularity where needed.
    - Facilitate creation of code groupers at the desired level of granularity.
    - Facilitate gaining industry consensus on appropriate level of granularity for specific use cases where needed.

Semantic interoperability requires standardization and industry consensus around information models (including meta-data) and associated terminologies

Observations:

Not all results are sent to clinicians in codified format with the use of industry-consensus information models (including necessary meta-data) and associated standard terminologies to allow integration and optimal use in EHRs. While there is general industry consensus on information models for “simple” results (e.g., a “simple” laboratory test), there is no industry consensus on more complicated results (e.g., blood pressure when considering issues such as cuff size, position, or whether orthostatic; wound cultures; etc.). For example, LOINC includes panels that present a post-coordinated approach to blood pressure measurements that specifically callout cuff size, standing vs. sitting and other attributes, but they are not universally used.

- To move beyond semantic interchange of “simple” results, more advancement is needed in these more complicated areas. Potential approaches to developing and defining these more complex information models include the use of more granular FHIR profiles, the use of Clinical Information Modeling Initiative (CIMI) models, learning from OpenEHR archetypes, etc. Health IT vendor support for such post-coordinated models will be critical for their utility.
- Such standardized delivery of information could allow, for example, trending semantically equivalent test results together, leveraging the results in clinical decision support, and providing interpretations of results based on the patient’s test results combined with other patient characteristics.

Recommendations:

- While the long term goal is to be able to exchange all clinical data with standardized information models and associated terminologies, in the short term there would be value

in identifying and prioritizing the most common/important results of each order type (including but not limited to laboratory, imaging, cardiac, pulmonary, and neuro-muscular) for standardization and exchange.

- Collaboration with clinical groups is essential. For example, in the area of referral requests, consider working with clinical groups, e.g., the American Medical Association (AMA) and/or professional/specialty societies, to define standards and expectations of collection/exchange for structured documentation of key observations that should be included in referral requests such as ejection fraction for congestive heart failure. For example, ejection fraction already exists in LOINC, but there is NOT industry consensus that the information should be exchanged if collected in a system, or that a heart failure referral should include that information.
- A relevant activity, Problem List MD (Meta Data) (https://problemlist.org/), relates problems/diagnoses to relevant tests and current treatments (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5373762/) and has been created in collaboration with specialty experts. This approach could serve as a foundation for more targeted resources needed for use cases such as referrals. Perhaps more importantly, it shows how clinical groups can be engaged for defining a relevant set of data for important use cases.
- Consider the priorities of multiple stakeholders/use cases, e.g., patients, clinicians across multiple disciplines, population health management, payers, quality measurement and reporting, safety, public health, and research.
- For prioritized results, specify which information models and/or LOINC code(s) should be used based on the test characteristics.
- Use the U.S. Core Data for Interoperability (USCDI) to assure that prioritized results are interoperable via HL7 Version 2 (V2), Consolidated Clinical Document Architecture (C-CDA), and FHIR.
- Mapped standard codes (i.e., LOINC for the observation ID and SNOMED CT for coded values of tests) must be included with test result data maintained in EHRs and other HIT systems.
- Metadata, including mapped standard codes and, in particular, order/result statuses, must be included with test result data as it is transmitted between HIT systems (e.g., LISs, imaging systems, EHRs, PHRs, health information exchanges [HIEs], payers, and public health organizations).
- Require that resulting agencies provide standardized metadata (including methodology, units [e.g., using Unified Code for Units of Measure [UCUM] units as called for by the FHIR standard], reference range, abnormal flags, etc. as applicable) to ordering, copy to, and other clinicians who subsequently request and/or retrieve result data.
- Consider whether data regarding the equipment/device generating the result should be included with recommended/required metadata.

Policy Levers / Responsibilities:

- ONC

    - Work with HL7 and other industry stakeholders to map and harmonize USCDI to LRI, Laboratory Order Interface (LOI) and associated implementation guidance, and Argonaut-profiled FHIR. Also support end-to-end stakeholder testing of discrete lab result and report transmission to providers and patients.
- CMS
    - Establish guidance promoting use of standards (e.g., LRI, LOINC and others) with certified HIT to address laboratory requirements for accurate reporting.
    - Include laboratory and other result transmittal requirements in Advanced Alternative Payment Model (APM) program requirements (e.g., require Medicare Shared Savings Program [MSSP] applicants to specify how provider participants will receive standards-based electronic laboratory results).
    - Work with NIST to develop and provide testing program to assure compliance.
- Other Federal Agencies
    - Require use of standards-based laboratory receipt in Veterans Administration (VA), Department of Defense (DoD), Military Health Service (MHS), Indian Health Service (IHS), and other applicable federal provider organizations (e.g., Department of Justice, Department of Homeland Security).

Non-medication orderables need to be standardized between systems and with mapping to standard terminologies

Observations:

Non-medication orderables are not standardized between systems and lack mapping to standard terminologies, limiting the portability and interoperability of both orders and results. Standardized codes should be used for orderable tests, similar to how RxNorm can be used for medication orders.

Recommendations:

- Support an ongoing consensus development process to prioritize the most common/important orderable tests of each order type, including the orders that link to prioritized results.
- Support the harmonization, advancement, and consensus development of standards-based catalogs of orderable tests, with mappings to associated code systems and codes, and with special emphasis on the following domains:
    - Lab orders, using LOINC Universal Lab Orders as a standard catalog of orderable tests. Non-panel LOINC codes can be used for ordering tests when they are specified as orderable.

    - Lab order details such as frequency, priority, timing, and other special instructions as prioritized in conjunction with community stakeholders.
    - Radiology orders and order details such as imaging modality, anatomic location, laterality, number of views, use of contrast, and priority (which are usually pre-coordinated in radiology test names and available in the LOINC/RSNA/RadLex catalog at https://loinc.org/collaboration/rsna/ and at https://search.loinc.org).
    - Encourage referral laboratories and health systems to submit their order specifications to LOINC for assignment of standard codes.
      Note that LOINC codes have already been defined for 61% of one large referral lab's over 8,000 orderables tests, so the gap for LOINC coding for orderable tests is closing.
    - Also, include other special instructions as prioritized in conjunction with community stakeholders.
- Standardize commonly used **order panels**, building on the existing initial list of order panels currently cataloged by LOINC.
    - LOINC has growing numbers of LOINC tests panels that go well beyond the relatively old and small set listed in the Common Order Codes Value Set.
- Support and assure the harmonization of the multiple existing code sets for orderable tests. Consider terminologies such as SNOMED CT, Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) billing codes, Proprietary Laboratory Analyses (PLA) codes, and LOINC codes as code sets requiring harmonization.
- Ensure terminologies are at a sufficient level of granularity to support the level of specificity needed for actual ordering systems. Avoid the use of proprietary or fee-based terminologies in the standardization of orderables and order details and make the work product of this initiative freely available to all users.
- Harmonize orderables and order details with existing information models in mind (e.g., FHIR, Clinical Information Modeling Initiative [CIMI]) so the appropriate degree of pre-coordination or post-coordination of terminologies can fit existing information models; and/or work with data model stewards to modify data models to match clinically meaningful order/order detail syntaxes.

Policy Levers / Responsibilities:

- ONC
    - Spearhead creation and adoption of industry standards around non-medication orderables. Consider prioritizing the most high-value/high-use orderables for standardization first.
    - Leverage prior work, such as RadLex/LOINC and the recommendations in the 04/30/2015 ONC LOINC Order Code S&I Framework Initiative report. See https://loinc.org/file-access/download-id/9526/ and

https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/LOINC+Order+Code.

Results need to be available for patients and their proxies to effectively view, receive, and use

Observations:

Not all results are available for patients and their proxies to effectively view, receive, and use.

Recommendations:

- Require that ordering providers make final results available to patients/proxies within a reasonable time frame, as allowed by state laws, assuring that, where appropriate, providers have an adequate opportunity to review and comment on results to facilitate patient interpretation. Collect industry experience and promulgate best practices.
- Enable an opt-in approach to earlier results release, such as results release as soon as final results are available. For example, if a patient specifies that her preference is to immediately receive results regardless of the content (e.g., a pathology report which may indicate cancer, and should be reviewed with a physician to properly interpret), work towards enabling such preferences to be honored.
- Make all results (including textual reports) in the EHR available to patients via APIs, free of charge, as allowed by state law, whether or not results are mapped to standard code sets.
- Encourage and eventually require resulting agencies to make results available electronically, directly to patients, as allowed by state laws, via APIs, free of charge. This could initially be encouraged via CLIA regulations. As necessary, this could be required as a condition of payment for resulting agencies.
- Encourage and eventually require the use of standard "patient friendly" order and result display names for patients based on LOINC standards (This work is in process; see https://loinc.org/download/loinc-display-name-file/).
- Recommend supporting the alignment of state and federal policies to assure consistent and predictable data accessibility to patients. This should begin with the development of a catalog of varying state and territorial requirements, followed by facilitation of the specification and promulgation of national standards to promote maximal sharing of data with patients in both human and machine readable formats.
- Advance and consider requiring the use of technical standards to support the secure authentication of patients and their designated proxies to support access to results including via mobile and cloud technology.

Policy Levers / Responsibilities:

- CMS
    - Make patient access to data via APIs a required measure for relevant programs.
    - Continue to promote patient access and API requirements using certified health information technology.
- ONC
    - Facilitate completion and maturation (with relevant stakeholder feedback) of ongoing LOINC work to define patient-friendly result display names.
    - Encourage and facilitate the use of these terms for patient-facing purposes.
    - Expand the scope of API requirements to include access to all results, through the USCDI process, to eventually include "all data" as required by the 21st Century Cures Act.
    - Build off of existing OCR guidance re: Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.

Need vendors to send unique reference IDs for results data

Observations:

Many vendors do not consistently send unique Reference IDs for discrete results data. This makes it difficult to identify and accurately update data already received. This issue also applies to data beyond orders and results (e.g., prescriptions).

Recommendations:

- All systems should generate, use, and send unique and consistent Reference IDs for all orders, procedures and result components.
    - The FHIR Observation Identifier is a persistent identifier that will identify a given result no matter where it is sent. The Observation Identifier could provide most of what is needed to deduplicate results.
- Require interoperability of order/result Reference ID metadata with orders and results such that receiving systems can recognize a specific order or result as having been received previously.
- Internal identifiers must be persistent and not change over the life cycle of an order or result.
- Internal identifier data inclusion should be independent of transport mechanism (e.g., HL7 v2, LOI, LRI, C-CDA, FHIR) and it should not matter if, e.g., an initial result arrives

via a LRI and a correction arrives via FHIR – the duplicated or modified result should be obviously detectable.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

<u>Tier 2 Issues and Recommendations:</u>

Result data exchanged between HIT systems may not include sufficient provenance metadata

Observations:

Result data exchanged between HIT systems may not include sufficient provenance metadata for the recipient to understand the source of the data.

- The FHIR Observation Identifier is a persistent identifier that will identify a given result no matter where it is sent. The Observation Identifier could provide most of what is needed to deduplicate results.
- FHIR is also developing a resource to deal specifically with provenance.
- This topic was brought up in the latest ONC NPRM and is also being worked on as a part of the Argonaut project.

Recommendations:

- Require interoperability of provenance metadata with orders and results.
- Provenance data inclusion should be independent of transport mechanism (e.g., HL7 v2, LOI, LRI, C-CDA, FHIR).

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

Need a standard way to differentiate the type of result within C-CDA documents

Observations:

There is currently no standard way to differentiate the type of result (e.g., Radiology, Microbiology, Pathology) sent in a C-CDA document.

Recommendations:

- Create a C-CDA standard component that identifies the different Result Types included in the Results section of a document and add it to current exchange specifications. Consider using the FHIR diagnostic report category codes or an expanded version of the same.
- Assure that FHIR specifications for test result components include the exchange of Result Type metadata to allow filing and integration of results by Type in receiving systems.

Policy Levers / Responsibilities:

- ONC & HL7
    - Convene stakeholders to advance the C-CDA standard to address clinical content and usability of received results data.

The C-CDA and FHIR standards do not prescribe how to group result components

Observations:

The C-CDA and FHIR standards do not prescribe whether to send result components individually or grouped by ordered/resulted procedure.

Recommendations:

- The C-CDA and FHIR standards should be updated to require that transmitted result components, whether sent with documents or as resources, be grouped by ordered procedure in order to keep the necessary context for interpretation on the receiving side.

Policy Levers / Responsibilities:

- ONC & HL7
    - Convene stakeholders to advance the C-CDA and FHIR standards to address clinical content and usability of received results data.

Integrate external decision support

Observations:

There is a need for a standard methodology to integrate external decision support for clinicians, patients and other stakeholders into the full range of order and results workflows.

Recommendations:

- Support the advancement of standards such as Clinical Decision Support (CDS) Hooks.
- Support the development of Hooks that can be activated/used when a provider or patient receives and/or is reviewing a result.
- Support the development and use of standards to determine and expose/display net pricing and suggested alternative order information to relevant stakeholders including ordering providers, clinical support staff, payers, and patients.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

Support the integration of prior authorization into EHR-based ordering workflows

Observations:

There is a need for standards to support the integration of prior authorization (PA) into all applicable EHR-based ordering workflows (e.g., medication ordering/prescribing, imaging, other test orders, procedures, referrals, durable medical equipment (DME) orders).

Recommendations:

- There is a need for standard methodologies to integrate external decision support for clinicians, patients and other stakeholders into the full range of order and results workflows including medications, laboratory, imaging, devices, supplies, and referrals.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

Tampering or other data modification may occur

Observations:

Results and other externally sourced observations may pass through many systems including consumer and unregulated app vendor-controlled systems where tampering or other data modification may occur.

Recommendations:

- With the advancement of consumer-mediated exchange, clinicians may not be able to tell if an order, result or document has been tampered with while under the control of the patient or unregulated HIT vendor system.
- Explore the value of requiring digital signatures on appropriate order and result data.
- A digital signature should allow the originating system to be confirmed, and the values to be verified, and reveal any tampering that may have occurred.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

C. Closed Loop Referrals & Care Coordination

Illustrative Story of what Recommendations will Enable:

You have a headache that has been occurring for much of your adult life, but recently it's starting to really interfere with your activities. In talking with your primary care doctor, she thinks it would be helpful for you to be seen by a headache specialist at the local university hospital. In her EHR, she starts the referral process, and she can also ideally see who is available to accept referrals in the specialty and associated coverage and costs. You can also see what providers are available and can discuss with your provider the best specialist for you to see. You and your provider see that the specialist she recommends does have availability and will be able to see you within a couple of weeks. Your personal physician is informed that, for a referral for a chronic headache, the specialist requests that specific laboratory and imaging tests be done prior to the consultation. Most of the recommended evaluations have already been done, so they are automatically identified in your record and sent over to the specialist's office with the referral. For the remaining items, your doctor places the orders, and lets you know the results will be automatically sent to the specialist the following day. You are now all set for the visit, knowing that the specialist will have all of the necessary information to perform a thorough and efficient evaluation. The headache specialist has some recommendations on the latest treatments, which are automatically sent back to your primary care doctor. The consultant's report includes the full documentation of the consultation, what has been recommended, the medications that were prescribed, the expected outcome, and the circumstances in which you should be referred back for further evaluation. The new medication works wonders, and your primary care doctor is fully in the loop, with the information already in your local medical record for when she needs to refill your prescription a few months down the line.

Tier 1 Issues and Recommendations:

Closed-loop Communication

Observations:

Current referral workflows are inefficient, and they fail to leverage available interoperability tools. This leads to increased cost, delays in care and poor care coordination.

- Needed patient care may be delayed due to difficulty identifying who is available to accept a referral, and what is their availability.
- Patients simply given a phone number to arrange their own appointment may never follow up.

- Specialist may not receive information required to efficiently and effectively care for the patient.
- Even when information is provided, if that information is not discrete data it cannot be ingested from the sending EHR system into the recipient EHR system, leading potentially to expensive data transcription, transcription errors and adverse events.
- Important information is lost, and unnecessary care delays are introduced, due to the lack of closed-loop communications between referring providers and consultants.
- There is promising work being done by the 360X Project to support closed loop referrals that leverages C-CDA for clinical content, Direct protocols for transport, XDM for establishing context, and HL7 v2 messages for referral workflow. This has been successfully tested, but is still in a pre-pilot stage.
- The success of 360X is dependent on specific patient identity management capabilities and the use of referral identifiers by EHR vendors.
- There are currently multiple potential methodologies for representing message context.
- FHIR supports provider directories as well as clinical and workflow messaging, and it could potentially provide an alternative transport mechanism to support referral workflows.

Recommendations:

- Establish minimum baseline requirements for HIT solutions supporting closed loop referral management, building on the work done by the 360X Project.
- Requesting systems must support:
    - Sending a referral to an external system
    - Receiving update messages from an external system
    - Support statuses including: Requested, In Progress, Cancelled, Rejected, Complete
    - Sending, receiving and managing cancellation messages
    - Receiving a referral from an external system
    - Receiving Update messages from an external system
    - Supporting statuses (as above)
    - Sending, receiving and managing cancellation messages
    - Providing available schedule information, and supporting external scheduling
- Encourage/support pilots of the 360X Project functionality with a variety of EHR systems and healthcare organizations.
- Iteratively enhance 360X approach based on real-world feedback.
- Encourage expansion of use cases for 360X beyond ambulatory referral management to include other referrals and transitions of care (e.g., acute care to and from long-term and post-acute care [LTPAC] services).
- Encourage exploration of the use of 360X for order and referral PA use cases.
- Make sure the referral approach, whether via 360X or an alternate mechanism, includes insurance and PA information to determine acceptability of referrals and to enhance real time scheduling.

- Support the 360X standards for Patient Identity Management and the further development and expansion of these capabilities to allow all referral orders to be tracked to completion.
- Encourage/support efforts to harmonize/unify existing approaches to representing Message Context (e.g., XDM and the DirectTrust Implementation Guide (IG) (http://wiki.directproject.org/file/view/Implementation+Guide+for+Expressing+Context+in+Direct+Messaging+v1.1.pdf)).
- Investigate how FHIR-based approaches can best be leveraged to support closed loop referral and care coordination messaging workflows.
- Encourage/support pilots of Argonaut Scheduling for external appointment creation.

Policy Levers / Responsibilities:

- ONC
    - Support 360X piloting via grants, contracts, certification requirements and/or facilitation and coordination.
    - Support FHIR-based efforts to address closed-loop referral and care coordination messaging needs.
    - Include defined baseline closed loop referral capabilities as a requirement for certification.
- CMS
    - Align relevant programs, including MIPS, MSSP, medical home, etc., to reward activity that improves care through electronic closed-loop referral.

Clinical data collected prior to and sent at the time of referring a patient

Observations:

- There is no standardization regarding what clinical data should be collected prior to referring a patient to a given specialist for a given problem or symptom.
- There is a need for specialty-specific minimum standards regarding what information the “referred to” clinician requires from the “referring” clinician to provide an effective and efficient clinical response for a specific clinical issue.
- Payers have varying requirements regarding the information required and criteria that must be satisfied in order to provide PA for referrals. These payer requirements must be aligned with best practice guidelines determined by recognized medical/specialist organizations.
- This need is also relevant to transitions between care settings, such as referrals to the acute care setting, e.g, emergency department, from any source, and discharges from acute to post-acute care.

Recommendations:

- Identify an organization, or convene and support a collaboration, to develop and evolve recommendations for what clinical data consulting/receiving providers should be sent in order to optimize the efficiency and value of referrals/consultations for all parties (e.g., patient, referring provider, payer, referred to provider, other members of the care team). Begin with prioritizing the top 80% of referral diagnoses across specialties.
- Identify, catalog and, as necessary, manage and evolve best practice standard data elements necessary for collection and transmission to support efficient, patient-centric referral workflows and processes including associated PA requirements.
- Potential collaborators:
    - American Medical Association (AMA) Integrated Health Model Initiative (IHMI)
    - 360X Project Group
    - Council of Medical Specialty Societies (CMSS)
    - Physicians' Electronic Health Record Coalition (PEHRC)
    - Physicians Consortium for Performance Improvement (PCPI)
    - Healthcare Services Platform Consortium (HSPC)
    - Healthcare Information and Management Systems Society (HIMSS)
    - Electronic Health Record Association (EHRA)
    - Da Vinci Project
    - FHIR at Scale Taskforce (FAST)
- Consider piloting FHIR Argonaut Questionnaires when additional information, beyond top 80%, is needed.
- Explore the use of referral management apps (e.g., using SMART technology solutions) to support referral management workflows and the associated information exchange.

Policy Levers / Responsibilities:

- ONC
    - Convene and/or support stakeholders to profile minimal standards of clinical and administrative data required and desirable for clinical referrals, with exemplars in C-CDA and FHIR, including best practice guidance for display of those standards.
    - Align the clinical referral profiles with the USCDI; specifically, allow for clinically relevant profiles of USCDI to be sent in clinical referral workflows.

Clinician to Clinician Patient-specific Messaging

Observations:

EHR-integrated solutions for secure clinician-to-clinician patient-specific messaging are lacking, especially when clinicians work in different organizations or with different EHR/HIT systems.

- While currently required Transitions of Care messaging and 360X leverage Direct, this standard has been implemented inconsistently by EHR and other HIT vendors and operationalized inadequately by many providers and healthcare organizations.
- The features and functions necessary to support the clinical usability of Direct messaging have been enumerated and prioritized (App Clin Informatics, Vol. 9 No. 1, 2018).
- Direct interoperable features, functions, implementations and usage could be improved, and FHIR could potentially support secure clinical messaging and provide an alternative transport mechanism for this function.

Recommendations:

- Support and incentivize EHR and clinician user adoption of functionality necessary to fully use the capabilities of Direct and/or other compatible transport mechanisms for cross-organizational secure clinical messaging.
- There should be a standard way to query this directory whether it is centrally located or federated.
- Ensure small physician practices have sufficient support.
- Investigate how FHIR-based approaches can be developed and leveraged to support clinical messaging for referrals and care coordination.

Policy Levers / Responsibilities:

- CMS: continue to encourage addition of contact and communication addresses needed for interoperability for providers via the National Plan and Provider Enumeration System (NPPES) central repository of provider information.

Referral Management & Care Coordination

Observations:

Referral management and care coordination both require the ability to reliably identify and locate providers and to have an understanding of the messaging capabilities of each provider.

- Argonaut has published a provider directory implementation guide (http://www.fhir.org/guides/argonaut/pd/).
- HL7 has published a Validated Healthcare Directory implementation guide (http://build.fhir.org/ig/HL7/VhDir/index.html).

Recommendations:

- Support the development and advancement of a nationwide standard for provider directories and their management to support referrals and care coordination, including cross-organizational clinical messaging. This should include information regarding:
    - National Provider Identifier
    - Contact information, including Direct address(es)
    - Preferred method(s) of communication
    - Messaging capabilities supported for each communication method
    - Organization(s)/place(s) of business

Policy Levers / Responsibilities:

- CMS: continue to encourage addition of contact and communication addresses needed for interoperability for providers via the NPPES central repository of provider information.

Governance

Observations:

Establishing the required governance for information sharing, enabling referral scheduling, etc., takes substantial effort and can be a barrier to closed-loop referrals and care coordination.

- Governance over Direct messaging is currently provided by DirectTrust, though this may not directly impact provider organizations' decisions regarding implementation or support of this functionality.
- The Trusted Exchange Framework and Common Agreement (TEFCA) called for by the Cures Act promises to provide a national framework and governance for connecting healthcare organizations, and may be leverageable as a governance structure for this purpose.

Recommendations:

- Include access to and governance of push messaging, and the associated technical and workflow requirements necessary to support referrals and care coordination, in the scope of the final TEFCA.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

Tier 2 Issues and Recommendations:

Automatically incorporate relevant patient information into EHR

Observations:

Referral management and care coordination currently rely on fax, telephone, and postal mail communications that do not automatically incorporate relevant information into patients' electronic medical records and clinicians' EHR workflows, with resultant process inefficiencies and increased clinical and privacy risks for patients.

Recommendations:

- Support efforts to transition to and eventually require standards-based, secure, cross-organizational, cross-vendor, EHR-integrated electronic messaging between providers, patients, payers and all care team members to enable closed-loop referrals.

Policy Levers / Responsibilities:

- ONC: Support the development of effective standards in this area and inclusion in certification criteria once available and validated.

Patient-clinician electronic messaging

Observations:

Patient-clinician electronic messaging is currently supported principally within proprietary and provider specific EHR-integrated patient portals. Most patient portals also do not support multi-party messaging capabilities, even when all care providers are from the same institution.

- Patients desire the ability to use methods of secure communication that allow them to choose their preferred application interface to message with providers and other caregivers at multiple institutions or using multiple HIT systems.
- Preferred methods for communications among patients and providers may include insecure methods such as email and SMS text.
- Early experience with patient-to-provider messaging via the Direct protocol suggests that this is a feasible solution, but there has been little adoption by patients or the provider community.
- Viable messaging solutions will integrate with one another as well as with established clinician workflows for portal-based messaging.
- FHIR could potentially support secure clinician-patient messaging.
- Reimbursement policies may need to be adjusted to encourage electronic non-traditional communications between patients and providers.

- Adequate connectivity (e.g., Internet and cell phone-based connectivity) may be needed for effective communications to occur.

Recommendations:

- Explore the potential benefits, costs, and feasibility of a standard gateway approach, such as requiring all HIPAA covered entities to implement an externally accessible gateway for all patient-physician conversations at the institution.
- Provide flexibility to individuals/patients and providers to select the messaging tool(s) of their choice and to easily manage messaging using disparate HIT solutions, while ensuring that other relevant concerns such as security, HIPAA compliance, patient safety, and integration with EHRs and clinical workflows are appropriately considered.
- Solutions to support patient-clinician communications should ideally integrate with existing EHR workflows to support efficiency for clinicians and appropriate documentation of communications and healthcare decision making in the patient's medical record.
- Support pilots of patient-to-provider messaging using multiple available technology solutions, e.g., Direct, FHIR.
- Encourage consistency of policy solutions regarding the inclusion of patient-clinician messaging as a part of the legal medical record.

Policy Levers / Responsibilities:

- ONC: Convene appropriate stakeholders to develop a standard to support flexible, integrated patient-clinician messaging. Such a standard should be:
    - Standards based
    - API enabled
    - Integrated into EHR workflow
    - Integrated with consumer devices
    - Freely available to consumers

Multi-stakeholder, Multi-institutional Care Plan

Observations:

Patient care is fragmented, inefficiencies and redundancies are introduced, and potential patient safety hazards are created due to the lack of coordination between care providers. A standard patient-centric, multi-stakeholder, multi-institutional care plan could help address this lack of coordination.

- There is some work in this area, but more foundational research and development is needed.

Recommendations:

- Investigate various approaches, such as those based on the FHIR and C-CDA Care Plan. A potentially relevant effort is the Gravity project, which is looking at terminology that might be necessary for this type of care plan (https://sirenetwork.ucsf.edu/sites/sirenetwork.ucsf.edu/files/wysiwyg/Gravity-Project-Charter.pdf).
- Ensure patient, caregiver and family goals and wishes are incorporated into the care plan.
- Over time an app-based approach is likely to be beneficial to support this use case.

Policy Levers / Responsibilities:

- ONC, CMS, Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH)
    - Sponsor research and development (R&D) in this area, with a particular focus on the use of standards-based approaches to enable scaling.

General observation – Closed Loop Exchanges

Observations:

There are similarities between the technology needs to support Referrals & Care Coordination and Orders & Results.

- These closed loop exchanges share a number of common processes:
    1. Initiator provides information to provoke a specific action from the responder.
    2. Responder reacts to this information by:
        a. Requesting additional information (clarification) and
        b. Messaging regarding the progress of the request.
    3. Messaging management to ensure completion of the exchange ("closing the loop").
- Examples of Closed Loop Exchanges include:
    1. Test orders/results
    2. Referral request/response
    3. Transitions of Care
    4. Shared Care Plan (longitudinal care coordination)

Recommendations:

- Identify opportunities for harmonization/unification of technology standards and governance support of the various instances of closed loop exchanges.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

General observation – Transition of Care

Observations:

Closed loop referrals between ambulatory providers is but one example of a Transition of Care (ToC) workflow.

- Other examples include:
    - Request for outpatient testing
    - Transitions to, from and between EDs, acute care facilities, ambulatory surgery centers, Long-Term and Post-Acute Care (LTPAC) facilities, home/community care providers, etc.
- Each of these workflows may require:
    - Specification of sender and receiver
    - Specification of urgency
    - Specification of whether the transition is meant to be temporary or permanent
    - Requested response, e.g., acknowledgement of receipt, returned test result, referral/care report, etc.

Recommendations:

- Identify opportunities for harmonization/unification of technology standards and governance support of the various instances of Transitions of Care (ToC).
- Consider ways to reduce spam messaging as use of these tools expands.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

D. Medication & Pharmacy Data:

Illustrative Story of what Recommendations will Enable:

You have difficulty breathing due to chronic lung disease and recently it's been getting worse. Your doctor says the next step would be to try what's known as a long-acting beta agonist (LABA) inhaler. He tells you that, until recently, it was really painful to order these medications, because they were expensive (hundreds of dollars a month), different insurers had different policies regarding which medication(s) are covered and different costs to the patient; there were a variety of manufacturers' coupons with different requirements; and even if you had the same insurance, coverage could change over time, and you may be subject to future deductibles and co-insurance that are hard to predict. Your doctor tells you that, until recently, he had to have people at the pharmacy submit "test claims" to see how much different medications would cost you, then get back to him, then he or his staff would have to change the prescription and get back to you to get you with the most effective prescription with coverage. Now, though, in his EHR, he can can enter an order to prescribe a LABA inhaler, and within seconds the system is able to communicate with various pharmacies in the area, including your preferred pharmacy. The system can automatically figure out, based on your current insurance company, plan, deductible, and individual situation, the options available and the expected costs for the next 1, 6, 12, and 24 months (e.g., after a coupon that only lasts for 1 year is used up). The system recommends the top three choices, and you find that your best bet is actually to pay out of pocket at a local superstore, which is running a special coupon sale, and will prevent you from running into your coverage donut hole before the end of the coverage year, after taking into account your other medication costs. Your doctor smiles and says, "Now, that was easy! And it looks like you saved $1,300 vs. what I would have recommended before all this was in place! This is exactly what an electronic health record was meant to do."

Tier 1 Issues and Recommendations:

Real-Time Prescription Benefit Checking

Observations:

There are barriers to broad-scale adoption of Real-Time Prescription Benefit (RTPB) checking that limit access to this functionality for both prescribers and patients.

- RTPB is a key component of knowing the True Out-of-Pocket (TrOOP) cost of medications.
- RTPB is used to confirm the price of a prescribed medication and provide appropriate patient-specific and benefit-specific therapeutic equivalent alternatives should price or availability be an issue.

- The National Council for Prescription Drug Programs (NCPDP) RTPB standard was voted on during the August, 2019 Work Group Meeting. NCPDP is considering this a beta standard that is not ready to be named in regulation.
- Prospective electronic Prior Authorization (ePA) using the NCPDP SCRIPT standard is driven by information from the NCPDP Formulary & Benefit (F&B) 3.0 standard as well as RTPB.
    - Both of these standards allow for the identification of the need for PA during e-prescribing so the provider can choose to either pursue the original drug or switch to a more cost-effective alternative.
- Consistent integration of RTPB checks in health IT systems and ePrescribing applications, using either available standard, would support cost-effective prescribing and patient choice.

Recommendations:

- Require payers and pharmacy benefit managers (PBMs) to make RTPB information, including cash, TrOOP, and total cost data, freely available to both prescribers and patients using existing standards.
    - Initially this functionality would be based on pending NCPDP standards for the content and transmission of RTPB queries.
    - NCPDP RTPB standard should include total drug cost data.
    - NCPDP RPTB standard should allow for multiple alternative drugs to be priced in a single transaction.
    - In time these data should be made freely available via FHIR APIs.
- Encourage and, when the standards are sufficiently validated, require EHR vendors to provide functionality that integrates real time patient-specific prescription benefit checking into the prescribing workflow, including decision support tools to facilitate the selection of cost-effective alternative medications/treatments.
- Incentivize prescribing providers and patients to implement and use available HIT functionality to select cost-effective medications/treatments including the use of shared patient savings as called for in the Oct 3rd 2019 Executive Order (Executive Order on Protecting and Improving Medicare for Our Nation's Seniors).

Policy Levers / Responsibilities:

- ONC: once sufficiently validated, include in the certification requirements for Certified EHR Technology a requirement for real-time, patient-specific formulary and pharmacy benefit checks and automatic delivery in the EHR at the time of prescribing where clinically appropriate.
- CMS: incentivize prescribing providers to use real-time formulary and pharmacy benefit checking functionality at the time of prescribing, including Medicaid pharmacy benefit and Medicare Part D programs.

- ONC/USCDI: Support the development and eventually require the use of FHIR profiles to support real-time formulary and pharmacy benefit checks by various HIT systems (EHR, PHR, pharmacy, population health management, patient-facing apps, etc.). Note: the CARIN Alliance is working on this.

Lack of a patient-facing API for RTPB check and pricing information

Observations:

NCPDP develops standards for pharmacy services, but there is currently a lack of a patient-facing API for RTPB check and pricing information.

- A FHIR-based API for RTPB information would allow a single Rx authorization experience to power both Rx benefit as well as claims information access (e.g., via Blue Button 2.0 or the upcoming CARIN Blue Button IG).
- For accurate pricing, the following information would likely be needed: dispense-as-written (DAW) status, preferred pharmacy (including mail order) preference, full plan (bin) info, and patient identification (although this could be handled by leveraging portal credentials for PBMs or health plans).

Recommendations:

- Support efforts to make RTPB check available to consumers (e.g., the current CARIN effort to develop an IG.
- Pricing returned should include: price of generic and brand product if DAW is set, price under plan's coverage including total cost information as well as cash price (in case it's less expensive than the copay), and Flexible Spending Account (FSA)/Health Reimbursement Arrangement (HRA) amounts that are separated out so the consumer sees the actual cost, not the cost post-FSA/HRA.

Policy Levers / Responsibilities:

- ONC: consider adding RTPBC data elements to the USCDI.
- CMS/HHS: consider requiring availability of RTPB information from federally sponsored health plans, similar to the recent Notice of Proposed Rulemaking (NPRM) requirements to make available patient-facing FHIR APIs.

Eligibility and Formulary checking

Observations:

Eligibility and formulary (E&F) checking are used together to inform the initial prescribing selection.

- E&F checks are a foundational part of ePrescribing that is embedded into nearly every EHR.
- Eligibility identifies a patient and their associated PBM.
    - ANSI X12 270/271 transactions support eligibility checking.
- Formulary displays group level formulary (e.g., which drugs are on/off plan, which ones are preferred, which ones require a PA, etc.).
    - NCPDP F&B 3.0 transactions support Formulary checks.
- E&F checks are proven to positively impact the patient in three ways:
    1. Drive more cost-effective prescriptions through formulary compliance,
    2. Drive higher patient pickup adherence at the pharmacy, and
    3. Decrease the number of prescription change transactions required between the prescriber and the pharmacy.
- E&F checks, however, may be viewed by providers as insufficiently useful, especially when the information is not insurance specific.
- Ultimately, over time, what would be most useful is real-time, patient-specific price information that is available universally. Less granular information from E&F (e.g., drug class X is not on formulary; within drug class Y, drug A is preferred) may still be useful.

Recommendations:

- Continue to support the use of existing transaction standards for E&F checks until such time that another standard proves itself superior and is fully integrated into ePrescribing systems.
- Encourage / incentivize health plans and PBMs to freely share E&F data with all vendors who use this data to provide ePA services to prescribers.
- Encourage / incentivize EHR vendors to support integration of E&F checks in their ePrescribing platform.
- Encourage / incentivize providers to implement and use E&F checks for all prescriptions.
- Encourage / incentivize the development, implementation and use of FHIR-based E&F transactions.
- Eligibility and formulary data must be accessible to the patient as well as providers.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

Prior authorization of medications

Observations:

PA transactions are required before coverage is allowed or approved for certain medications.

- Medication PA can be a time- and labor-intensive process that frustrates prescribers and patients, leading to delays in treatment, unfilled prescriptions and possible harm to patients.
    - Traditional PA workflows are retrospective (i.e., the need for PA is identified at the pharmacy) and require clinical staff to use telephone, fax and/or log into a portal to complete a series of questions used by the payer/PBM to determine whether and how the medication will be covered.
- ePA can reduce the number of times that PA requirements interrupt clinicians and their staff.
    - ePA queries and responses are currently supported by both X12 administrative transaction standards (Eligibility, Claims & Encounter, Claims Status, Authorizations, Payments & Remittance Advice) and NCPDP standards (Formulary & Benefit, SCRIPT-PA).
    - The NCPDP SCRIPT ePA standard has been gaining industry adoption since May 2015, with providers in every state and Puerto Rico using the service to process PAs under the pharmacy benefit.
    - NCPDP SCRIPT ePA enables the need for PA to be identified during the ePrescribing process. The provider can either choose a drug that does not require a PA or initiate and process the PA electronically in the EHR prior to sending the prescription order to the pharmacy.
- A number of vendors have developed and implemented ePA functionality which integrates with EHR-based ePrescribing workflows to allow clinicians to view and respond to PBMs' PA requirements in near real time.
    - These workflows provide only partial automation and often require clinical staff to collect data from the EHR and manually respond to questions.
    - The value of ePA services depends on which payers/PBMs are represented by each vendor.
    - Not all EHRs or providers have implemented ePA integration.
    - Payers/PBMs use custom question sets to determine whether or not a given medication should be approved within a specific patient context. Many questions rely on free text, as opposed to structured data responses.
- There is currently an active CMS NPRM for ePA for pharmacy benefits for Medicare Part D members.
- API-based data access and exchange could further streamline the ePA process, reducing burden and delays.
    - FHIR-based Clinical Data Exchange use cases and IGs are being developed under the auspices of the Da Vinci Project to automate ePA transactions.
- Patients often bear the burden of ensuring providers and plans are communicating to obtain PAs so they can receive their needed medications.

- There may be a limit to which PAs can be made easy, due to insurers having business incentives to reduce the use of expensive medications and other clinical services.

Recommendations:

- Encourage / incentivize health plans and PBMs to freely share PA requirements with all vendors who use this data to provide ePA services to prescribers.
    - To make this work, we will need PBMs to create coded PA forms that can be incorporated into EHRs.
- Encourage / incentivize EHR vendors to support integration of ePA services in their ePrescribing platform.
- Encourage / incentivize providers to implement and use ePA services.
- Encourage / incentivize the development, implementation and use of FHIR-based ePA workflows.
- ONC should invest in testing existing standards and appropriate workflows in the field, developing implementation guidance for stakeholders.
- Patients should be notified electronically of PA statuses in real time.
- Support the development of standardized clinical questions and responses to support the PA process, e.g., Rxs tried and failed; patient-specific data, such as demographics, vital signs, lab results, diagnoses, and medical history.

Policy Levers / Responsibilities:

- NCPDP: review current standards and identify/address gaps.
- ONC: coordinate effort to enable widespread PA for Rxs at the point of choice.

Alternative Therapies

Observations:

Prescribers and patients desire to be informed of potential Alternative Therapies at the time of prescribing.

- Alternative information may include:
    - Trade name vs. generic options for the prescribed medication,
    - Alternate medications in the same pharmaceutical class,
    - Alternate medications in the same therapeutic class,
    - Alternate medications for the same condition from a different therapeutic class, and
    - Alternate therapies (potentially non pharmaceutical) that may be helpful for the patient's condition/diagnosis.

Recommendations:

- Encourage / incentivize health plans and PBMs to freely share Alternative Therapy data with all vendors who use this data to provide alternative information to prescribers.
- Encourage / incentivize EHR vendors to support integration of Alternative Therapy data in their ePrescribing platform.
- Encourage / incentivize providers to implement and use Alternative Therapy data for all prescriptions.
- Encourage / incentivize the development, implementation and use of FHIR-based Alternative Therapy transactions.

Policy Levers / Responsibilities:

- No policy levers/responsibility identified.

Medication Reconciliation

Observations:

Medication reconciliation is a challenging and burdensome process that typically requires the time-consuming engagement and input of clinicians (nurses, pharmacy staff, physicians, advanced practice clinicians).

- Medication reconciliation should ideally be performed at transitions of care and prior to prescribing.
- The demands of current medication reconciliation workflows lead to a situation where this process may not be completed prior to the time of medication prescribing, leading to missed opportunities to improve patient safety.
- Similar medication data entered by different users and in different systems may be difficult to reconcile due to the lack of standard data formats.
- There may need to be updates to patient medication lists based on changing formularies as insurance coverage changes over time.
- Medication reconciliation is not incentivized.
- There may be opportunities to automate steps in the medication reconciliation workflow to decrease the time and effort that clinicians must dedicate to this process to improve both efficiency and safety.
- Patients have the right of access to their medication list, but amending or correcting the medication list is cumbersome and sometimes virtually impossible. Inaccurate or out-of-date medication lists remaining in the EHR creates a significant patient safety risk, and patients are the only ones who have knowledge about the actual medications that they are taking.

- A recognized "source of truth" does not exist; it is not clear who the responsible party is.

Recommendations:

- Critically explore solutions (including business models) that capture identifiers for medication data reconciliation instances, actors, and results.
- Investigate potential approaches to centralized or coordinated medication list stewardship, potentially "owned" by a specified primary care provider (PCP), the patient's preferred pharmacy, or the patient herself. Such "ownership" may potentially be appropriate for tracking in EHRs, as is done for PCPs. This investigation should be mindful that similar approaches taken internationally have had challenges; thus, the pros and cons should be carefully researched.
- Explore and encourage pilots to incentivize medication reconciliation at both the individual medication and full medication list level (either as a specific task or as part of the patient management fee).
- Support analysis and pilots of the automation of medication reconciliation workflows including using Augmented Intelligence (AI)/Machine Learning (ML).
- Patients should be able to always have the same view of the medication list as their providers, and providers must implement an easy, efficient, timely, and user-friendly process for patients to amend and correct their medication lists.

Policy Levers / Responsibilities:

- Argonaut/ONC/USCDI: provide provide additional support to US Core FHIR profiles for provenance and reconciliation history/results. Potentially leverage existing NCPDP SCRIPT standard, if functional overlap exists.
- Federal agencies (perhaps ONC, CMS, and/or AHRQ): support investigations into better approaches to medication reconciliation.
- ONC and CMS: work together to explore multiple billing/reimbursement codes that could be used to reimburse clinicians (including advanced practice clinicians) for partial or full reconciliation of a patient's current medication list (e.g., codes appropriate for use by specialists, PCPs/hospitalists, pharmacists, etc.).
- CMS: review/enhance quality measures related to medication reconciliation to optimize medication reconciliation.

Discrete/structured medication Sig information

Observations:

Discrete/structured medication Sig Information provides multiple benefits including more consistent display of medication information, support for clinical decision support and analytics.

- Examples: calculation of opioid morphine milligram equivalents, comparing Sigs to support medication reconciliation.
- Free text Sigs are prevalent in ambulatory EHRs.
- Free-text Sigs need to be parsed and interpreted to support automation, analytics, and decision support.
- Discrete Sig information, even when documented by prescribers, can get "lost in translation" as medication orders get filled, refilled, etc. In particular, even when an EHR sends discrete sigs, pharmacies may return refill requests as free text Sigs.
- EHR vendors and providers could be better incentivized to use discrete Sigs if pharmacy systems returned renewal request with discrete Sigs.
- In addition to the Sig, patient-reported manner of actually taking the medication would be valuable to have in a structured form.
- NCPDP has a Structured Sig Task Group.
- Undue prescriber burden should be avoided, e.g., to remove the possibility for prescribers to use free text Sigs when appropriate.

Recommendations:

- Identify potential failure points for discrete Sig data to get lost, and correct them (whether through standards refinement or improved standards compliance).
- Encourage pharmacies to receive, maintain and send structured Sigs in a meaningful way, which will naturally incentivize providers.
- Encourage the HIT community to identify and share best practices regarding how to capture structured Sigs when possible (e.g., for ramp/taper regimens).
- Facilitate and incentivize the use of discrete/structured Sigs wherever feasible, but do not prohibit free text Sigs as this could place undue burden on providers.
- Encourage the maintenance of discrete Sig information as part of the medication Sig as data moves between providers, payers, PBMs, pharmacies, and patients.
- Consider developing public-good resources for converting free-text Sigs to structured Sigs, leveraging available resources such as the Apache cTakes natural language processing (NLP) tool and NLM's MetaMap resource.
- Could build off of an open-source resource developed for CDC/ONC project to parse opioid Sigs for morphine milligram equivalents.

Policy Levers / Responsibilities:

- NCPDP: review current standards and identify/address gaps.
- ONC: coordinate effort to identify best practices for capturing structured Sigs.
- ONC: consider funding for publicly available tool for converting free-text Sigs to structured Sigs.

- Argonaut/ONC/USCDI: consider expanding US Core FHIR profiles for medications to include the input/output/metadata (e.g., degree of NLP parsing confidence) requirements to enable market-based but interoperable competition on such parsers.

Medication administration and dispense history

Observations:

Clinicians, patients, and payers can benefit from access to patients' medication administration and dispensing history.

- Medication dispensing history should be traceable to the original prescription. There is an RxFill NCPDP standard, but it is not widely adopted.
- Relevant historical information includes inpatient, outpatient and mail-order pharmacy data.
- Medication dispensing information is especially valuable for controlled substances.
- When this information is integrated into EHR systems in real time, it can beneficially inform the prescribing process.
- This information may be available from several sources including payers, PBMs, pharmacies, and Prescription Drug Monitoring Programs (PDMPs).
- This information is not made available universally nor integrated into EHR workflows today.
- Medication administration/dispensation information is currently missing from US Core FHIR profiles.
- ONC 2015 Edition certification for e-prescribing includes the use of the RxFill transaction coming from a pharmacy with dispensing information.

Recommendations:

- Support pilots of the automated real-time query for medication administration and dispensing history data from all available sources.
- Support pilots that integrate medication administration and dispensing history information into routine prescribing workflows.
- Consider, in the future if necessary, requiring the capability to query for, download, integrate and use medication administration and dispensing history in EHRs. The eRx criterion in e-prescribing requirements may already support this requirement.
- Consider, in the future, requiring pharmacies to respond to such medication dispensing queries.
- Encourage the further profiling of the MedicationDispense Resource within FHIR and the development of a US Core FHIR profile for MedicationDispense.
- Could build off of US IG for MedicationDispense (https://www.hl7.org/fhir/medicationdispense.html).

- Reconcile the use of NDC vs. RxNorm codes.
- The server should send whatever code(s) is/are used in the source system--usually a National Drug Code (NDC) if it's a dispensing organization.
- Adding a requirement for RxNorm codes would be beneficial.
- PDMPs should also be queryable as a source of medication administration and dispense data, where not prohibited by relevant regulations. Similarly, other sources of controlled substance fill data, such as pharmacies and pharmacy benefit managers, should also enable this data to be queryable, where not prohibited by relevant regulations.
- Consider requiring API-based availability of medication dispensing info to patients and providers from pharmacies, PBMs, and health systems that dispense.

Policy Levers / Responsibilities:

- Argonaut project: propose for addition/support.
- USCDI: propose for addition/support.
- ONC: facilitate inclusion in HL7 US Core FHIR profiles for USCDI-prioritized items.
- ONC: ensure relevant data holders are engaged and can effectively share appropriate data (this would include PDMP data).
- Engage the CARIN Alliance to possibly help drive the IG development process for the MedicationDispense Resource within FHIR as they are currently part of the HL7 Accelerator program and doing the same thing for FHIR claims/Explanation of Benefits (EOB) data.

Mapping between RxNorm and NDC codes

Observations:

While there are key relevant resources available, such as the RxNav API, a challenge remains that there is not a single standardized coding system for medications.

- RxNorm codes are used by health systems, EHRs and other ePrescribing systems to define the "prescribable product" (e.g., a brand name Semantic Branded Drug (SBD] or a generic Semantic Clinical Drug [SCD]) as well as the amount or duration to be dispensed.
- NDC codes are used by pharmacies and PBMs to manage inventories of individual manufacturers' products.
- There are use cases which require translation/mapping between RxNorm and NDC codes. For example, RxNorm could be used to define the brand name or generic "prescribable product" as well as the amount to be dispensed or dispensing duration to enable a consumer to query for the price of a specific prescribed medication. The

pharmacy or PBM would map that to a "Representative NDC" which would be used to query its inventory and pricing info.

Recommendations:

- Continue to support the use of RxNorm codes to describe medications within FHIR APIs.
- The complex mappings between RxNorm's SBD/SCD codes and Representative NDC codes should be catalogued by the NLM, working in conjunction with NDC (as they do for other private code mappings like Multum and First Databank [FDB]).
- The translation from RxNorm to a specific NDC inventory item should be performed by the PBM or pharmacy, rather than by the consumer's software (as the consumer will often only have access to the RxNorm code delivered via a FHIR API).
- Consider incentives for pharmacies to make medication dispensing information available via a patient-facing API. These medications would likely be coded with NDC +/- RxNorm.

Policy Levers / Responsibilities:

- NLM: continue work to catalogue mapping of RxNorm to NDC (https://www.nlm.nih.gov/research/umls/rxnorm/docs/techdoc.html).
- ONC: remain steadfast in recommendation to adhere to FHIR + USCDI for consumer APIs, plus use of RxNorm per US Core.
- FDA or other central government agency: develop and maintain a database of the multiple NDC codes that map to a given RxNorm code.

Tier 2 Issues and Recommendations:

Provenance

Observations:

The provenance and details of "the original prescribing event" are not persisted across exchange of the information (e.g., who prescribed, where). This information is valuable to recipients of medication data and should be considered for inclusion in USCDI.

Recommendations:

- Pursue standards development to define metadata content to maintain with medication information as it is transmitted across the healthcare ecosystem.
- Potentially include (but not limit to) the following, where already collected and available: patient, author, author's organization, time stamp, medication (which includes brand vs. generic for RxNorm codes), dose, frequency, duration, indication / intent / associated

diagnoses, clinician responsible for managing, change history, and fill history (including costs).
- The goal is to capture and maintain, as medication data transmits across HIT systems and stakeholders, meaningful/useful data regarding the provenance of the medication without introducing undue burden to stakeholders.

Policy Levers/Responsibilities:

- No policy levers/responsibility identified.

Prescription Drug Monitoring Program (PDMP) Data

Access to PDMP data can be cost prohibitive.

- Fees may be required to download PDMP data into EHRs.
- PDMP data access is regulated through a patchwork of state regulations.
- Some states do not allow PDMP data to be incorporated into the EHRs for decision support.

Recommendations:

- If feasible, seek approaches to streamlining/standardizing PDMP regulations across states.
- Enable low cost direct access to state PDMP data (there is a current ONC project/pilot on this).
- Provide US Core FHIR profiles/IGs to support access to PDMP data in addition to existing NCPDP standards. This may be the same as for any medication administration and dispense data.
- Explore making PDMP data available for third party apps to download and transmit to support innovative services, with appropriate privacy controls, e.g., by designated authorized organizations such as public health agencies.

Policy Levers / Responsibilities:

- ONC/HHS/Congress/state legislatures: if feasible, streamline and unify regulations in this area.
- ONC and state PDMP providers: continue support for enabling direct, low-cost, FHIR-based access to state PDMPs.
- CDC/SAMHSA: in relevant grants, incentivize integration of PDMP data into EHRs where not prohibited by regulations.

PDMP query and reporting transactions

Observations:

- PDMP Query and Reporting transactions with providers and pharmacies are not standardized.
- NCPDP gives providers a way to download data from PDMPs. Some states, such as California, have additional requirements about reporting to the PDMP that the data were viewed.
- Often outpatient pharmacies report to PDMPs. Reporting currently varies by state and uses a non-ANSI accredited standard called ASAP.

Recommendations:

- Encourage adoption of provider and pharmacy reporting to PDMPs via appropriate standards.

Policy Levers/Responsibilities:

- No policy levers/responsibility identified.

Adverse drug event (ADE) detection

Observations:

Adverse Drug Event (ADE) detection is presently a largely manual process.

- Due to liability concerns, healthcare organizations routinely document ADEs and related patient safety events in IT systems that are separate from or not integrated with EHRs and other HIT systems.
- Reporting out of an EHR risks circumventing the legal protections provided by working with a Patient Safety Organization (PSO) to carve out processes and procedures for generating patient safety work products and reporting those details in a de-identified manner to the PSO or other relevant third parties.
- It would be valuable to facilitate easy reporting out of EHRs to a third-party Risk Management Information System (RMIS), adverse event reporting system, or equivalent, which meets the goal of encouraging more voluntarily reported and data-rich incident reports.
- RMIS use also provides a mechanism for investigation, Root Cause Analysis, and associated follow-ups, data analytics, and a central place to manage the various reporting specifications for the different downstream groups that might want to or be required to receive that information.

- Work is underway by AHRQ to automate portions of the chart review process in an effort to identify and characterize potential ADEs.
- It would be beneficial to have a "one-click" adverse event reporting function wherein a clinician could click a button and it would snapshot the patient's current medication profile and pop-up a question on what the adverse event was and communicate that to relevant entities such as PSOs for subsequent analysis.
- Note that in any case, any allergies to medications should be separately documented in the EHR.

Recommendations:

- Explore the data standards and implementation specifications that would be required to further automate the identification, documentation, analysis, and reporting of ADEs.
- Explore the technology and data requirements necessary to support AI/ML-enabled real time use of population-based ADE data in conjunction with individual patient data (e.g., demographics, dispense/administration, -omics, patient generated, device, social determinants, EHR clinical, etc.) to inform clinical care and population health management related to safe medication usage.
- Support coordination between ADE-related work being done by PSOs, AHRQ, FDA, EHR vendors, the pharmaceutical industry, and other stakeholders.
- Explore and encourage new approaches to address liability concerns on the part of provider organizations which limit the transparency of ADE events and data.
- Coordinate this effort ideally with similar approaches regarding the identification and reporting of other patient safety events.
- Explore / address issues related to the liability associated with documenting and reporting these events.

Policy Levers / Responsibilities:

- ONC in collaboration with AHRQ, PSOs, and other stakeholders: facilitate improved ADE detection and submission, while maintaining provider assurances currently offered by PSOs.

Medication prior authorization as a medical benefit

Observations:

Some medications are covered under a patient's medical benefit, as opposed to the patient’s pharmacy benefit coverage. Some are covered by both.

- Medications covered under the medical benefit often require a PA and/or the documentation and submission of additional clinical data, which makes the prescribing process more complex.
- The determination of whether a given medication is approved/covered under the pharmacy or the medical benefit is not standardized and is left up to the payers/PBMs.
- The technology standardization of these processes lags behind the benefits verification and authorization process for medications covered by pharmacy benefits.
- Medical benefit queries and responses typically require X12 278 transactions.
- The medium term solution to streamline and standardize PA processes may involve a combination of multiple technical standards, similar to how today's pharmacy benefits verification process blends a combination of X12 and NCPDP.
- Multiple initiatives have spun up around the medical benefits verification and authorization use case under the auspices of X12, NCPDP and the Da Vinci Project.

Recommendations:

- Support multiple pilot approaches to the automation of PA for medications and services covered under medical benefits with the goal of standardizing and integrating these processes with other EHR workflows.
- Regardless of whether an item/service is managed under the pharmacy or medical benefit, the process for managing the PA process should be sufficiently coordinated such that HIT vendors/systems are able to provide a seamless experience for end users.

Policy Levers/Responsibilities:

- No policy levers/responsibility identified.

Medication indication

Observations:

Medication Indication is oftentimes not captured at the time of prescription.

- When captured, medication indication may be entered as free text rather than using a standard/structured approach.
- There could be substantial value from both unstructured and structured medication indication information being available.
- Patients may benefit when the indication(s) for a prescribed medication is/are included on the prescription label and in other systems that display their medication data. This information will provide the greatest value to individuals/patients/caregivers when displayed using "patient-friendly" terminology.

- Current EHR and prescribing systems may allow medication indication to be documented using International Classification of Diseases (ICD) diagnosis codes and/or proprietary discrete code sets.

Recommendations:

- Encourage/incentivize EHRs and other e-prescribing systems managing and exchanging electronic prescription and medication data to support the documentation, maintenance and transmission of medication indication data in both free text and discrete data fields.
- Sponsor an effort to determine whether discretely captured medication indication data should be captured using ICD or another (inter)national standard code set or whether proprietary (vendor-specific) code sets are acceptable for this use case, acknowledging that the use of proprietary code sets limits the value of exchanging this data between HIT systems. ICD-10 codes should be considered for how diagnosis is documented. An indication example is to take a medication for pain. This is different than a diagnosis which could be "falling from stairs."
- Add medication indication as a new data element in USCDI, so that when this data is captured it is consistently transmitted between stakeholders with prescription data.
- Encourage/incentivize pharmacy prescribing systems to display medication indication information to patients, ideally using "patient-friendly" terminology, on medication labels and in print and online patient-facing materials.
- New requirements should be informed by the desire to avoid undue provider burden related to capturing this data. For example, free-text documentation of the reason for a prescription may potentially be adequate in some cases.
- New requirements should consider the implications of off-label usage of medications and potential professional liability issues associated with documenting off-label usage.
- Research has been carried out by AHRQ on this topic (https://www.ahrq.gov/funding/grantee-profiles/grtprofile-schiff.html) and should inform recommendations.

Policy Levers/Responsibilities:

- No policy levers/responsibility identified.

RxNorm codes for discontinued drugs

Observations:

The NLM RxNorm API does not return RxNorm codes for discontinued drugs.

- This can create gaps in the analysis of prior medications.

Recommendations:

- Support access to archived RxNorm codes in NLM RxNorm APIs.
    - NLM is aware, so this would be a matter of resourcing and prioritization.

Policy Levers / Responsibilities:

- NLM: prioritize completing this work.
- ONC: provide NLM with contract to complete the work, if needed.

VI. Summary and Conclusions

There are critical needs in healthcare that can be addressed in part through the optimal use of health IT. The ISPTF identified three priority uses of health IT, in the areas of (1) orders & results, (2) closed loop referrals & care coordination, and (3) medication & pharmacy data. This report provides a vision for what can be achieved for patients through improved use of health IT standards in these priority areas, as well as specific recommendations for achieving this vision as a nation.

In addition to the three priority uses of health IT addressed in this report, the ISPTF identified three additional priority uses of health IT through its balloting process but did not have the time to explore these in detail: evidence-based care for common chronic conditions, social determinants of health, and cost and price transparency beyond medications. We recommend continued focus and deliberation on these additional priorities.

The task force was unsuccessful in its attempts to reach out to the FDA to identify opportunities to improve interoperability between EHRs and other HIT systems and the agency's drug and device approval and monitoring programs. The HITAC recommends that the path forward for these outstanding priorities be defined, whether through a continuation of the ISPTF, the creation of a new HITAC Task Force, or other mechanisms available to the ONC.

The ISPTF has played a unique role in the evolution of interoperability standards. It has taken a high-level overview of the current state of standards and matched them to the most pressing clinical issues and processes. No other body has performed a similar role. As a result of this approach, the ISPTF has identified significant gaps in standards and implementation of standards needed to support important advances in interoperability, price transparency, care coordination, medication management and burden reduction.

The success of this Task Force raises several questions. Once the term of this ISPTF expires, who will assume the responsibility to perform a broad overview of existing standards and document gaps in how existing standards support evolving interoperability and other health IT challenges? Who is going to make specific recommendations for additional standards? Who is

going to propose policy levers to advance these standards and their implementation? We believe it is important that this overview process continues in a form that is sustainable.