



ONC HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force:

Report Overview and Implications for Interoperability Standards Priorities Task Force

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The Office of the National Coordinator for Health Information Technology



Agenda

- Background:
 - 21st Century Cures and Federal Collaboration
 - Standards Rulemaking Authorities Separated Across Programs
 - ONC Charge to HITAC
 - ICAD Task Force Members
- ICAD Final Report
 - Ideal State and Guiding Principles
 - Recommendations
- Alignment and Advancement Opportunities
- Discussion

21st Century Cures and Federal Advisory Collaboration

- The 21st Century Cures Act encourages ONC/HITAC and NCVHS to engage:
 - “The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.”
- Some HIPAA transaction standards have low utilization rates despite 2003 mandate
- Electronic Health Record (EHR) capabilities notably advanced over the past decade in parallel to care delivery and payment reimbursement models
- The lack of harmonized clinical and administrative data standards and policy leads to ecosystem burden such as:
 - Inefficient workflows impacting patient outcomes
 - Time consuming discovery of payer specific requirements
 - Technical barriers related to vendor support and integrated platforms
- All this impacts patient safety and the quality of health care delivery

Standards Rulemaking Authorities Separated

- HIPAA standards are adopted by the Secretary of HHS who has delegated the authority to the National Standards Group in the Office of Burden Reduction in CMS
 - HIPAA rules apply to all covered entities – health care providers, clearinghouses and health plans, including Medicare and Medicaid as health plans
 - HIPAA stipulates NCVHS's role to provide input into standards adoption and implementation through recommendations to the HHS Secretary
- EHR standards & EHR certification are under the authority of the Office of the National Coordinator (ONC)
- ONC's federal advisory committee is Health Information Technology Advisory Committee (HITAC) as established by 21st Century Cures Act
- New standards such as HL7 Fast Healthcare Interoperability Resources (FHIR) adopted in 2020 under various authorities and implemented by industry
 - The CMS Interoperability Rule will affect Medicare Part C, D, Medicaid, the Exchanges, and Medicare health care providers
- ISPTF 4/29/21 ONC is adopted FHIR standards under the Health IT Certification program

ONC Charge to HITAC

Overarching charge: Produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules and protections, for electronic prior authorizations to support work underway, or yet to be initiated, to achieve the vision.

Specific Charges: Design and conduct research on emerging industry innovations to:

- Validate and extend landscape analysis and opportunities
- Invite industry to present both established and emerging end-to-end solutions for accomplishing medical and pharmacy prior authorizations that support effective care delivery, reduce burden and promote efficiencies.
- Identify patient and process-focused solutions that remove roadblocks to efficient medical and pharmacy electronic prior authorization and promote clinical and administrative data and standards convergence.
- Produce Task Force recommendations and related convergence roadmap considerations for submission to HITAC for their consideration and action. The Task Force will share deliverables with NCVHS to inform its convergence and prior authorization activities.
- Make public a summary of its findings once Task Force activities are complete, no later than Sept. 2020.

ICAD Task Force Process Overview

- Launch weekly meetings with compendium of prior work (3/3/20)
- Establish foundation of understanding and approach
- Engage industry to inform Task Force analyses
- Analyze prior authorization landscape
- Consider standards alignment and capabilities
- Describe ideal state
- Define guiding principles
- Create recommendations
- Synthesize body of work into a draft report
- Iterative review, comment, modify
- Submit final report for approval vote (11/10/20)

ICAD Final Report:

https://www.healthit.gov/sites/default/files/page/2021-02/2020-11-17_ICAD_TF_FINAL_Report_HITAC_508_0.pdf

ICAD Task Force Members

Sheryl Turney, Co-Chair - Anthem	Alexandra (Alix) Goss, Co-Chair - Imprado/NCVHS
Steven Brown – VA	Gaspere C. (Gus) Geraci – Individual
Mary Greene/Alexandra Mugge – CMS	Anil K. Jain - IBM Watson Health
Jim Jirjis – HCA	Jocelyn Keegan – Point-of-Care Partners
Richard Landen – Individual/NCVHS	Arien Malec – Change Healthcare
Thomas Mason – ONC	Aaron Miri – University of Texas Austin
Jacki Monson – Sutter Health/ NCVHS	Alexis Snyder – Patient Representative
Ram D. Sriram – NIST	Sasha TerMaat – Epic
Debra Strickland – Conduent/NCVHS	Denise Webb - Individual
Andrew Truscott – Accenture	

ICAD Task Force: Industry Presentations & Commenters

ICAD 2020 Presenters:

- April 28th • Surescripts • CoverMyMeds
- May 5th • Humana • Regence
- May 12th • American Medical Association
- June 2nd • Centers for Medicare & Medicaid Services
- June 9th • America's Health Insurance Plans
 - Premier, Inc.
- June 16th • X12
- June 23rd • AHIMA • CAQH CORE
- July 7th • Electronic Health Record Association

ICAD 2020 Report Commenters:

- American Hospital Association (AHA)
- American Health Information Management Association (AHIMA)
- American Medical Association (AMA)
- American Psychiatric Association (APA)
- California Public Employees' Retirement System (CalPERS)
- Council for Affordable Quality Healthcare (CAQH)
- CoverMyMeds
- Health Innovation Alliance
- Medical Group Management Association (MGMA)
- National Council for Prescription Drug Programs (NCPDP)

ICAD Report Outline

FRONT MATTER:

- Foreword by Co-Chairs
- Vision and Charge
- Task Force Member List
- List of Tables

EXECUTIVE SUMMARY

I. INTRODUCTION

II. ANALYSIS OF THE CURRENT PRIOR AUTHORIZATION LANDSCAPE

III. ICAD TASK FORCE FINDINGS AND RECOMMENDATIONS

IV. SUMMARY AND CONCLUSION:TOWARD FURTHER INTEGRATION OF CLINICAL AND ADMINISTRATIVE DATA

LIST OF APPENDICES

- List of Acronyms
- Glossary
- Presentation Summaries and Key Points
- Compendium of Landscape Artifacts

Ideal State

The ICAD Task Force heard from various stakeholders on improving the Prior Authorization (PA) process and the opportunity for broader intersection of clinical and administrative data frameworks. A re-imagined ideal state with particular focus on PA includes:

- An end-to-end integrated, closed-loop process
- Reduces the burden across all stakeholders
- Accounts for the vast majority of situations
- Leverages existing investments and efforts, where appropriate, acknowledging the existing gaps
- Enable innovation and continuous improvement

Achieving the Ideal State: Guiding Principles

Patient
Centered
Design and
Focus

Transparency

Design for the
Future While
Solving Today's
Needs

Measurable and
Meaningful

Continuous
Improvement

Real-Time Data
Capture and
Workflow
Automation

Aligned to
National
Standards

Information
Security and
Privacy

Reduce Burden
on All
Stakeholders

ICAD Recommendations

- 01 Prioritize Administrative Efficiency in Relevant Federal Programs
- 02 Establish a Government-wide Common Standards Advancement Process
- 03 Converge Health Care Standards
- 04 Provide a Clear Roadmap and Timeline for Harmonized Standards
- 05 Harmonize Code and Value Sets
- 06 Make Standards (Code Sets, Content, Services) Open to Implement Without Licensing Costs
- 07 Develop Patient-centered Workflows and Standards
- 08 Adopt a Member ID Card Standard
- 09 Name an Attachment Standard
- 10 Establish Regular Review of Prior Authorization Rules
- 11 Establish Standards for Prior Authorization Workflows
- 12 Create Extension and Renewal Mechanism for Authorizations
- 13 Include the Patient in Prior Authorization
- 14 Establish Patient Authentication and Authorization to Support Consent
- 15 Establish Test Data Capability to Support Interoperability

Recommendations:

- Focus on what needs to change, not how it will happen
- List is in no particular order
- Frames key opportunities and intended to lead to further engagement
- *Most are standards related and have implications for ISP TF*

Overarching Recommendations:

Recommendation 1: Prioritize Administrative Efficiency in Relevant Federal Programs

The Task Force recommends that ONC work with CMS and other Federal Agencies to **work aligned administrative efficiency objectives into relevant federal payment programs** (e.g., HEDIS, MA/MADP STAR ratings, MIPS, MSSP, Promoting Interoperability, etc. and private payers contracting through Tricare and FEHP), and that ONC and CMS **jointly establish relevant certification criteria** associated with the health information technology used to further administrative efficiency, reduce clinician burden, and improve the patient experience.

To accomplish this, the Task Force suggests that federal payment programs **provide targeted incentives** that address the **challenges of small practices** to implement new standards, i.e., access to capital, lack of on-board technical expertise, and a clear need for aggressive outreach and education.

Recommendation 2: Establish a Government-wide Common Standards Advancement Process

The Task Force recommends that ONC, working in concert with CMS and other relevant Federal Agencies (including, but not limited to, Department of Defense and Tricare, Department of Veterans Affairs, and the Office of Personnel Management/Federal Employee Health Benefits Program) **establish a single consistent process for standards advancement for relevant standards** for health care interoperability, including transactions, code sets, terminologies/vocabularies, privacy and security used for conducting the business of health care, irrespective of whether that business is clinical or administrative. The Task Force recommends that the standards advancement process incorporate **multiple rounds of development testing and production pilot use** prior to adoption as national standards.

Overarching Recommendations:

Recommendation 3: Converge Healthcare Standards

The Task Force recommends that ONC, working in concert with CMS, the National Library of Medicine (NLM), voluntary consensus standards organizations and other relevant federal agencies, **harmonize standards to create a consistent set of standards for Code Sets, Content and Services that are evolved together to address multiple workflows, both clinical and administrative.** The harmonized standards should use an **underlying data model** that is sufficiently comprehensive to serve both clinical and administrative needs.

The Task Force recognizes that different standards development organizations may have particular expertise, and the Task Force recommends that ONC, working with those standards development organizations, **establish domains of expertise around common standards.** For example, if it is determined that HL7 FHIR is a logical choice for the initial underlying content model, ONC would logically work with ASC X12 and NCPDP to establish authority for the FHIR domain for the relevant administrative standards, even though the underlying content model is defined by HL7.

The intent is for a **patient-centric model** that would underline both the **clinical workflow and administrative processes.** From wherever data originated in the interoperable system, they should **flow** to wherever they are needed **without having to be manually re-captured or re-entered if the data remain clinically applicable.** The harmonized clinical and administrative standards should take into **account the differences in data and workflow** needs required by clinical and administrative processes.

It is important to clarify that the Task Force's recommendation to harmonize standards does not imply that the complete clinical or administrative record should be sent with all administrative transactions or that legitimate users of the data should have unfettered access to the complete data set; the **principle of minimum necessary must still apply.**

Overarching Recommendations:

Recommendation 4: Provide a Clear Roadmap and Timeline for Harmonized Standards

The task force recommends that ONC, working in concert with the aforementioned organizations, **establish a clear roadmap and timeline for harmonized standards**, following the common standards advancement process, including adequate pilot and production usage, to raising the national floor.

Recommendation 5: Harmonize Code and Value Sets

The task force recommends that ONC work with CMS, NLM, and relevant **value set authorities to harmonize code and value sets** to serve clinical and administrative needs.

Where specialized code and value sets are needed, they must be mapped to more general underlying code and value sets. As an example, in order to streamline prior authorization workflows, the code and value sets used to encode orderables, procedures, or referrals must be reusable across or cleanly mappable or cross-walked to the code and value sets used to determine administrative authorization for payment for the relevant orderable, procedure, or referral. The Task Force finds applicable to this harmonization the work of the **National Committee on Vital and Health Statistics, specifically its February 13, 2019, recommendations on Terminology/Vocabulary adoption/implementation processes and on Guidelines for Curation and Dissemination.**

Overarching Recommendations:

Recommendation 6: Make Standards (Code Sets, Content, Services) Open to Implement Without Licensing Costs

End-user licensing of adopted standards, code sets and vocabularies is burdensome. In order to drive innovation and make standards-based capabilities available to the widest set of actors, the Task Force recommends that **converged standards** (and their included component code sets, etc.) **named in certification programs be available to implementers without licensing costs for developers implementing the named standards.** Ideally, such converged standards would be available via one of the business models that support full and open access to standards (e.g., NLM national licensing for code sets or standards development business models, such as those deployed for HL7 FHIR or Internet standards, that support member prioritization for the advancement of standards while making the resulting standards and implementation guidance available through broad usage licensing). The Task Force **recognizes the need for financial support for the development and curation of standards.**

Overarching Recommendations:

Recommendation 7: Develop Patient-centered Workflows and Standards

The ICAD Task Force discussed the critical importance of patient access and the involvement of the patient into key administrative workflows. These workflows define access to and reimbursement for care, and delays in these workflows are a key source of care delays and sub-optimal outcomes within the health care system. Accordingly, “patient-centered design and focus” must be a system design philosophy and built in from the ground up.

Engagement in the workflow should be available to patients at their discretion, and not a requirement of the process. The Task Force believes that administrative workflow information is part of the Designated Record Set (DRS) (as it is patient-specific information used for decision making). **If there is uncertainty on the inclusion of administrative workflows in the DRS, the Task Force recommends ONC work with OCR to clarify the status of administrative workflows under the access provisions of HIPAA and ensure that patients have visibility into bi-directional workflows and exchanges of such data.**

The ICAD Task Force recommends that ONC work with other federal actors and standards development organizations to **prioritize and develop administrative standards that are designed for patients’ bi-directional digital data exchange.** Even “workhorse” administrative standards like eligibility, claiming, and electronic EOB/remittance that are traditionally considered provider-to-payer should allow access through the same API frameworks already supporting API access. Converged clinical and administrative workflows, including prior authorization, should be designed to **support API access and patient engagement as a matter of course.** As an example, benefits information provided to the provider via eligibility transactions should also be available to the patient via APIs; the content and status of claiming/remittance should be available to the patient not only at the end of the process through the current EOB API, but throughout the process of claiming and adjudication. As another example, the patient should have the ability to bi-directionally share health data (including patient generated data) with providers and other third parties from their applications of choice without special effort.

Overarching Recommendations:

Recommendation 8: Adopt a Member ID Card Standard

The Task Force recommends that ONC work with CMS (for Medicare, Medicaid, Medicare Advantage and MADPs), OPM/FEBP and DOD/Tricare to **adopt a standard for member ID cards** (following on INCITS 284-2011; reaffirmed as INCITS 284-2011 (R2016)). Alternatively, a virtual ID card could be permissible provided it complies with the INCITS ID card capability requirements and HIPAA privacy/security requirements. Standard IDs would reduce burden by supporting patient access, clinical and administrative automation, and transparency between member/patient, provider and plan. Member ID should be sufficient, along with HIPAA-appropriate levels of assurance, to reference patient-specific plan and product requirements like drug formularies and prior authorization.

Recommendation 9: Name an Attachment Standard

The ICAD Task Force recommends that ONC work with CMS and other federal actors to **establish a national approach to exchanging clinical data needed to support clinical information exchange, whether for care delivery or for administrative processes**. Consistent with previous NCVHS recommendations and this report, an attachment standard must be evolved that **reduces burden by harmonizing standards to ensure granularity of data to achieve automation**.

Overarching Recommendations:

Recommendation 10: Establish Regular Review of Prior Authorization Rules

The ICAD Task Force recommends that ONC work with CMS and other federal actors to **establish consistent processes and guidelines for prior authorization rulesets to apply to CMS, MA, FEHP, and other similar federally controlled or contracted plans**. Such processes should simplify rules, and remove rules that have high burden (e.g., those that are frequently approved, frequently overturned on appeal, or otherwise have low utility) and **reviews should take place no less frequently than annually**.

The ICAD Task Force recommends that ONC work with CMS and other relevant Federal actors to **establish transparency in the Prior Authorization process via published metrics on authorization and denial rates, rates of appeal and metrics on appeals**.

Overarching Recommendations:

Recommendation 11: Establish Standards for Prior Authorization Workflows

The ICAD Task Force recommends that ONC work with CMS, other Federal actors and standards development organizations to **develop programmatic (API) specifications to create an authorization** (electronic Prior Authorization or related determinations such as Medical Necessity) such that the authorization and related documentation can be **triggered in workflow** in the relevant workflow system where the triggering event for the authorization is created. Task Force recommends that the **chosen standard or standards be sufficient to address suggested criteria.**

The Task Force recommends that ONC work with CMS and other Federal actors overseeing benefits plans (e.g., Tricare, FEHP) to **establish policy mechanisms to provide or incent electronic prior authorization.**

The Task Force recommends these standards include **sufficient guidance on operating rules, including service level objectives on latency and availability sufficient for prior authorization to be incorporated in interactive workflows.**

The Task Force recommends that **standards and implementation guidance specify requirements on denials such that denials are accompanied with clear, complete and computable reason** for denial such that actors can correct, if relevant and applicable, causes for denial. The standards and implementation guidance should require any denial to address all deficiencies in the request, i.e., must evaluate the entire request and not simply issue a denial citing only the first in a potentially longer sequence of identifiable deficiencies.

Overarching Recommendations:

Recommendation 12: Create Extension and Renewal Mechanism for Authorizations

The ICAD Task Force recommends that ONC work with other federal actors and standards development organizations to **develop programmatic (API) specifications to renew or extend an authorization** where prior authorization applies to services that have long durations.

The Task Force recommends that ONC work with CMS and other Federal actors overseeing benefits plans (e.g., Tricare, FEHP) to **ensure that authorizations can be renewed through these means without requiring a new authorization** and that such renewals and the status of existing authorization be **enabled via standards-based APIs**.

Recommendation 13: Include the Patient in Prior Authorization

The ICAD Task Force recommends that ONC work with CMS and other Federal actors administering health benefits (e.g., FEHP, Tricare, VHA) to ensure that **prior authorization systems be designed with patient engagement as a critical design goal**, such that the patient is included throughout the process.

The patient (or designee) should **receive notification and status of key activities** and have the ability to view content associated with the prior authorization (for informed decision making and correction) and provide patient-generated information into the prior authorization process (e.g., ability to point out errors and to respond to such questions, if any, which only the patient herself/himself can answer).

Overarching Recommendations:

Recommendation 14: Establish Patient Authentication and Authorization to Support Consent

The Task Force recommends the creation of standards that will **enable patients/caregivers to authorize sharing of their data with the tool of their choice to interface with their corresponding provider and payer systems**. HHS should establish a standard that **supports efficient 3rd party patient authentication** that allows patients to access and bi-directionally share their data across the landscape (i.e., from all their providers, payers, and actors such as clearinghouses, HIEs, and Public Health), using a consistent authentication and authorization token allowing them easier integration with their health data application.

Overarching Recommendations:

Recommendation 15: Establish Test Data Capability to support Interoperability

The Task Force recommends that HHS lead development of a **national approach to have test data beds** to drive innovation and ensure real-world functionality and interoperability. To accomplish this, the following actions are needed:

- Review the current administrative transactions and associated value/code sets to **ensure USCDI supports** data concepts and elements needed downstream to support clinical and administrative functions.
- Establish (illustrative) **information models**, in stages, to align clinical and administrative data for secondary use in stages based on the highest societal priorities.
- Establish a **sufficient data set** for transactions at the intersection of clinical and administrative data that adheres to “minimum necessary” requirements.
- **Advance an appropriately constrained implementation guide** as a standard.
- **Offer incentives** for stakeholders to pilot and test innovative solutions

In Summary, ICAD Recommendations:

- Create patient-centered design approaches to enhance patient experience, safety, and health outcomes
- Ensure patient consent, privacy, and security are established and maintained throughout interoperable processes
- Use digital capabilities to automate manual, time-consuming activities
- Optimize approaches to achieve “record once and reuse”
- Address key barriers to effective information exchange
- Improve transparency and timeliness of the prior authorization and decision-making processes for all stakeholders
- Build and extend current standards to enable maturity and evolving processes and resolve conflicting standards which inhibit innovation and adoption
- Provide a path forward to harmonize today’s national health care policies, vocabularies, and transport standards
- Create an ecosystem that enables patients and caregivers to focus on their well-being rather than problem-solving administrative process complexities.

Alignment and Advancement Opportunities for ISP TF:

- **SVAP, Convergence, and Roadmap and Access to Harmonized Standards**
 - ICAD Rec #'s 1, 2, 3, 4, 5, 6, 7, 15
 - Iterate HIPAA and 21st Century Cures *governance*, exception processes, certification criteria, *testing* and pilots
 - Advance USCDI data model to promote efficiencies and reusability of bi-directional exchange capabilities: “HIPAA” data content *mapping* to “21st Century” API/FHIR resources and value sets
- **Member ID Card Standard**
 - ICAD Rec # 8
 - Cited in report: INCITS 284-2011 [R2016]
 - Development of HL7 CARIN [Digital Insurance Card](#) Implementation Guide project sponsored by Payer-Provider Information Exchange (PIE) Workgroup

Alignment and Advancement Opportunities, continued:

- **Attachment and Prior Authorization Workflows**
 - Rec #'s 9, 11, 13, 14
 - Revisit standards needed leveraging NCVHS Attachment recommendations letter ([July 5, 2016](#)) to update/link to current 21st Century Cures API FHIR capabilities
 - Promote Reducing Burden APIs to support data transfers
 - Advance standards for attribution lists, enrollment/concurrent payers, APIs – payer to payer data exchanges and coverage discovery along with documentation rules and services review (CMS-9123)
 - Implementation Guides Standards:
 - HL7 [Da Vinci](#) Member Attribution, PDex's, PCDE, CRD, DTR, PAS
 - HL7 [CARIN](#) Blue Button

Alignment and Advancement Opportunities, continued:

- **Explore implementation guides opportunities with HL7 to:**
 - enable transparency in prior authorization processes via reporting metrics (denial rates, rates of appeals, etc.) (#10)
 - create extension and renewal mechanism for authorizations (#12)
 - ensure appropriate visibility for patients of the status of an authorization with ability to contribute data points (#13)
 - support efficient authentication and authorization processes (#14)



Discussion



Thank you!

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