Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

A Path Toward Further Clinical and Administrative Data Integration

~~DRAFT~~FINAL REPORT AND RECOMMENDATIONS TO THE HITAC, PREPARED BY THE INTERSECTION OF CLINICAL AND ADMINISTRATIVE DATA TASK FORCE

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Foreword

We are pleased to present this Intersection of Clinical and Administrative Task Force (ICAD) final report. This report describes the work undertaken by and resulting recommendations from the ICAD Task Force in response to its charge from the Office of National Coordinator (ONC).

To address the charge, industry experts collaborated with representatives from two Federal advisory bodies, the Health Information and Advisory Committee (HITAC) and the National Committee on Vital and Health Statistics (NCVHS). HITAC will use this report to advance its efforts related to 21st Century Cures Act responsibilities on interoperability and burden reduction, while NCVHS will use the final report to inform its HIPAA responsibilities, its own project on data convergence, and ongoing coordination with ONC.

In this report, ICAD evaluates the convergence of clinical and administrative data landscape of the United States for areas of burden and opportunities to inform creation of guiding principles tied to an ideal state and corresponding recommendations. The Task Force gathered input from HITAC, NCVHS, and other Federal agencies as well as industry stakeholder groups to help inform the analysis of the current landscape. The report describes our findings about the current landscape and analysis, nine guiding principles describing the ideal state, and fifteen recommendations to improve the intersection of clinical and administrative data and corresponding policy and standards frameworks.

We wish to acknowledge and appreciate all the hard work done by Task Force members and additional members of the public and industry stakeholders who participated in our efforts, as well as ONC's staff and support teams who supported our meetings and report creation.

It is our privilege to serve as co-chairs for the ICAD Task Force. The commitment and diverse expertise of the ICAD members have brought both energy and insight to this report, which provides a path forward toward further clinical and administrative data integration.

Sheryl Turney and Alix Goss,
Co-Chairs, Intersection of Clinical and Administrative Data Task Force

Vision and Charge

VISION

Support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency—furthering implementation of "record once and reuse."

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 September 2020.

Task Force Member List

Member Name	Affiliation	Organization
Alexandra (Alix) Goss, Co-Chair	NCVHS	Imprado Consulting, a division of DynaVet Solutions
Sheryl Turney, Co-Chair	HITAC	Anthem, Inc.
Steven Brown	Federal Representative	United States Department of Veterans Affairs
Gaspere C. (Gus) Geraci	Individual	Individual
Mary Greene/ Alexandra Mugge	Federal Representative	Centers for Medicare & Medicaid Services
Jim Jirjis	HITAC	HCA Healthcare
Anil K. Jain	HITAC	IBM Watson Health
Jocelyn Keegan	Individual	Point-of-Care Partners
Richard Landen	NCVHS	Individual
Arien Malec	HITAC	Change Healthcare
Thomas Mason	Federal Representative	Office of the National Coordinator for Health Information Technology
Aaron Miri	HITAC	The University of Texas at Austin, Dell Medical School and UT Health Austin
Jacki Monson	NCVHS	Sutter Health
Alexis Snyder	HITAC	Individual
Ram D. Sriram	HITAC	National Institute of Standards and Technology
Debra Strickland	NCVHS	Conduent
Sasha TerMaat	HITAC	Epic
Andrew Truscott	HITAC	Accenture
Denise Webb	HITAC	Individual

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Executive Summary

INTRODUCTION

Today, patients and their caregivers and health care providers struggle with information exchange barriers that stem from the lack of integration of clinical and administrative data. The impacts of fragmented data are especially acute with respect to prior authorization, where access to and downstream payment for procedures, pharmaceuticals, and durable medical equipment meet many obstacles. The burdens and delays impede joint decision-making by patients and clinicians and have serious impacts on the quality, cost, and outcomes of health care.

This report and its recommendations are the product of an initiative to improve data integration and reduce the burdens on patients, caregivers, and health care providers. Reducing administrative cost and burden in health care workflows and increasing transparency about medical benefit in workflows upstream or within clinical care can lead to better patient outcomes and benefit all stakeholders.

HITAC, NCVHS, and the ICAD Charge

In early 2020, the Office of the National Coordinator for Health Information Technology (ONC) charged its Health Information Technology Advisory Committee (HITAC) to establish the Intersection of Clinical and Administrative Data (ICAD) Task Force to consider the convergence of clinical and administrative data and make recommendations to the HITAC. The charge focuses on reducing the burdens associated with prior authorization, which is seen as emblematic of broader integration issues. The two Federal advisory bodies charged with advising on relevant standards, the HITAC and the National Committee on Vital and Health Statistics (NCVHS), joined forces in this effort. NCVHS will use the final ICAD analysis and recommendations to inform its own project on data convergence.

The ICAD Task Force is composed of stakeholders from industry and HHS, including HITAC and NCVHS representatives. It brings together representatives of a number of public and private bodies already working to improve the automation and interoperability of administrative and clinical data. The ICAD membership roster is listed on page 6 of this report.

ICAD's overarching goal is to support the convergence of clinical and administrative data and improve data interoperability across the ecosystem, to enhance patient access and improve health care efficiency. ICAD further seeks to enable innovation and continuous improvement, minimizing the need for special effort on the part of ecosystem participants.

This report synthesizes the substantial industry input that contributed to the Task Force's analysis and its vision for an ideal future state for prior authorization and harmonized data. Appendices 3 and 4, respectively, provide summaries of the expert presentations and a list of the artifacts that informed the report.

As described further below, the Task Force analyzed the current prior authorization and standards landscape and articulated guiding principles for achieving the ideal state for prior authorization. On that basis, they developed a set of recommendations.

The recommendations are designed to:

- ~~Put the~~Create patient~~ at the center of our~~-centered design approaches to enhance patient ~~care~~experience, safety, and health outcomes;
- Ensure that 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 the 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; and
- Create an ecosystem that enables patients and caregivers to focus on their well-being rather than problem-solving administrative process complexities.

ANALYSIS OF THE CURRENT PRIOR AUTHORIZATION LANDSCAPE

The Task Force began by creating a typical multi-stakeholder workflow diagram, using the prior authorization of durable medical equipment (wheelchair) as an example. It translated this workflow diagram into a workbook highlighting the data classes required to support the clinical workflow for durable medical equipment, admission, procedures, pharmacy, and specialty services. It then assessed gaps and opportunities in the current prior authorization process. The landscape analysis created a picture of the current state of digital prior authorization in the light of an envisioned ideal state in which administrative and clinical data can be securely and reliably exchanged for use when and where they are needed. (Note: Digital prior authorization is also sometimes called “electronic prior authorization,” and that more historical terminology appears in some places in this report when appropriate to the context.)

The Task Force also assessed the current status of existing health care interoperability standards for meeting stakeholders’ needs related to prior authorization. After inventorying specific information needs, it made observations about the applicability of each standard to the authorization information needs. It summarized its analysis in a series of five tables (included the full report) covering standards alignment, capability, and adoption status, plus a summary of the analysis. Finally, they provided commentary on the major applicable standards—X12, NCPDP, HL7®, and SMART® on FHIR®. The list of acronyms and glossary in Appendices 1 and 2 (respectively) provide keys to technical terms and acronyms used in the report.

ICAD TASK FORCE FINDINGS AND RECOMMENDATIONS

The Ideal State for Clinical and Administrative Data Integration

The Task Force articulated the ideal state for prior authorization on the basis of its vision for an integrated workflow for prior authorization. This sample workflow vision depicts an integrated system that contains all of the data required to support the clinical and administrative interactions among patients, providers, payers, and other partners in the care journey.

Guiding Principles

The Task Force developed guiding principles to help guide its recommendations. The guiding principles are intended to ensure that the recommendations address the gaps in the current process in a way that moves the prior authorization ecosystem toward the ideal state as well as fostering the intersection of administrative and clinical frameworks. The principles, each of which is discussed in detail in the full report, are:

A) Patient~~ at the Center~~-centered Design and Focus
B) Transparency
C) Design for the Future While Solving Today's Needs
D) Measurable and Meaningful
E) Continuous Improvement
F) Real-Time Data Capture and Workflow Automation
G) Aligned to National Standards
H) Information Security and Privacy
I) Burden Reduction for All Stakeholders

ICAD Task Force Recommendations

The Task Force developed the following recommendations for achieving data integration, each of which is discussed in the full report. These recommendations, which are not listed in priority order, identify the specific areas in which resources and energies must be focused to bring about the desired ideal state. As such, they reflect the Task Force's focus on "the what" but not "the how." Federal leadership and broad participation and coordination will be needed to clarify and carry out the details needed to accomplish each one.

1) Prioritize administrative efficiency in relevant Federal programs.
2) Establish a government-wide common standards advancement process.
3) Converge health care standards.
4) Provide a clear roadmap and timeline for harmonized standards.
5) Harmonize code and value sets.
6) Make standards (code sets, content, services) open to implement without licensing costs.
7) Develop patient-centered workflows and standards.
8) ~~Create~~Adopt a ~~standardized~~ Member ID Card Standard.
9) 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.

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

The Office of the National Coordinator for Health Information Technology's support of the HITAC and the ICAD Task Force is highly appreciated, as it enabled the structure necessary to create this body of work. Such leadership and coordination are essential to solidifying the underpinning details required to fulfill the report recommendations and reduce burdens for all stakeholders. This process should continue to include alignment with other health care improvement initiatives, robust interagency coordination, and ongoing industry and Federal advisory committee engagement.

We gratefully thank all of the ICAD Task Force members and industry stakeholders who contributed to the Task Force's information gathering, analysis, discussion, development of the ideal state, guiding principles, and recommendations.

The Task Force believes that the recommendations in this report will form a solid basis on which to develop the future policies, standards, and enabling technologies that will truly put the patient at the center of an efficient health care information ecosystem. That ecosystem would seamlessly and multi-directionally move appropriate data from the point of initial capture to the point(s) of use without any special effort by those capturing or consuming the data. Those data flows would be protected by robust security practices and privacy policies. Overall burden would be reduced while clinical care, patient experience, and health outcomes would be improved. HHS and industry stakeholders should take these recommendations as a basis for initiating follow-on actions to bring the described ideal state to life.

I. Introduction

THE PROBLEM AND ITS IMPACTS

There is broad agreement within health care, policy, standards, and industry circles that the lack of harmonized clinical and administrative data standards and policy imposes burdens on the health care ecosystem, and especially on patients and their caregivers. The impacts of this lack of harmonization include inefficient provider and payer workflows that affect patient outcomes, time-consuming discovery of payer-specific requirements, and technical or financial barriers related to vendor support and integrated platforms. In response, industry and policy makers are looking for ways to improve data integration and exchange capabilities, along with the corresponding legal frameworks, in order to reduce burden for all stakeholders while improving patient experience and outcomes.

The impacts of the lack of integration of clinical and administrative data are especially acute in the area of prior authorization, which is seen as emblematic of the broader integration issues. When done ethically and with good clinical rules, prior authorization can prevent unnecessary care, reduce cost, and improve quality. However, the lack of interoperability bogs down authorization of, access to, and downstream payment for procedures, pharmaceuticals, and durable medical equipment. The lack of interoperability also makes it impossible for providers to understand the full impact of patients' member benefits on their care options. These burdens have serious impacts on timeliness, patient safety, and the quality of health care delivery, and can be a source of anguish for patients and clinicians alike.

Patients and their caregivers take the brunt of barriers that delay authorization for essential treatments, spending numerous hours as the go-between to help facilitate the process. The current process does not generally offer transparent access to the information needed to help move the authorization forward in a timely manner without extensive effort on the part of the patient. This not only causes stress and anxiety, but may also lead to worse health outcomes.

Prior authorization burdens also have been identified as a major cause of low morale and burnout for health care providers. Clinicians spend a tremendous amount of time managing the prior authorization process that they could spend caring for patients. The American Medical Association's (AMA) most recent annual survey of 1000 practicing physicians asked about the impact of prior authorization on patients, and 28 percent of respondents said that prior authorization has led to a serious adverse event for a patient, including death, hospitalization, disability, or permanent bodily damage. The same survey revealed that every week, physicians and their staff spend 14.4 hours, or two business days, completing prior authorizations.

The lack of integration also affects the cost curve of the US health care system. Despite significant progress with administrative and financial standards, studies support that administrative costs continue to represent an important component of the overall cost of health care, and that these costs can be reduced through greater standardization and interoperability. Reduced administrative cost and burden in workflows,

combined with increased transparency about medical benefit in workflows upstream or within clinical care, can lead to better patient outcomes that benefit individuals, caregivers, and our communities.

Issues and Opportunities in Integrating Clinical and Administrative Data

Administrative and clinical workflows start to converge as appropriate, minimum-necessary clinical data are needed to adjudicate or validate administrative processes such as those related to eligibility determination, service authorization, and claims and remittance. For example, clinical data are needed for decision making related to prior authorizations, value-based payments, and risk adjustments. Although administrative transactions historically have been seen as "business to business," clinical interoperability has evolved to include patient access and participation as a design and policy goal. Given that the administrative and payment experience is a necessary part of the overall patient experience of health care, it is essential to include patient access, engagement, and transparency throughout all aspects of health care processes as a critical design goal for standards evolution.

Historically, standards for clinical and administrative workflows have been developed separately, resulting in misaligned and redundant processes. Separation of these data has caused and continues to cause inefficient workflows, time-consuming processes to discover payer-specific requirements, and technical barriers related to vendor support and integrated platforms. All of these obstacles can negatively affect patient safety and the quality of health care delivered. Dealing with fragmented standards, whether policy or technical standards, increases clinician burden by making it more difficult for health information technology developers and informaticians to create integrated capabilities. Relevant standards for clinical and administrative data have different policy and regulatory frameworks, use different information models and content specifications, and are sent via different service models. Furthermore, as health care moves to an application programming interface (API)-driven world, administrative standards that were typically designed for batch processing are not well suited for integrated digital workflows of provider electronic health records (EHRs), clinical decision support (CDS) algorithms, and systems.

Allowing for bi-directional sharing of administrative and clinical data at the point of care can support clinicians in caring for their patients and guiding them through their shared decision-making about treatment options. Providers participating in alternative payment models are particularly interested in determining how to leverage and combine clinical and administrative data to inform their care management programs and clinical decision-making. Further, patients need clinical and administrative data to flow together in a transparent fashion to enable seamless transitions along the continuum of care, available to patients so they can track progress and address any gaps that may be causing delays or denials.

Harmonizing the US health care frameworks to support integration of clinical and administrative data can enable interoperable electronic exchange of administrative and clinical information and help reduce the burden of administrative tasks such as billing, prior authorization, and benefits determination.[1] Fundamentally, patient safety and the quality of health care delivery lie at the heart of the need for changes.

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[1] For example, the use of health information technology (IT) has increased the speed and consistency of the Social Security Administration's (SSA) disability determination process. The SSA processes more than three million disability claims annually and requests 15 million medical records from approximately 500,000 providers when making decisions. The use of health IT has cut the time it takes the SSA to receive records from weeks or months to minutes or hours.

MULTI-STAKEHOLDER EFFORTS TOWARD DATA INTEROPERABILITY AND INTEGRATION

In 2019, the Office of the National Coordinator for Health Information Technology (ONC), in partnership with the Centers for Medicare and Medicaid Services (CMS), released a strategy to reduce the regulatory and administrative burden that clinicians experience relative to the use of health information technology (IT) and electronic health records, as required by the 21st Century Cures Act (Cures). The strategy includes recommendations to reduce the time and effort clinicians need to document information in EHRs, meet regulatory reporting requirements, and improve the usability of EHRs. It lays out "a vision for interoperable health information exchange that centers on the experience of patients and clinicians."

The Department of Health and Human Services (HHS) has taken several steps to implement this strategy, and continues to work across its constituent agencies to identify sources of, and ultimately reduce, clinician as well as patient burden. Previous work has highlighted the excess burden placed on the health system at large, and particularly on providers, by the lack of harmonized clinical and administrative data standards and policy. (See the Compendium in Appendix 4 for further details about that work.)

A number of organizations also are working together to improve the automation and interoperability of administrative and clinical data. For example, the Da Vinci Project has a use case supporting payers sending administrative data to providers using HL7 FHIR, and it is working closely with X12.[2]

Through such stakeholder efforts within and beyond government, a vision is emerging of a converged ecosystem that includes stakeholders across the continuum—including public health, vital records, research, and policymakers—while minimizing additional data capture or other burdens on patients and providers. Such a converged ecosystem could also support specialty and long-term care settings, and could help in identifying gaps in care. Seamlessly capturing and exchanging data across all these functions will require consistency, and that consistency has real potential to reduce burden and benefit patient experience and outcomes.

HITAC, NCVHS, AND THE ICAD TASK FORCE CHARGE

HITAC and NCVHS

As noted, in the iterative work of improving US health care, two separate frameworks have evolved for addressing clinical and administrative data. They stem from foundational laws passed in 1996 (HIPAA) and 2009 (HITECH).[3] Federal regulations were developed to provide adoption guidance for these laws, and two Federal advisory bodies with separate authorities provide insight and support to the regulators and advise on health care matters, one on clinical and one on administrative data. These bodies are the Health Information Technology Advisory Committee (HITAC) and the National Committee on Vital and Health Statistics (NCVHS).

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[2] HL7 and FHIR are the registered trademarks of Health Level Seven International and the use does not constitute endorsement by HL7.
[3] HIPAA is the 1996 Health Information Portability and Accountability Act. HITECH is Health Information Technology for Economic and Clinical Health, enacted as part of the 2009 American Recovery and Reinvestment Act.

The HITAC was established as a Federal Advisory Committee to ONC under the 21st Century Cures Act, to advise the National Coordinator of Health Information Technology. ONC is the principal Federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology (IT) and to expand the electronic exchange of health information.

NCVHS was established in 1949 as a Federal Advisory Committee to the Secretary of HHS. It serves as the statutory [42 U.S.C. 242k(k)] public advisory body to the HHS Secretary for health data, statistics, privacy, and national health information policy and HIPAA. The Committee advises the HHS Secretary, reports regularly to Congress on HIPAA implementation, and serves as a forum for interaction between HHS and interested private sector groups on a range of health data issues.

NCVHS reports in recent years have contributed to the emerging work on data integration and convergence. Notably, the NCVHS reports identify a tremendous opportunity to improve prior authorization, as documented in a 2016 NCVHS/HIPAA Review Committee report.[4] The reports also stress the need to improve the predictability and nimbleness of standards adoption and related testing and evaluation activities, and to address long-standing barriers to supporting changing business needs and innovation opportunities.[5]

Over time, a host of clinical, policy, and business practices have increasingly highlighted the need for a convergence of clinical and administrative data. Widespread awareness of this need has created an unprecedented opportunity for these two Federal advisory bodies to work together to facilitate convergence and interoperability. In 2016, the 21st Century Cures Act laid the foundation for collaborative work between the HITAC and NCVHS to help bring about the needed convergence. The Cures Act encourages ONC/HITAC and NCVHS to work together to address the barriers.[6] Pursuant to the Cures Act, ONC has been advancing efforts to strengthen the intersection of clinical and administrative data. This includes its work on Clinician Burden Reduction, in partnership with CMS.[7] [8]

In addition to coordinating with ONC/HITAC to address burden areas through collaboration and targeted projects, NCVHS is also developing a project on the convergence of administrative and clinical data. The project is based on its prior work on the Predictability Roadmap. The NCVHS Convergence Project will be informed by the HITAC recommendations on the integration of clinical and administrative data.

Establishment of ICAD Project and Task Force

The HITAC and NCVHS held a joint hearing on Prior Authorization on March 19, 2019, followed by further meetings at which they discussed opportunities to identify and support potential approaches to allow

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[4] https://ncvhs.hhs.gov/wp-content/uploads/2018/03/RC_Report_TD-Final-as-of-Oct-12-2016rh.pdf
[5] 1) https://ncvhs.hhs.gov/wp-content/uploads/2019/12/NCVHS-Recommendation-Letter-HHS-Actions-to-Improve-the-Adoption-of-Standards-Under-HIPAA-December-2019.pdf
2) https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf
[6] "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." 21st Century Cures Act, signed into law on December 13, 2016
[7] Background: https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs
[8] Report: https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf

administrative and clinical data to converge. Following these conversations, in early 2020, ONC charged the HITAC to establish the Intersection of Clinical and Administrative Data Task Force (ICAD) to consider convergence of clinical and administrative data and make recommendations to the HITAC.

The ICAD Task Force is composed of stakeholders from industry and HHS, including representatives of both the HITAC and NCVHS. It began work in early 2020, with weekly public meetings and numerous offline small working groups. The results of its work, once finalized and approved by the HITAC, will be used by NCVHS to inform its ongoing work on its parallel convergence project. This parallel-project approach maximizes efficient solicitation of industry input and alignment with Federal advisory committee authorities and ongoing collaboration.

ICAD's vision is to support the convergence of clinical and administrative data to improve data interoperability, in order to reduce burden and improve efficiency for all stakeholders. This is intended to improve patient access and, where possible, further implementation of "record once and reuse." To achieve this goal, ONC charged ICAD to produce information and stakeholder input about the harmonization of clinical and administrative data and the transport structures, rules, and protections for digital prior authorizations that support work underway or yet to be initiated.[9]

Further, the charge required a focus area on reducing burden associated with prior authorizations, with the following goals and actions:

- 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 and timely care delivery, reduce burden and promote efficiencies.
- Identify patient and process-focused solutions that remove roadblocks to efficient medical and pharmacy electronic (digital) 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.

The ICAD Approach and Process

Prior authorization is a single point of data intersection long noted for its contribution to provider burden and care disruption. The charge to focus on this exemplar provided a context in which the ICAD Task Force could consider the broader interoperability needed across clinical and administrative data to support health system improvement and burden reduction.

[9] Digital prior authorization is also sometimes called "electronic prior authorization," and that more historical terminology appears in some places in this report.

To understand the current prior authorization landscape, the Task Force invited industry and government leaders to share their perspectives on current issues, current statistics, gaps and opportunities, and recommendations and solutions. (See Appendix 3 for the presentation summaries.) It reviewed and considered a compendium of industry artifacts and Federal Advisory Committee work products and source documents to inform and enrich the discussions. The compendium artifacts highlight many of the challenges noted above and their impacts on care processes and outcomes, as well as current efforts to address them. (See Appendix 4 for the compendium.)

The Task Force created a typical multi-stakeholder workflow diagram demonstrating the prior authorization of durable medical equipment (wheelchair) as an example. It then translated this workflow diagram into a workbook, highlighting the data classes required to support the clinical workflow for durable medical equipment, admission, procedures, pharmacy, and specialty services. It used this process to document gaps and opportunities in the current prior authorization process as it relates to burdens on providers, patients, payers, and other health care stakeholders.

As can be seen in the next section, the landscape analysis focused in particular on the policy and technical standards that are relevant to prior authorization. The analysis created a picture of the current state of digital prior authorization in the light of the desired ideal state, when administrative and clinical data converge and can be securely and reliably exchanged for use when and where they are needed. This examination made it clear that today's friction and inefficiencies arise when the data, policies, and business practices at points of intersection between clinical and administrative aspects of the health system cannot be reliably or easily integrated to optimally support care provision.

The landscape analysis led the Task Force to envision an "ideal state" and supporting guiding principles for the integration of clinical and administrative data to facilitate prior authorizations and other essential activities. On that basis, it developed a set of recommendations designed to address the underlying data, standards, and policies needed to achieve interoperability and integration.

In the following pages, section II presents the Task Force's prior authorization landscape analysis, and section III presents its findings about the ideal state, guiding principles, and recommendations. The report concludes in section IV with observations about further steps toward integration of clinical and administrative data.

II. Analysis of the Current Prior Authorization Landscape

Industry and government efforts to define and align terminologies have generated much progress for a variety of data classes that are relevant to the exchange of clinical and administrative data. The purpose of the analysis in this section is to define relevant classes of information that are commonly shared in the context of prior authorization (PA). The results of this analysis allow for an assessment of the current state as well as identifying gaps in standards that should be addressed to facilitate and promote prior authorization.

PRIOR AUTHORIZATION DATA CLASSES

ONC can encourage IT developers to create innovative solutions and a competitive marketplace that enhance the quality of care and improve patient engagement while reducing unnecessary burden among stakeholders. The initial assessment includes creating a common terminology and consistent constructions to identify, standardize, and externalize common data classes across PA use cases (as outlined in Table 2). The data classes include patient identity and demographics, insurance plan, benefits, patient-generated information, requested services, rules and requirements, justification, follow-up, determination decision, appeal, status completion, and metadata. This approach is aligned with the USCDI and third-party API standards in the ONC regulations from May 2020. Creating common terminology, crosswalks, and value sets to be used across the various standards will enable an environment for providers, payers, and their support partners to streamline and bring together disparate workflows to enable innovation and in particular to reduce, remove, or automate prior authorization when necessary.

ROLES AND STAKEHOLDERS

The rows in the following table (Table 1) indicate the major breakdowns across steps required before and leading up to a prior authorization being identified and processed. (The subcomponents shown in the columns of Table 1 are examples, and are not meant to be exhaustive, but instead are illustrative of the discrete, although not always linear, steps.) Clearly, many actors must provide information to succeed in getting a patient identified and approved for a particular treatment, order, or care pathway. In almost all instances, the patient-specific benefit coverage must be identified, generally in the format of a patient member identification number, and/or supporting personally identifiable information. It is critical to identify the appropriate plan-specific benefit in order to accurately understand the clinical and patient and provider specific data required for approval. The breadth of clinical data required can vary significantly from plan design to plan design, or among service types.

The vision underlying the ICAD Task Force's proposed guiding principles and recommendations includes supporting innovation in prior authorization workflows. Mapping out the variations in workflows between

and within the authorization use cases makes it clear that an enormous number of hand-off permutations occur between actors. Because of the volume and variation, the Task Force recommends focusing on normalizing the data across the myriad of interoperability specifications, to enable emerging standards to interoperate with existing investments in more longstanding or adjacent transaction sets, fueling innovation and iterative improvement instead of constraining implementation with well-documented challenges of existing named standards.

To ground its work, the workgroup defined common workflow categories by participants in the following table.

Table 1. Major Categories of Prior Authorization (Illustrative)

Prior Authorization Workflow	Patient or Delegate	Provider	Facility	Ancillary Service	Dispense or Fulfillment	Payer
Inpatient Services	✓	✓	✓			✓
Outpatient Services						
Physical /Occupational Therapy	✓	✓		✓		✓
Behavioral Health	✓	✓				✓
Specialty Physician	✓	✓				✓
Outpatient Procedures						
Prior Authorization Workflow	Patient or Delegate	Provider	Facility	Ancillary Service	Dispense or Fulfillment	Payer
Colonoscopy	✓	✓	✓	✓		✓
Imaging	✓✓	✓	✓	✓		✓
Surgery	✓	✓ (often multiple)	✓	✓		✓
Infusion	✓	✓	✓	✓		✓
Pharmacy						
Retail	✓	✓			✓	✓
Mail Order	✓	✓			✓	✓
Specialty Retail	✓	✓			✓	✓

Prior Authorization Workflow	Patient or Delegate	Provider	Facility	Ancillary Service	Dispense or Fulfillment	Payer
Durable Medical Equipment						
Orthotics	✓	✓		✓	✓	✓
Implantables	✓	✓		✓	✓	✓
Devices	✓	✓		✓	✓	

STANDARDS ALIGNMENT

Drawing on the collective knowledge and experience of its membership, as well as input from public and private sector volunteer contributors, the Task Force sought to define the relevant data classes and to analyze the utility of existing health care interoperability standards in satisfying the information needs of stakeholders in the context of prior authorization. Table 5 summarizes the analysis, based on the components outlined in Tables 2, 3, and 4.

The Task Force began by inventorying the kinds of information each party provides or requires throughout the lifecycle of ordering a service, procedure, or medication for a patient that may require tasks such as a prior authorization request. In order to bind this inventory and make it more meaningful, the Task Force then envisioned these “information needs" as data classes, borrowing the notion from the model established by ONC in the USCDI. Table 2 below includes a detailed description of each of the data classes envisioned.

Table 2. High-Level Description of the Type of Activities under each Category of Potential Workflow Steps

Data Class	Description of Data Class
Patient Identity	Includes, at a minimum, specific fields to uniquely identify a patient as a plan member and allow the patient’s provider to begin the discovery process to obtain information about the patient's benefits. The patient/plan relationship must first be defined so information can be obtained regarding the benefit type and the specific plan coverage at a given point in the plan year. In order to sufficiently de-duplicate a member from a plan’s list of patients, the following data at a minimum are useful: the member’s full name, date of birth, plan ID, and at least some minimal address information.
Patient Demographics	Includes basic demographic information captured by the provider about a patient in order to complete any transactions required to obtain a determination on the requested medication, treatment, procedure, service, or product.
Insurance Plan (Primary, Secondary, Tertiary)	Includes identifying information for each of the payers and plans under which a patient is covered. The information should be collected by the provider and used to interact with the payer to inform the patient's care and obtain reimbursement.

Data Class	Description of Data Class
Patient Benefits Transparency	Includes patient-specific coverage details requested by the provider and returned by the payer to inform the patient's care during a specific encounter. This should include information about which medications, treatments, procedures, services, and products require prior authorization. These data will enable providers to consider and discuss the financial and timing aspects of potential treatment options with the patient.
Patient-Generated	Would enable patients and their caregivers to provide information to support the approval of a PA Request (e.g., patient/caregiver statement about necessity), feedback on the fitment of a particular piece of durable medical equipment, or relevant historical information such as previous approvals.
PA Request	Includes information submitted by the provider to the payer regarding the medication, treatment, procedure, service, or product for which prior authorization is requested, as well as information about the requester and site of service.
PA Rules and Requirements	Includes information provided by the payer in response to a PA Request. The response should include a detailed description of the predefined rules that must be satisfied for a particular PA Request to be approved, including the data the payer requires for approval to be granted. Precise and transparent rules and requirements will reduce the ambiguity in what is required for a PA Request to be approved, thus resulting in fewer denials (i.e., because PA Requests that would have been denied would not be submitted in the first place) and reducing waste in the process. It also allows for providers to learn what facts may have been inappropriately or incompletely documented, and to reduce erroneous future referral submissions.
PA Justification	Includes information provided by the provider to the payer satisfying the requirements specified in the PA Rules and Requirements data class such as: documentation supporting medical necessity, history of past treatments provided, clinical diagnoses, test results. Because much of the information required to satisfy the requirements is fluid, it is important to note that the provider should control the timing of its transmission to the payer to prevent unnecessary denials (which would likely result in a subsequent attempt through a new PA Request), thereby reducing waste in the process.
PA Follow-Up	Includes additional data required by the payer to support the PA request. Would enable the payer to request additional information if more is needed than what is submitted with the PA Justification data class. The intent is to prevent denials on the basis of insufficient documentation, which would likely result in a subsequent attempt through a new PA Request, thus reducing waste in the process.

Data Class	Description of Data Class
PA Determination	Includes information provided to the provider by the payer--and transparent to the patient--officially communicating whether the PA Request was approved or denied. In the event it was approved, this would include a standard code indicating such approval which could be referenced for payment during the billing process. In the event it was denied, this would include sufficient detail to allow the provider to learn from the denial and improve compliance with the coverage rules for similar patients in the future. PA Requests should be placed in a "pending" status in only rare cases in which additional information is required of the requester in accordance with the predefined PA Rules and Requirements previously mentioned.
PA Appeal	Includes data required to support a PA appeal. Would enable providers, care team members, and patients to appeal a PA Determination electronically, responding to any gaps identified by the payer.
PA Status	Includes information related to the status of the PA Request and, ultimately, the PA Determination. The intent is to enable providers, care team members, and patients to understand the current status of a PA Request; obtain detailed information about the medication, treatment, procedure, service, or product approved; and reduce the number of duplicate PA Requests in process.
Payment	Includes information related to the actual processing of payment for the approved medication, treatment, procedure, service, or product.
Metadata	Includes pertinent information gathered from interoperable systems involved in the prior authorization workflow. This information should be transparent to all constituents.

STANDARDS CAPABILITY

As part of the prior authorization current landscape analysis, the Task Force made observations regarding the applicability of each standard to the information needs described in a particular data class. Table 3 below provides definitions for each standards capability category based on the Task Force's assessment. The standards capabilities are used in Table 5 to help identify gaps in the current landscape as compared to our descriptions of the ideal states' guiding principles.

Table 3. Explanation of Capability Categories

Capability Analysis	Description of Capability Analysis
Proprietary	The Task Force was able to identify one or more one-off solutions to meet the information needs described in a particular data class developed by market participants in the context of a given standard. Since some of these proprietary solutions may form the basis of future standards development efforts, the Task Force felt it important to highlight their existence, where applicable.

Capability Analysis	Description of Capability Analysis
Emerging	The Task Force deems the information needs described in a particular data class to be met by a given standard; however, that standard has not yet achieved normative (i.e., mature, by ANSI standards) status.
Available	The Task Force deems the information needs described in a particular data class to be met by a given standard that has achieved normative status; however, the standard is not in common use throughout the market.
In Use	The Task Force deems the information needs described in a particular data class to be met by a given standard that has achieved normative status and is in common use throughout the market.
N/A (Not Applicable)	The Task Force was unable to confirm that a given standard is currently capable of meeting the information needs described in a particular data class.

STANDARDS ADOPTION LEGEND

In this part of the analysis, the Task Force made observations about the level of adoption of each standard to meet the information needs described in a particular data class. Table 4 below provides an explanation for each category (assigned using the colors below at the intersection of a given standard and a particular data class). The categories (and colors) are then used in Table 5 to summarize these observations by data class and standard.

Table 4. Analysis of Standards Adoption Status

Adoption Analysis	Description of Adoption Analysis
Proprietary	The Task Force was able to identify one or more one-off solutions to meet the information needs described in a particular data class developed by market participants in the context of a given standard. Since some of these proprietary solutions may form the basis of future standards development efforts, the Task Force felt it important to highlight their existence, where applicable.
Draft Standard	The Task Force deems the information needs described in a particular data class to be met by a given standard; however, that standard has not yet achieved normative status.
Low	The Task Force deems the information needs described in a particular data class to be met by a given standard, and that standard was described as either “low adoption” or “low-medium adoption” by ONC in its latest Interoperability Standards Advisory.
Medium	The Task Force deems the information needs described in a particular data class to be met by a given standard, and that standard was described as “medium adoption” by ONC in its latest Interoperability Standards Advisory.

Adoption Analysis	Description of Adoption Analysis
High	The Task Force deems the information needs described in a particular data class to be met by a given standard, and that standard was described as either "medium-high adoption" or "high adoption" by ONC in its latest Interoperability Standards Advisory.
Unclear	The Task Force deems the information needs described in a particular data class to be *either* unmet *or* theoretically met by a given standard; however, if theoretically met, it is unclear how many, if any, market participants are leveraging the standard in this capacity.

SUMMARY OF ANALYSIS

The Task Force used the components and analyses outlined above to assess the current status of existing health care interoperability standards for meeting stakeholders' needs related to prior authorization. Table 5 below summarizes the results of the Task Force's analysis conducted for the relevant standards identified in light of the information needs described in each data class. Data classes (from Table 2) are listed in column 1. The words in the subsequent columns, each pertaining to a specific standard, indicate capability (from Table 3). The colors indicate the standard's adoption status (from Table 4). Further commentary on the findings follows Table 5. See the list of acronyms and glossary in Appendices 1 and 2 (respectively) for the keys to acronyms and technical terms.

Table 5. Summary of Existing Standards Analysis vis-a-vis Prior Authorization

	State of Existing Prior Authorization Content Standards									
	X12N			NCPDP		HL7 FHIR			HL7 CCDA	HL7 v2
Data Class	X12N 270/271	X12 275	X12 278	SCRIPT ePA	RTPB	CRD IG	DTR IG	PAS		
Patient Identity	In Use	N/A	N/A	Uses 270/271	Emerging	Emerging	Emerging	Emerging	In Use	In Use
Patient Demo-graphics	In Use	Available	Available	In Use	Emerging	Emerging	Emerging	Emerging	In Use	In Use
Insurance Plan (Primary, Secondary, Tertiary)	In Use	Available	Available	In Use	Emerging	Emerging	Emerging	N/A	In Use	In Use

	State of Existing Prior Authorization Content Standards									
	X12N			NCPDP		HL7 FHIR			HL7 CCDA	HL7 v2
Data Class	X12N 270/271	X12 275	X12 278	SCRIPT ePA	RTPB	CRD IG	DTR IG	PAS		
Patient Benefits Transparency	In Use	N/A	N/A	In Use	Emerging	Emerging	Emerging	N/A	N/A	In Use
Patient-Generated	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PA Request	N/A	Available	Available	In Use	N/A	N/A	N/A	Emerging	N/A	In Use
PA Rules and Requirements	N/A	N/A	Available	In Use	N/A	N/A	N/A	Emerging	N/A	In Use
PA Justification	N/A	Available	Available	In Use	N/A	N/A	N/A	Emerging	In Use	In Use
PA Follow-Up	N/A	N/A	Available	In Use	N/A	N/A	N/A	Emerging	N/A	In Use
PA Determination	N/A	N/A	Available	In Use	N/A	N/A	N/A	Emerging	N/A	In Use
PA Appeal	N/A	N/A	Available	Available	N/A	N/A	N/A	N/A	N/A	N/A
PA Status	N/A	N/A	Available	Emerging	N/A	N/A	N/A	N/A	N/A	N/A
Service Completion	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	State of Existing Prior Authorization Content Standards									
	X12N			NCPDP		HL7 FHIR			HL7 CCDA	HL7 v2
Data Class	X12N 270/271	X12 275	X12 278	SCRIPT ePA	RTPB	CRD IG	DTR IG	PAS		
Routing and Transport Metadata	Prop	Prop	Prop	Prop	Prop	Emerging ONC FAST Solutions			Prop	In Use

FINDINGS ON THE STATE OF EXISTING STANDARDS

The quest to improve the prior authorization process and reduce burden requires acknowledgment that current challenges are tightly connected to all of the steps within the workflow, which go beyond prior authorization. The data class view shared above breaks down the prior authorization process into data classes across the functional workflow steps that may be performed by different actors within the workflow. Below we have included a brief commentary on the standards group activities that impact prior authorization and the intersection of clinical and administrative data. (See the glossary in Appendix 2 for the keys to technical terms and acronyms.)

X12 Insurance Subcommittee (X12N)

The industry has a long-standing investment in X12N standards, as cemented by the HIPAA regulations for medical related transactions.[10] X12N 270/271 eligibility and benefit verification occurs before most existing electronic standards across workflows, including administrative claims, referrals, pharmacy, and authorizations, to determine what organization and plan owns the member for benefit determinations.

Table 6 below shows HIPAA standards and their adoption rates using data derived from the recent CAQH Index Report. Claims and eligibility standards are more mature, while prior authorization standards are still in early stages of adoption.

Table 6. HIPAA Standards Adoption Rates

Percent Industry Implementation of Seven Transaction Standards	2013	2018	2019
Health Care Claim Submission	90%	96%	96%
Eligibility for a Health Plan	65%	85%	84%
Coordination of Benefits	NR	80%	86%

[10] This includes operating rules authored by CAQH CORE (Committee on Operating Rules for Information Exchange).

Percent Industry Implementation of Seven Transaction Standards	2013	2018	2019
Health Care Claim Status	48%	71%	70%
Claim Payment	50%	63%	70%
Remittance Advice	43%	48%	51%
Prior Authorization	NR	12%	13%

Source(s): 2018 CAQH Index, 2019 CAQH Index

The X12N 278 authorization standard has limited adoption to complete two portions of the workflow required for prior authorization, initial submission, and status checking. Adoption of complete prior authorization workflow has lagged due to many independent factors. The primary limitations pertain to the specificity/flexibility of the transaction set, the lack of a clear named standard for the payload for required clinical data, and the lack of any meaningful regulatory enforcement.

Several proprietary API and portal solutions in the market incorporate the X12N 278 transaction set to enable payers/providers to meet the HIPAA requirement. The majority require manual, out-of-workflow rekeying of information.[11]

The quest for an attachment standard has a long history, and a national approach remains elusive. The X12N 275 attachments standard has been anticipated by HIPAA and ACA laws. For context, the 275 transaction has been recommended historically as the transport mechanism for clinical data payload that aligns with Promoting Interoperability. Emerging technologies and API approaches are rapidly evolving to meet clinical conversation exchange needs at the point of care. Anticipated proposed rulemaking for attachments will provide the opportunity for industry to further weigh in on which standards to adopt.

National Council for Prescription Drug Programs (NCPDP)

HIPAA regulations initially adopted NCPDP standards for pharmacy exchanges**. The NCPDP SCRIPT standard for electronic Prior Authorization** (ePA) launched in 2013 as a draft standard after being tested via pilot. The NCPDP ePA Workflow to Transaction Task Group under Workgroup 11 created a standalone XML-based standard after failed progress to utilize the X12N 278 standard for pharmacy prior authorizations.

Since its launch, the ePA standard has had meaningful adoption through “retrospective” submission of prior authorizations. Currently, the pharmacy test claim functions as the source of truth on whether a product requires prior authorization, so many providers wait for a prescription to fail at pharmacy before completing the prior authorization.

Recent advancements with a standards-based **Real-Time Benefit Check** transaction have enabled progress to increase prospective ePA, submission of prior authorization before or during ePrescribing

[11] https://ncvhs.hhs.gov/wp-content/uploads/2018/03/RC_Report_TD-Final-as-of-Oct-12-2016rh.pdf

workflow. The Real-Time Prescription Benefit (RTPB) Standard Version 11 was approved for ballot at the August 2020 NCPDP Work Group Meeting. The standard supports XML and EDI syntaxes.

Historically, adoption of prospective ePA usage has been thwarted by data quality challenges in Formulary and Benefit (F&B) files. There are a number of converging challenges: file size, frequency of updates, and/or lack of patient- or plan-specific data in the F&B file have resulted in a lack of trust in F&B data as a signal for Prior Authorization submission by providers in practice. The vendor, payer, and provider community is actively addressing the challenges to adoption of ePA at the point of prescribing. A number of proprietary vendors, pharmacy benefit managers, and payer integrations with RTBC APIs are in use in the market today.

In addition, NCPDP and HL7 have a joint project to incorporate a FHIR payload into the NCPDP transaction set to improve the ability to pull field-level data from a patient's EHR record into an accompanying Enrollment transaction for more complex therapies that require patient-specific demographic, clinical results, or findings to assist getting patient coverage and on therapy for specialty and more costly products. The project is progressing through HL7 and NCPDP standards process development. Early pilots are underway, generating draft solutions.

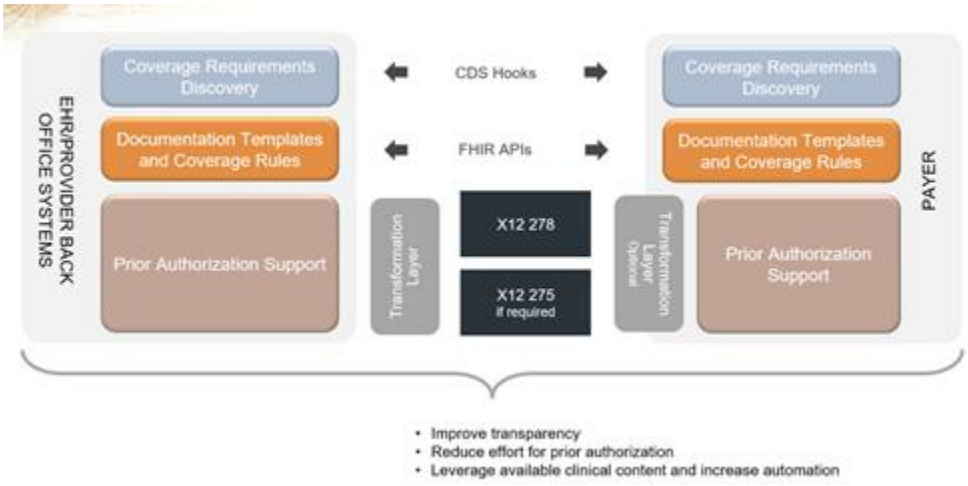
Health Level Seven (HL7)

Burden reduction and automation can benefit from existing and emerging HL7 standards. HL7's Fast Healthcare Interoperability Resource (FHIR) standard is an interoperability standard intended to facilitate the exchange of health care information between providers, patients, caregivers, payers, researchers, and anyone else involved in the health care ecosystem. FHIR has gained rapid acceptance on a global scale as an unprecedented, innovative platform standard that can truly enable health data interoperability. Collaborative groups are using the FHIR standard to create implementation specifications to meet their market segment data exchange needs. HL7 recognizes these groups through their FHIR Accelerator Program.

One of the Accelerators is the Da Vinci Project, a private sector initiative focused on solutions to integrate value-based care (VBC) data exchange across communities. The goal of the Da Vinci Project is to help providers and payers to positively impact clinical, quality, cost, and care management outcomes. Da Vinci has undertaken creating conciseness, clarity, and certainty to the predecessor steps to prior authorization submission. At its core is the goal of creating transparency about a patient's specific coverage options as part of the workflow for the provider and care team.

Figure 1 below represents three Da Vinci Project use cases (and corresponding HL7 FHIR-based implementation guide specifications) that support the integration of clinical and administrative data. The description of each use case and its relationship to the others is provided below the image. Combined together, the three use cases reduce burden in the provider-payer exchange related to treatment options and related insurance coverage. The use cases offer a framework to inquire, discover, and resolve insurance coverage applicability for a proposed course of treatment. In other words, they offer the ability to create a "conversation" between EHR and payer systems in an automated fashion, in support of prior authorization.

Figure 1. Da Vinci Project Use Cases Supporting Integration of Clinical and Administrative Data



Coverage Requirements Discovery is the first use case. It enables providers real-time access to payer approval requirements, documentation, and rules at the point of service to reduce provider burden and support treatment planning. The implementation guide allows the EHR to request information from a payer at the time an order is made. The payer response informs the provider if documentation or prior authorization is required. If documentation is required, a link is provided that launches an application defined by the next guide. If no prior authorization or documentation is required, the provider can proceed with ordering.

Documentation Templates and Rules is the second use case, building on the information obtained in the first use case. In this step, the exchange creates electronic versions of clinical and administrative requirements, including payer coverage criteria, and leverages available data in the EHR through FHIR calls during provider workflow. This guide leverages the SMART on FHIR technology (described in the next section) to launch an application within the EHR that, combined with embedded rules, will gather available structured data from the EHR and minimize data entry for providers. The rules are outlined and present the required documentation information for the provider to confirm. This documentation provides a record that information for the order is complete. If prior authorization is required beyond documentation, the application will allow the user to submit this information to the payer through the Prior Authorization Support implementation guide.

Prior Authorization Support, the third and final step, enables providers at the point of service to request authorization (including necessary clinical information to support the request) and receive prompt adjudication responses from the payer. With this capability, combined with the previous two implementation guides, the provider can submit a prior authorization request to the payer that includes the orders and supporting documentation. This process provides payers with structured information that can be used for automated adjudication and a more timely response whenever possible.

Each of the FHIR-based implementation guides is designed for in-workflow support of the provider team to enable them to better understand patient-specific benefits. Da Vinci community members are actively working to support crosswalk between FHIR and the mandated X12N 278 transaction to ensure support of the existing HIPAA transaction set. Roll-out of the draft standards is occurring with early adopters of FHIR

and Da Vinci implementation guides. The draft guides do not replace the existing X12 278 and 275 functions. Community members from both HL7 and X12 are working to create critical crosswalks between the two standards. Significant work is required to finalize, curate, and establish a clear path for implementers across the two standards and supporting value sets.

SMART on FHIR

To work effectively, the prior authorization process will need to be central to the workflow of the clinical team when their input or interaction is needed. Having HL7 FHIR as the foundation will simplify much of the integration; but where timely provider interaction is needed, frameworks such as CDS Hooks could be useful for successful integrations. SMART on FHIR and CDS Hooks are important in the prior authorization workflow to facilitate consistent and efficient decision-making.

The CDS Hooks specification describes the RESTful APIs and interactions used to integrate Clinical Decision Support between EHRs or other health information systems and CDS services. The elements include the CDS service, the system accepting requests and providing information with the CDS client, typically the EHR or other clinical system. The CDS hooks framework defines points within the workflow where information is requested and received. And finally, the information provided can take the form of Cards representing discrete pieces of information, or it can even launch a SMART on FHIR app to provide an interactive session, where required. Specific hooks including appointment-book or encounter-discharge would enable timely interaction with providers to obtain or share critical information, often when the patient is still present. This standardized methodology for interacting with the workflow could be key to integrating the prior authorization workflow at the right time and place and with the right user to successfully complete the process.[12]

[12] https://cds-hooks.hl7.org/

III. ICAD Findings and Recommendations

THE IDEAL STATE FOR CLINICAL AND ADMINISTRATIVE DATA INTEGRATION

The Task Force articulated the ideal state for the broader intersection of clinical and administrative data on the basis of its vision for an ideal, integrated workflow for prior authorization. This sample workflow vision depicts an integrated system that contains all of the data required to support the clinical and administrative interactions among patients, providers, payers, and all partners in the care journey. It depicts the ideal state as an end-to-end, closed-loop process that reduces the burden across all stakeholders, accounting for the vast majority of scenarios and leveraging existing investments and efforts where appropriate, while acknowledging that there are indeed gaps. This idealized workflow vision helped highlight the gaps between the current landscape and the ideal state.

The Task Force developed guiding principles to help guide its recommendations. The purpose of the guiding principles is to ensure that the recommendations address the gaps in the current process in a way that moves the ecosystem toward the ideal state. Thus, the ideal state can be viewed as the sum of all the characteristics enumerated in each of the guiding principles, as articulated below. The overarching goal is to enhance patient experience and health outcomes by reducing burden across the ecosystem and enabling innovation and continuous improvement without necessitating special effort on the part of ecosystem participants.

In the next section, the discussion of each guiding principle articulates specific components of the ideal state that this principle must assure.

GUIDING PRINCIPLES FOR CLINICAL AND ADMINISTRATIVE DATA INTEGRATION IN PRIOR AUTHORIZATION

The Task Force developed the following guiding principles, which apply in particular to prior authorization, to memorialize the goals and ideal state it had identified. The principles, in turn, informed the development of the recommendations.

The ICAD Task Force heard suggestions from a range of stakeholders about how to improve the prior authorization process. With those suggestions in mind, it re-imagined an ideal state prior authorization process with the following characteristics: an end-to-end, closed-loop process that reduces the burden across all stakeholders, accounts for the vast majority of situations, and leverages existing investments and efforts where appropriate, acknowledging the existing gaps. The prior authorization ideal state is guided by

principles that derive from the needs and perspectives of the stakeholders who engage in the prior authorization process, with particular focus on the patient's needs and perspectives.

The Task Force identified the following nine guiding principles for moving the prior authorization process toward the envisioned Ideal State:

Table 7. Nine Guiding Principles for Moving Prior Authorization to an Ideal State

A. Patient ~~at the Center~~-Centered Design and Focus	B. Transparency	C. Design for the Future While Solving Today's Needs ~~Today~~
D. Measurable and Meaningful	E. Continuous Improvement	F. Real-Time Data Capture and Workflow Automation
G. Aligned to National Standards	H. Information Security and Privacy	I. Reduce Burden on All Stakeholders

The following sections describe how characteristics of each guiding principle contribute to the ideal state.

A. Patient ~~at the Center~~-Centered Design and Focus

This guiding principle places the patient at the center of care and focuses on process solutions that remove roadblocks and support the coordination of timely care while reducing burdens, improving the patient experience, and ultimately improving outcomes.

To be consistent with the principle of patient-centered design and focus, the ideal state must include the following characteristics:

1) The burden is removed from patients and caregivers to serve as the driving force to push the prior authorization process and other administrative processes forward to completion.
2) Upfront price transparency allows the patient to see price variations specific to the site of care and/or service provider. Identifying an accurate cost for the patient will require sharing of additional data that are currently lacking in price transparency tools, such as the costs of mail order vs. brick-and-mortar pharmacy and cost variation between sites when it influences costs to patient—for example, comparing the costs of an off-site, out-patient office visit with a hospital out-patient office.
3) A shared decision-making process between clinician and patient exists with respect to treatment options, and considers any restrictions due to prior authorization, possible denial, and potential costs to the patient, including self-pay/out-of-pocket implications.
4) Information about all potential sources of coverage is accounted for, aligned, and made available to the patient and provider to avoid a pended or denied authorization.

5) Tools are readily available for all patients to lessen burden and overcome barriers related to the digital divide, access, socio-economic factors, and literacy.
6) Patients are able to share data bi-directionally with third parties electronically from an application of their choice without special effort, including patient-reported data.
7) Patients have the choice to use a 3rd party credential/authorization/consent service, which enables them to use the service to support seamless authorization and access functions to their data across the landscape (i.e., from all their providers, payers, and actors such as clearinghouses, HIEs, and Public Health) with minimal additional effort.

B. Transparency

Increase patient and provider access to real-time information about care, including coverage and price of services; the status of a prior authorization request; and other information in order to minimize delays, provide clarity, and ensure that the patient is able to manage care and follow through with treatments or services across the care continuum.

To be consistent with the principle of transparency, the ideal state must include the following characteristics:

1) Channels of communications are improved between health insurance providers, health care professionals, and patients to minimize care delays and ensure clarity on prior authorization requirements, rationale, and changes. This will include intra- and inter-organization communication to ensure that the data generated by all the transactions are made available to actors to support continuous process improvements.
2) Providers and patients have access to readily available information about which events require prior authorizations upfront, and about the status of the PA transaction at each step in the process, providing a common source of truth regarding the PA status.
3) There is transparency about when a prior authorization-related policy was last reviewed, with effective dates.
4) Patients have access to their patient-specific pricing at the point of decision-making or prior to the performance of the service.

C. Design for the Future While Solving Today's Needs

The future ecosystem should support today's comprehensive requirements while being extensible and resilient to support the evolving nature of the health system and encourage ongoing innovation.

To be consistent with the principle of designing for the future while solving today's needs, the ideal state must include the following characteristics:

1) The approach is sensitive to potential burden and potential digital divide, ensuring that stakeholders at all levels of technology and standards-use maturity can integrate clinical and administrative data at the individual patient and population levels, in support of improved outcomes and reduced burden.

2) The approach allows for standards development and evolution, so as to not preclude innovation, while including a "floor" of standards and implementation guides (if any) to promote rapid adoption through common implementation. The process both enables broad participation among stakeholders and avoids imposing unnecessary barriers to those who wish to innovate; and it provides for rapid innovation and piloting, testing, and validation of new tools and standards that meet evolving reality.

   a. The process provides a common service/ecosystem with a synthetic test data bed (representing the complexity of real-world data and transactions, including variances in state laws) that allows app developers and partners to go in and test against it without every participant having to create their own data, to aid initial validation that can support piloting.

   b. This infrastructure is supported as a public good, with investment for the long term.

3) Any necessary operating rules continue to raise the foundational level of adoption while encouraging and supporting organizations that wish to raise the ceiling of enhanced capabilities in the best interest of PA stakeholders.

D. Measurable and Meaningful

The process of reforming and improving prior authorization should be measurable so that progress can be tracked, and it should be meaningful for all stakeholders. Reforms should have a significant impact across the entire process and range of stakeholders, instead of having a marginally incremental impact or a significant impact for just a single stakeholder that leaves others behind or on the sidelines.

In order for the reform process to be measurable and meaningful, the ideal state must include the following characteristics:

1) Prior Authorization process reform and improvements are driven by patient safety, evidence-based medicine, and the goal of reducing burden across stakeholders.

   a. Patient safety and Evidence-Based Medicine protocols are timely, from authoritative and peer-reviewed published sources, and accessible to any stakeholder.

   b. Measurement of "burden" is quantifiable and reflects the real-world experience of stakeholders.

2) At the end of the phase-in process described below, 95% of PA's have clear decision and related determination specifics communicated to applicable stakeholders. Further, the processes enable participants to learn from pended requests and denials, aided by clear and unambiguous value-sets for automated responses.

   a. Based on each type of PA Workflow, the 95% goal can be phased in – e.g., using annual targets (45% - 65% - 80% - 90% - 95%, etc.), recognizing that some types of PA processes may reach goals earlier than others. The maturity of specific PA workflows should be the focus rather than a single target for all PA activity, given the variations in complexity. For example, PA workflows for specialty drug therapies may more quickly achieve aggressive goals than a complex DME PA workflow, where goals for the latter may need to be phased in over a greater period of time.

b. The PA responses are tracked and analyzed to provide metrics on the basis of which further improvements can be made.

c. Surveys by groups representing the various stakeholders (consumer/patient, plan/payer, and provider) are used to assess satisfaction related to the experience of both process and outcomes.

3) There is recognition that at any single point in time, some prior authorization transactions may not be feasible using a fully electronic automated prior authorization process. Nevertheless, the goal is to encourage electronic submission of additional standardized data and machine-actionable appeal requests over time, rather than perpetuating legacy methods such as paper/manual chart review when a PA transaction results in a “pended” or “denied” state.

E. Continuous Improvement

The prior authorization process should embrace the concepts of evidence-based, data-driven continuous improvement (akin to learning health care systems) among stakeholders, with metrics and goals.

To support continuous improvement, the ideal state must include the following characteristics:

1) A standard framework is used to provide transparency for the decisions/rules governing the PA process and to reduce burden among stakeholders. This will help engender trust, thus accelerating adoption.
2) Protocols for PA review are established.

a. Payers have an established process (e.g., consensus peer-reviewed guidelines and/or expert panels) for regularly reviewing and communicating the services and medications that require prior authorization and eliminating requirements for therapies/equipment/services that no longer warrant them.

b. Payer review/communication processes have an established, predictable cadence similar to the CPT annual update process.

3) A continuous improvement process exists for reassessing prior authorizations annually in order to determine if they can be eliminated or improved. In the event that a pattern of transactions emerges in which a prior authorization process results in a “denial” or is “pended” and requires manual processing, attempts are made to identify and incorporate codifiable/machine-actionable recourse methods that support the continuous improvement methodology. The idea here is to ensure that all aspects of the workflow or interaction between the actors in the prior authorization process are supported within the digital workflow.
4) The measured usability and adoption metrics are used to optimize the design of an automated electronic PA process including remediation of unintended consequences, errors, etc., in previous versions.

F. Real-Time Data Capture and Workflow Automation

In transactions in which clinical and administrative data intersect, clinical care should be supported by automated processes that reduce the time and effort used to document information for prior authorization.

These processes should operate in real-time in the background, to improve usability and efficiency for all stakeholders. Processes will focus on what information can be exchanged to make shared care decisions better, faster, and more transparent.

To support real-time data capture and workflow automation, the ideal state must include the following characteristics:

5) All or nearly all the data needed for PA are routinely collected during the ordering steps, in efficient workflow approaches for providers and their patients.
6) Regardless of the venue of care, the prior authorization process is mechanically similar for both the clinician and their patient regardless of health plan. Patients move across the health ecosystem, and providers are not burdened with disparate workflows depending on venue.
7) Automation of ordering and PA processes for medical services and equipment are supported through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, payers, and patients.
8) Any workflow used to support PA auto-generates editable content to document the medical necessity in the progress note/visit note so that clinicians do not need to re-document and re-justify the prior authorization request.
9) Patients have full visibility into coverage requirements and benefits across all their coverage plans. All insurance coverage is identified and verified on or before the point of service. Related supports are provided for ongoing coordination of benefits that allows for efficient and comprehensive coverage, as allowed.
10) The source provides all information required for recommendations and decision-making at the same time, to avoid an initial rejection followed by a secondary rejection.
11) Data are collected once and reused for additional permissible purposes when feasible and clinically meaningful, to reduce undue burden on stakeholders. Data that must be updated continually (such as height and weight) are noted in a manner that does not allow for automated re-use of previously collected data.
12) End-to-end automation for processing PA data request and response is increased, using recognized standards and code set values.
13) Continuity of care is protected for patients on an ongoing, active treatment or a stable treatment regimen in the event of changes in coverage, health insurance providers, or PA requirements.
14) Workflow practices include triggers for expiring PA to prompt renewal activities, if applicable.
15) Relevant clinical and administrative data are available in useful form at the point of need – whether patient decision-making and/or consultation to support shared decision-making, administrative review, or care transition – to the right actor, to support care decisions and administrative workflows.

16) There is a single workflow (ideally single standard) for all transactions at the intersection of clinical and administrative data regardless of payer/plan, with capabilities available without special effort in the system that the relevant actor normally uses in regular workflow (e.g., EHR for provider, management for practice staff, claims for payers, ideally a single portal or point of access for patients).

G. Aligned with National Standards

The prior authorization process should leverage and align to existing national standards (e.g., vocabularies, terminologies, messaging protocols, etc.) and contribute to the community development of additional national standards where gaps are identified, rather than inventing new methods.

To support alignment with national standards, the ideal state must include the following characteristics:

1) Standardized data aligned with USCDI are the basis of data exchanged for prior authorization. For any key/priority data not incorporated into the USCDI, HITAC will provide prioritized feedback to the ONC for consideration in subsequent versions.
2) Standard format and related policy is adopted and ubiquitous at a national level for additional documentation requests and for the response to provide any supplemental information needed to process the prior authorization request.
3) The ability to share clinical data in consistent standard formats is critical. Existing standards exist for transport to receive a payload of provider's attachment submissions for patient information such as demographics, clinical, and other supporting data that may be needed for an authorization.
4) The ability for the industry to codify the specific data values in semantically consistent formats and standards will also be required for the industry to accomplish end to end automation in a meaningful way.
5) Providers and their vendor partners have clarity on both acceptable formats and the required clinical data necessary for a PA determination to be collected at the point of submission, to avoid needless delays or denials of PA because information was not sent in the initial request.
6) A consistent standards advancement process is used for administrative and clinical standards adoption. In addition, where multiple legacy standards exist and are in widespread use, efforts to harmonize those standards (including mapping and translation) are undertaken to simplify implementation for stakeholders.
7) New standards fill identifiable gaps, with low additional development and implementation costs relative to the benefits.
8) For both existing standards and future standards, educational/training materials, implementation guides, and operating rules are freely accessible to the stakeholders.
9) Development activities are funded through private and public sector investments and initiatives, with clarity around intellectual property and licensing terms.

H. Information Security and Privacy

The ICAD Task Force's recommendations are grounded in foundational security and privacy considerations that are intended to benefit the design of future processes and technologies. This guiding principle will advance and maintain trust in interoperability to support and encourage the exchange of information via health IT. Future solutions should be patient-centric and meet current health information and patient rights laws and regulations to promote the privacy and security of health information and protect against disclosures of personal health information.

To support information security and privacy, the ideal state must include the following characteristics:

1) Information practices adhere to current health information and patient rights, laws, and regulations, including the Federal HIPAA Privacy, Security and Breach Notification rules, 42 CFR Part 2 - Confidentiality of Substance Use Disorder Patient Records, as well as state requirements, as applicable.
2) Information practices meet the minimum necessary standard when requesting and disclosing information. We note that minimum necessary is often defined differently in provisions such as:

    a. HIPAA Privacy Rule – minimum necessary standard plus the anticipated OCR updates
    b. State Laws
    c. Data use agreements and business associate agreements
3) Patients and caregivers are empowered and able to have a role from inception to conclusion in providing and expediting their consent, when required to share information necessary for PA decisions. Transparent Information about what the patient is consenting to is provided in a format that is easy for the patient/caregiver to access and understand.
4) Prior authorization stakeholders have reached common agreement on implementation of minimum necessary protected health information-sharing for PA. When required beyond HIPAA treatment, payment, and operation permissions, consent format consistency is established and streamlined for automated collection and use.
5) Harmonized Federal regulation primarily governs PA in the ideal state, minimizing variation of requirements between states. Where variation in requirements exists, such variations are available in a standards-based, machine-readable and interpretable fashion.

I. Burden Reduction for All Stakeholders

A converged ecosystem should enable all stakeholders across the continuum -- including patients and caregivers, primary and specialty care, public health, vital records, research, payers, and policymakers -- to have the information they need, without creating additional data capture or burdens on providers and patients, by supporting seamless exchange across the continuum of care. This has great potential to reduce burden by furthering the implementation of 'record once and reuse.'

To support the principle of burden reduction for all stakeholders, the ideal state must include the following characteristics:

1) CDS processes provide the right level of evidence-based and patient-centric guidance during the care process. CDS tools such as digitally accessible practice guidelines and patient decision aids, when integrated with administrative processes and implemented appropriately, improve the efficiency of or reduce the need for PA.
2) Patients and caregivers are able to focus on their well-being rather than having to problem-solve administrative process complexities.

To achieve the envisioned ideal state for all stakeholders and align with the guiding principles as outlined above, the ICAD Task Force presents the following recommendations.

RECOMMENDATIONS TO ACHIEVE INTEGRATION OF CLINICAL AND ADMINISTRATIVE DATA FOR PRIOR AUTHORIZATION AND OTHER USES

The ICAD Task Force presents the following recommendations on the harmonization of clinical and administrative data, its transports, structures, rules, and protections for the purpose of reforming digital prior authorization. These recommendations, which are not listed in priority order, outline necessary steps on the path toward clinical and administrative data integration. In other words, they focus on "the what," not "the how," and clarify the areas in which resources and energies must be focused to solidify the details needed to fulfill them. Using the recommendations as a basis for initiating follow-on activities, industry partners and other stakeholders now need to get involved in translating the "whats" into "hows" and moving forward toward the ideal state. Federal leadership is essential to ensure that this process includes robust interagency coordination, industry and Federal advisory committee engagement, and alignment with other relevant initiatives.

The recommendations include references to 'Federal actors,' 'relevant Federal agencies,' 'associations,' 'Federal advisors,' and other entities. Those entities include, but are not limited to:

- ONC
- CMS programs: Medicare FFS, Medicare Advantage, Part D, Medicaid, QHPs, FQHCs, CHIP
- Military Health Programs: DOD, Tricare, VHA
- Office of Personnel Management: Federal Employee Program (FEP)
- Indian Health Service (IHS)
- Office of Management and Budget (OMB)
- Office of Civil Rights (OCR)
- National Standards Group (CMS/NSG)
- Federal Trade Commission (FTC)
- Federal Advisory Committees
- Congress (when no authority or incentives are available otherwise)
- Standards Development Organizations / Standards Setting Organizations
- Operating Rule Authoring Entities

- Federal advisors such as HITAC, NCVHS, WEDI, etc.
- Associations such as AMA, AHA, ADA, HIMSS, CHIME, EHRA, etc.

The recommendations differentiate between Federal agencies with operational programs and Federal agencies with regulatory authority. For example, CMS can implement recommendations under its Medicare and Medicaid program requirements as well as under its regulatory authority from HIPAA, HITECH and ACA.

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/MAPD 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, e.g., access to capital, lack of onboard 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.

Recommendation 3: Converge Health Care 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 (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), 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.

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 raise 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 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.

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.

Recommendation 7: Develop Patient-centered Workflows and Standards

The Task Force discussed the critical importance of transparency to the patient of 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** that 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 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.

Recommendation 8: ~~Create Standardized~~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 ~~create and incorporate standards~~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 ID cards 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 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.

Recommendation 10: Establish Regular Review of Prior Authorization Rules

The 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.

Recommendation 11: Establish Standards for Prior Authorization Workflows

The Task Force **recommends** that ONC work with CMS, other Federal actors, and standards development organizations to develop programmatic (API) specifications to create an authorization (digital 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.[13] As an example, when an authorization is required for payment for a procedure or referral for evaluation or treatment, the prior authorization workflow should be enabled in the relevant ordering or referral clinical workflow.

The Task Force **recommends** that the chosen standard or standards be sufficient to:

- Determine which orderables, procedures, referral, or other activities are subject to prior authorization, medical necessity, or other similar pre-approval checks;
- Determine the requirements and rules for approval of an orderable, procedure, referral, etc. sufficient to collect the required documentation or justification;
- Automate the pre-approval workflow using the provider's chosen technology platform without relying on portals or payer-specific workflows;
- Determine the definitive status of a pre-approval request programmatically in the provider's chosen workflow; and
- Ensure that transparency occurs in near real-time, based on a specific patient at a specific time in a specific location.

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 increased benefit transparency and automated digital prior authorization. The Task Force further **recommends** that these regulations and

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[13] Examples of emerging areas that should be looked at:
○ CDS Hooks supporting a variety of hook actions is needed for Real-Time clinical decision support across multiple use cases
○ Full FHIR profiles
○ Bulk Data on FHIR for multiple use cases
○ Bi-directional data flow (to and from EHRs; read-write capabilities)
○ Standardized (open API-based) electronic health information (EHI) Export functionality –for persistent, real-time EHI access for multiple provider-facing use cases (i.e., population health and outcomes management, analytics, research)
○ Ongoing refinement and updating of USCDI standardized data classes and data elements)

requirements for trading partners include service level objectives on latency and availability sufficient for prior authorization to be incorporated in interactive workflows. The Task Force further **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, the 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.

Recommendation 12: Create Extension and Renewal Mechanism for Authorizations

The 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 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 process is transparent to the patient ~~is included throughout the process~~. In particular, 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 or caregiver can answer).

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.

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 that 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 ~~Minimum~~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.

IV. Summary and Conclusion: Toward Further Integration of Clinical and Administrative Data

The ICAD Task Force was charged with creating recommendations to support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden, and improve efficiency—furthering implementation of "record once and reuse."

As noted in the opening section, there is strong agreement within health care policy, standards, and industry circles that the lack of harmonized clinical and administrative data standards and policy imposes risk on patients and burdens the entire health care ecosystem. This report synthesizes substantial industry input that informed the Task Force's vision of an ideal, future state.

The goals of our recommendations to reduce burden are to:

- 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; and
- Create an ecosystem that enables patients and caregivers to focus on their well-being rather than problem-solving administrative process complexities.

The Office of the National Coordinator for Health Information Technology's support of HITAC and the ICAD Task Force is highly appreciated, as it enabled the structure necessary to create this body of work. Such leadership and coordination are essential to solidifying the underpinning details required to fulfill the report recommendations and reduce burdens for all stakeholders. The process should continue to include

alignment with other health care improvement initiatives, robust interagency coordination, and ongoing industry and Federal advisory committee engagement. Notably, NCVHS is developing a project on the convergence of administrative and clinical data, based on its prior work on the Predictability Roadmap. The Convergence Project will be informed by the HITAC recommendations on the integration of clinical and administrative data.

We gratefully thank all of the ICAD Task Force members and industry stakeholders who contributed to the Task Force's information gathering, analysis, discussion, development of the ideal state, guiding principles, and recommendations.

The Task Force believes that these recommendations will form a solid basis on which to develop the future policies, standards, and enabling technologies that will truly put the patient at the center of an efficient health care information ecosystem. That ecosystem would seamlessly and multi-directionally move appropriate data from the point of initial capture to the point(s) of use without any special effort by those capturing or consuming the data. Those data flows would be protected by robust security practices and privacy policies. Overall burden would be reduced while clinical care, patient experience, and health outcomes would be improved. HHS and industry stakeholders should take these recommendations as a basis for initiating follow-on actions to bring the described ideal state to life.

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APPENDIX 1: List of Acronyms

ACA - Patient Protection and Affordable Care Act

AHA - American Hospital Association

AHIMA - American Health Information Management Association

AHIP - America's Health Insurance Plans

AMA - American Medical Association

ANSI - American National Standards Institute

API - Application Programming Interface

APM - Alternative Payment Model

ASC - Accredited Standards Committee (X12)

CAQH - Council for Affordable Quality Healthcare

CAQH CORE – Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange

C-CDA - Consolidated-Clinical Document Architecture

CHIME - College of Healthcare Information Management Executives

CHIP - Children's Health Insurance Program

CMS - Centers for Medicare & Medicaid Services

CRD - Coverage Requirements Discovery

Cures Act - The 21st Century Cures Act

DoD – United States Department of Defense

DRLS - Documentation Requirement Lookup Service

DRS - Designated Record Set

DTR - Documentation Templates and Coverage Rules[14]

EDI - Electronic Data Interchange

ePA - Electronic Prior Authorization

EHI - Electronic Health Information

EHR - Electronic Health Record

EHRA - HIMSS Electronic Health Record Association

EOB - Explanation of Benefits

FACA - Federal Advisory Committee Act

F&B - Formulary and Benefit

FDA - Food and Drug Administration

FEHB or FEHP - Federal Employees Health Benefits Program

FFS - Fee-for-service

FHIR® - Fast Healthcare Interoperability Resources

FQHC - Federally Qualified Health Center

FTC - Federal Trade Commission

ICAD - Intersection of Clinical and Administrative Data

IHS - Indian Health Service

HEDIS - Healthcare Effectiveness Data and Information Set

HHS - United States Department of Health and Human Services

HIMSS - Healthcare Information and Management Systems Society, Inc.

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[14] This use case is interchangeably referred to as “Documentation Templates and Rules,“ and “Documentation Templates and Coverage Rules”

HIPAA - Health Insurance Portability and Accountability Act

HITAC - Health Information Technology Advisory Committee

HITECH - Health Information Technology for Economic and Clinical Health Act

HL7® - Health Level Seven International

INCITS - International Committee for Information Technology Standards

MA - Medicare Advantage

MAPD - Medicare Advantage Part D

MIPS - Merit-based Incentive Payment System

MSSP - Medicare Shared Savings Program

NCPDP - National Council for Prescription Drug Programs

NCVHS - National Committee on Vital and Health Statistics

NLM - National Library of Medicine

NSG - National Standards Group (CMS)

OCR - Office for Civil Rights (HHS)

OMB - Office of Management and Budget

ONC - Office of the National Coordinator for Health Information Technology

OPM - Office of Personnel Management

PA - Prior Authorization

PAS - Prior Authorization Support

PBM - Pharmacy Benefit Manager

QHP - Qualified Health Plan

REST - Representational State Transfer

SMART® - Substitutable Medical Applications, Reusable Technologies

SDO - Standards Developing Organization

SSA - Social Security Administration

SSO - Standards Setting Organization

SVAP - Standards Version Advancement Process

TEFCA - Trusted Exchange Framework and Common Agreement

USCDI - United States Core Data for Interoperability

VA - Department of Veterans Affairs

VHA - Veterans Health Administration

WEDI - Workgroup for Electronic Data Interchange

XML - Extensible Markup Language

APPENDIX 2: Glossary

Disclaimer: This glossary provides a general list of industry terms related to the intersection of clinical and administrative data. It attempts to capture the range of terms used in this report but is not all-inclusive.

Application Programming Interface (API) - A set of tools, definitions, and protocols for building and integrating application software. It lets a product or service communicate with other products and services without needing to know how they're implemented.[15]

American National Standards Institute (ANSI) - Private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. Founded in 1918, the Institute works in close collaboration with stakeholders from industry and government to identify and develop standards- and conformance-based solutions to national and global priorities. [16]

CAQH CORE - Established in 2005, the Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) is a multi-stakeholder collaboration of more than 110 organizations – providers, health plans, vendors, government agencies, and standard-setting bodies – developing operating rules to simplify healthcare administrative transactions. CAQH CORE participating organizations include health plans representing more than 75 percent of commercially insured lives, plus Medicare and Medicaid beneficiaries.[17]

CAQH Index Report - Industry resource developed by the Council for Affordable Quality Healthcare for benchmarking progress to reduce administrative complexity. Tracks adoption of HIPAA-mandated and other electronic administrative transactions for conducting routine business between healthcare providers and health plans in the medical and dental industries. Transactions include verifying a patient's insurance coverage, obtaining authorization for care, submitting a claim and supplemental medical information and sending and receiving payments. The CAQH Index also estimates the annual volume of these transactions, their cost and the time needed to complete them.[18]

CAQH CORE Operating Rules - Operating rules developed by the Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) that support a range of existing standards to make electronic data transactions more predictable and consistent, regardless of

[15] Red Hat Inc. (n.d.). *What are APIs?* Retrieved from https://www.redhat.com/en/topics/api/what-are-application-programming-interfaces
[16] The American National Standards Institute. (n.d.) *About ANSI*. Retrieved from https://www.ansi.org/
[17] The Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE). (n.d.). *Operating Rules*. Retrieved from https://www.caqh.org/core/operating-rules
[18] CAQH. (n.d.). *The CAQH Index Report*. Retrieved from https://www.caqh.org/explorations/caqh-index-report-0

the technology. CAQH CORE operating rules facilitate many high-volume transactions that involve multiple parties, such as automated banking transactions and airline ticket bookings. CAQH CORE has been designated by the Secretary of the Department of Health and Human Services (HHS) as the author for federally mandated operating rules per Section 1104 of the Patient Protection and Affordable Care Act (ACA).[19]

Clinical Decision Support (CDS) - Clinical decision support provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools.[20]

CDS Hooks - A technical functionality supporting clinical decision support that enables the creation of standardized places within an EHR workflow where the EHR can issue a notification that an event is occurring. This notification can be received by an external application, which in turn can return pertinent information to the EHR for display to the EHR user.[21]

Consolidated-Clinical Document Architecture (C-CDA) - A document standard for the transmission of structured summary data between providers, and between providers and patients. Transmitted data supports care transitions, referrals, and care coordination.[22]

Convergence Project - National Committee on Vital Health Statistics (NCVHS) project to develop recommendations to support convergence of clinical and administrative data with initial focus on the prior authorization transactions and workflow. In collaboration with the Office of the National Coordinator for Health Information Technology (ONC), NCVHS will: (i) identify and recommend a path toward convergence of administrative and clinical data standards, and (ii) propose to use the prior authorization processes of industry as an exemplar, and to better understand and guide convergence paths for health care policy and standards.[23]

Coverage Requirements Discovery (CRD) - First of three HL7® Da Vinci Project use cases that support the integration of clinical and administrative data. Enables providers real-time access to payer approval requirements, documentation and rules at the point of service to reduce provider burden and support treatment planning. The CRD implementation guide allows the EHR to request information from a payer at the time an order is made. The payer response informs the provider if documentation or prior authorization

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[19] CAQH CORE. (n.d.). *Committee on Operating Rules for Information Exchange*. Retrieved from https://www.caqh.org/caqh-core
[20] Office of the National Coordinator for Health Information Technology. Retrieved from https://www.healthit.gov/topic/safety/clinical-decision-support
[21] Burger, M. (2019). *CDS Hooks can Use FHIR APIs to Trigger Robust Decision Support in EHRs.* Retrieved from https://www.pocp.com/hit-cds-hooks
[22] HIMSS Interoperability & Standards Practices Task Force. (2014). *C-CDA Review. Retrieved From https://www.himss.org/c-cda-review*
[23] National Committee on Vital and Health Statistics. June 2020. *Subcommittee on Standards Update*. Retrieved from https://ncvhs.hhs.gov/wp-content/uploads/2020/06/H-REVISED-Standards-Subcommittee-Update-0618-2020-508.pdf

is required. If documentation is required, a link is provided that launches an application defined by the next guide. If no prior authorization or documentation is required, the provider can proceed with ordering.

Covered Entity - An individual, organization, or agency that must comply with HIPAA requirements to protect the privacy and security of health information and must provide individuals with certain rights with respect to their health information. Examples include a health plan, a health clearinghouse, or a healthcare provider who transmits any information in an electronic form in connection with a transaction for which HHS has adopted a standard.[24]

Documentation Requirement Lookup Service (DRLS) Initiative - Prototype Medicare Fee for Service (FFS) Documentation Requirement Lookup Service that is designed to streamline workflow access to coverage requirements – including documentation and prior authorization requirements. The prototype will be made accessible to pilot participants and will be populated with 1) a list of items/services for which prior authorization is required, and 2) the documentation requirements for Oxygen and Continuous Positive Airway Pressure (CPAP) devices.[25]

Documentation Templates and Rules (DTR) - Interchangeably referred to as "Documentation Templates and Rules," and "Documentation Templates and Coverage Rules," this, the second of three HL7® Da Vinci Project use cases that support the integration of clinical and administrative data. In this use case, the exchange creates electronic versions of clinical and administrative requirements, including payer coverage criteria, and leverages available data in the EHR through FHIR calls during provider workflow. The DTR implementation guide leverages SMART on FHIR technology to launch an application within the EHR that, combined with embedded rules, will gather available structured data from the EHR and minimize data entry for providers. The rules are outlined and present the required documentation information for the provider to confirm. This documentation provides a record that information for the order is complete. If prior authorization is required beyond documentation, the application will allow the user to submit this information to the payer through the Prior Authorization Support implementation guide.

Da Vinci Project - Private sector initiative that addresses the needs of the Value Based Care Community by leveraging the HL7 FHIR platform. The goal of the project is to help payers and providers to positively impact clinical, quality, cost and care management outcomes.[26]

Electronic/Digital Prior Authorization - Electronic transmission of information between the prescriber and payer to determine whether or not the prior authorization is granted.[27]

Electronic Prescribing/ePrescribing - Computer-to-computer transfer of prescription data between pharmacies, prescribers, and payers. Electronic prescribing functions include messages regarding new

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[24] Department of Health and Human Services, Office for Civil Rights. (2017). *Covered Entities and Business Associates.* Retrieved from https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html
[25] Centers for Medicare & Medicaid Services. (n.d.). *Documentation Requirement Lookup Service*. Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/LookupServiceInitiative
[26] HL7 International. (n.d.). *About Da Vinci*. Retrieved from https://www.hl7.org/about/davinci/
[27] National Council for Prescription Drug Programs. January 2015. *NCPDP SCRIPT Standard Supports Electronic Prior Authorization (ePA) Fact Sheet*.

prescriptions, prescription changes, refill requests, prescription fill status notification, prescription cancellation, and medication history.[28]

Fast Healthcare Interoperability Resources (FHIR®) Standard - An interface specification that specifies the content of the data exchanged between healthcare applications, and how the exchange is implemented and managed. The data exchanged includes clinical data as well as healthcare-related administrative, public health, and research data.[29]

Fee-For-Service (FFS) - A method in which doctors and other healthcare providers are reimbursed for each service performed.[30]

FHIR Accelerator - The HL7 FHIR Accelerator Program is designed to assist communities and collaborative groups across the global health care spectrum in the creation and adoption of high quality FHIR Implementation Guides or other standard artifacts to move toward the realization of global health data interoperability.[31]

Formulary and Benefit (F&B) Standard - NCPDP standard used in electronic prescribing in which Pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) communicate formulary and benefit information to prescribers via technology vendor systems.[32]

Health Level Seven International (HL7) - A not-for-profit, standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services.[33]

Intersection of Clinical and Administrative Data (ICAD) Task Force - The Task force of the Office of the National Coordinator for Health IT's Advisory Committee (HITAC) charged with investigating and supporting the convergence of established healthcare frameworks for clinical and administrative data. Its membership includes members of the HITAC, the National Committee on Vital and Health Statistics (NCVHS), and industry.

Interoperability - Health information technology that (a) enables the secure exchange of information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (b) allows for complete access, exchange, and use of all electronically accessible health

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[28] National Council for Prescription Drug Programs. May 2014. *NCPDP Fact Sheet on ePrescribing*. Retrieved from https://ncpdp-main.ncpdp.org/NCPDP/media/pdf/EprescribingFactSheet.pdf
[29] HL7 International. (2018). *FHIR Exchange Module.* Retrieved from http://www.hl7.org/implement/standards/fhir/exchange-module.html
[30] Centers for Medicare & Medicaid Services. (n.d.). *Fee for Service.* Retrieved from https://www.healthcare.gov/glossary/fee-for-service/
[31] HL7 International. (n.d.). HL7 FHIR Accelerator Program. Retrieved from https://www.hl7.org/about/fhir-accelerator/
[32] National Council for Prescription Drug Programs. September 2014. *NCPDP Electronic Prescribing Standards*. Retrieved from https://ncpdp-main.ncpdp.org/NCPDP/media/pdf/NCPDPEprescribing101.pdf
[33] HL7 International. (n.d.). *About HL7*. Retrieved from http://www.hl7.org/about/index.cfm?ref=nav

information for authorized use under applicable state or federal law; and (c) does not constitute information blocking as defined in section 3022(a) of the 21st Century Cures Act.[34, 35]

Minimum Necessary Standard Requirement - The minimum necessary standard, a key protection of the HIPAA Privacy Rule, is derived from confidentiality codes and practices in common use today. It is based on sound current practice that protected health information should not be used or disclosed when it is not necessary to satisfy a particular purpose or carry out a function. The minimum necessary standard requires covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate access to and disclosure of protected health information. The Privacy Rule's requirements for minimum necessary are designed to be sufficiently flexible to accommodate the various circumstances of any covered entity.[36]

Merit-based Incentive Payment System (MIPS) - A quality payment incentive program administered by the Centers for Medicare & Medicaid Services which ties provider reimbursement to quality and cost-efficient care. This program aims to drive improvement in care processes and health outcomes, increase the use of healthcare information, and reduce the cost of care.[37]

National Council for Prescription Drug Programs (NCPDP) - Not-for-profit American National Standards Institute (ANSI)-accredited Standards Development Organization consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.[38]

National Committee on Vital and Health Statistics (NCVHS) - The National Committee on Vital and Health Statistics (NCVHS) serves as the statutory [42 U.S.C. 242(k)] public advisory body to the Secretary of the Department of Health and Human Services (HHS) in the areas of health data, standards, statistics, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C.242k[k]). In this capacity, the Committee provides advice and assistance to HHS and serves as a forum for interaction with relevant private sector groups on a range of health data issues.[39]

Predictability Roadmap - The NCVHS Predictability Roadmap outlines a process of updating and adopting standards and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that would be more predictable and transparent. The development of the Predictability Roadmap includes evaluation of the barriers to the update, adoption, and implementation of certain standards and

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[34] 21st Century Cures Act, Pub. L. 114-255, 130 Stat. 1033, codified as amended at §§300jj–19a
[35] Anthony, E.S. & Morris, G. (2018, January 8). 21st Century Cures Act Overview for States. Retrieved from https://www.healthit.gov/sites/default/files/curesactlearningsession_1_v6_10818.pdf
[36] U.S. Department of Health & Human Services. (n.d.). *Minimum Necessary Requirement*. Retrieved from https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/minimum-necessary-requirement/index.html
[37] Quality Payment Program. (n.d.). *Merit-Based Incentive Payment System Overview.* Retrieved from https://qpp.cms.gov/mips/overview
[38] National Council for Prescription Drug Programs. January 2015. *NCPDP SCRIPT Standard Supports Electronic Prior Authorization (ePA) Fact Sheet*.
[39] National Committee on Vital and Health Statistics. (n.d.). *About NCVHS*. Retrieved from https://ncvhs.hhs.gov/

operating rules, specifically those adopted under the authorities of HIPAA and the Patient Protection and Affordable Care Act of 2010.[40]

Prior Authorization - Prior authorization or preauthorization refers to rules required by some payers that require approval for a medication, procedure, device, or other medical service be obtained prior to provision to the beneficiary. Intended to ensure appropriate utilization of services and items, and to reduce subsequent denial of claims and related appeals, these authorizations can require the payer to determine member eligibility, benefit coverage, medical necessity, location, and appropriateness prior to delivery of services or items.[41]

Prior Authorization Support (PAS) – Third of three HL7 Da Vinci Project use cases (after Coverage Requirements Discovery and Documentation Templates and Coverage Rules) that support the integration of clinical and administrative data. Enables providers at the point of service to request authorization (including necessary clinical information to support the request) and receive prompt adjudication responses from payer. With this capability, combined with the previous two implementation guides, the provider can submit a prior authorization request to the payer that includes the orders and supporting documentation. This process provides payers with structured information that can be used for automated adjudication and a more timely response whenever possible.

Promoting Interoperability Programs - In 2011, CMS established the Medicare and Medicaid EHR Incentive Programs to encourage eligible professionals (EPs), eligible hospitals, and CAHs to adopt, implement, upgrade (AIU), and demonstrate meaningful use of certified electronic health record technology (CEHRT). CMS renamed the EHR Incentive Programs to the Promoting Interoperability Programs in April 2018. This change moved the programs beyond the existing requirements of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information.[42]

SMART® on FHIR - Substitutable Medical Applications, Reusable Technologies on Fast Healthcare Interoperability Resources (SMART) Health IT was launched with a New England Journal of Medicine article proposing a universal API (application programming interface) to transform EHRs into platforms for substitutable iPhone-like apps. With funding from the Office of the National Coordinator for Health Information Technology (ONC), the SMART on FHIR API was developed as an open, free and standards-based API.[43, 44]

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[40] National Committee on Vital and Health Statistics. December 12-13, 2018. *Subcommittee on Standards Meeting Summary*. Retrieved from https://ncvhs.hhs.gov/wp-content/uploads/2019/04/Summary-Standards-Subcommittee-Predictability-Roadmap-December-12-13-2018.pdf
[41] Office of the National Coordinator for Health Information Technology. February 2020. *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*, Retrieved from https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf
[42] Centers for Medicare & Medicaid Services. (n.d.). *Promoting Interoperability Programs*. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index?redirect=/EHRIncentiveprograms/
[43] SMART Health IT. (n.d.). *About SMART Health IT*. Retrieved from https://smarthealthit.org/
[44] Office of the National Coordinator for Health Information Technology. (n.d.). *Pop Health on FLAT FHIR: A SMART Approach to Universal Healthcare Reporting*. Retrieved from https://www.healthit.gov/topic/scientific-initiatives/leap/pop-health-flat-fhir

Trusted Exchange Framework and Common Agreement (TEFCA) - The TEFCA is designed to scale electronic health information (EHI) exchange nationwide and help ensure that health information networks (HINs), health care providers, health plans, individuals, and many more stakeholders have secure access to their electronic health information when and where it is needed.[45]

U.S. Core Data for Interoperability (USCDI) - Standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The first version of the USCDI is adopted as a standard in the ONC Cures Act Final Rule. The USCDI sets a foundation for broader sharing of electronic health information to support patient care.[46]

Usability - The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.[47]

X12 – Chartered by the American National Standards Institute (ANSI) for more than 40 years, X12 develops and maintains Electronic Data Interchange (EDI) standards and Extensible Markup Language (XML) schemas that drive business processes globally. X12 members meet regularly to develop and maintain EDI standards that streamline and facilitate consistent electronic interchange of business transactions, such as order placement and processing, shipping and receiving information, invoicing, payment and cash application data. X12 has two committees, the Accredited Standards Committee (ASC) and Registered Standards Committee (RSC).[48]

X12 Transaction Sets - X12 defines and maintains transaction sets that establish the data content exchanged for specific business purposes. Transaction sets are identified by a numeric identifier and a name. Each transaction set is maintained by a subcommittee operating within X12's Accredited Standards Committee. Although a specific subcommittee is assigned maintenance responsibilities, any X12 subcommittee can utilize any X12 transaction set.[49]

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[45] Office of the National Coordinator for Health Information Technology. (n.d.). *Trusted Exchange Framework and Common Agreement*. https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement
[46] Office of the National Coordinator for Health Information Technology. March 2020. *Cures Act Final Rule Fact Sheet: United States Core Data for Interoperability*. Retrieved from https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf
[47] National Institute of Standards and Technology. (n.d.). *Health IT Usability.* Retrieved from https://www.nist.gov/programs-projects/health-it-usability
[48] X12. (n.d.). *About X12*. Retrieved from https://x12.org/about/about-x12
[49] X12. (n.d.) *X12 Transaction Sets*. Retrieved from https://x12.org/products/transaction-sets

APPENDIX 3: Index of Presentation Summaries and Key Points

INTERSECTION OF CLINICAL AND ADMINISTRATIVE DATA TASK FORCE

Presentations by Industry/Government

April 28, 2020

- Surescripts
- CoverMyMeds

May 5, 2020

- Humana
- Regence

May 12, 2020

- American Medical Association (AMA)

June 2, 2020

- Centers for Medicare & Medicaid Services (CMS)

June 9, 2020

- America's Health Insurance Plans (AHIP)
- Premier, Inc.

June 16, 2020

- X12

June 23, 2020

- American Health Information Management Association (AHIMA)
- Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE)

July 7, 2020

- HIMSS Electronic Health Record Association (EHRA)

SURESCRIPTS

Electronic Prior Authorization: Update on Automation

Luke Forster-Broten, Director, Product Innovation

April 28, 2020

Background

Surescripts certifies software used by prescribers, pharmacies and payers/Pharmacy Benefits Managers (PBMs) for access to three core services: Prescription Benefit, Medication History and Prescription Routing.

Prior Authorization Landscape

Prior authorization causes a lot of unnecessary delay and affects constituencies across a wide spectrum of care: physicians, pharmacies, plans and patients.

- **Physicians:** Prior authorization is a huge challenge for physicians, both administratively and in terms of clinician burnout. Family doctors report the highest burnout rate at 47%. The last thing physicians want to do is spend a lot of time on unnecessary administrative red tape and prior authorization is one of the things they spend the most time on.
- **Plans:** Plans also spend a lot of time on the phone with prescribers trying to walk them through the process and figuring out how to get needed medications.
- **Pharmacies:** Once a prescription actually makes it to the pharmacy, pharmacists are spending valuable time reaching out to health plans trying to determine if: (i) the patient is on the best medication, and/or if (ii) medications exist that wouldn't require prior authorization to be dispensed.

In the manual prior authorization model:

- Physicians are looking at a traditional formulary data at a group or plan level, which prevents them from viewing costs across different channels and makes it difficult for them to compare therapeutic alternatives. The result is that the physician is practicing and prescribing in the dark without knowing if prior authorization is going to be required for the patient.
- Forty (40) percent of the time, when a patient arrived at a pharmacy and was turned away because prior authorization was needed, the patient never actually went on to get any medication at all. This has negative health impacts for the patient and causes a lot of unnecessary delay and frustration across the spectrum of care.

In the enhanced prescribing model:

- Identification of the need for prior authorization is part of the e-prescribing process, rather than having the prior authorization only be identified once the prescription has already arrived at the pharmacy. The electronic prior authorization process is really an additional layer onto the traditional e-prescribing process and isn't something that happens after the fact or outside of the physician workflow.

- In an ideal scenario, the member is arriving at the clinic, the EMR system is using the X12 eligibility standard to determine where that patient has pharmacy benefit coverages, and then they're cross-referencing that with the NCPDP formulary data that the EMR is downloading on a weekly basis.
- The best way to identify for a patient-specific prescribing event what the best medication would be for that patient is through real-time prescription benefits. Using that data, the physician is able to see not only alternatives that are patient-specific for the medication that they try to prescribe, but they can also see cost at those different channels, whether it's a 30-day retail, 90-day retail, or mail-order, and are able to see at a patient-specific level if prior authorization is required.
- If the physician wants to switch to a medication that doesn't require prior authorization, she can do that, or if she wants to pursue the original medication that she wanted to prescribe, she can kick off the electronic prior authorization process prospectively, which enables her to get prior authorization out of the way before the patient even gets to the pharmacy.

The electronic prior authorization model provides:

- Proactive notification of medication prior authorization requirements
- Prior authorizations questions specific to patient, plan and medication
- Pre-population of required information

The above results in reduced office complexity and frustration with real-time prior authorization responses from health plans.

Rapid Growth of Electronic Prior Authorization

The top five specialties using electronic prior authorization are: family practice, internal medicine, psychiatry, pediatrics, and neurology.

While driving adoption of electronic prior authorization, Surescripts has learned four key lessons that center on supporting and improving the provider experience, collaboration by standards bodies, and data quality (ensuring that the right information is shared at the right time).

These are:

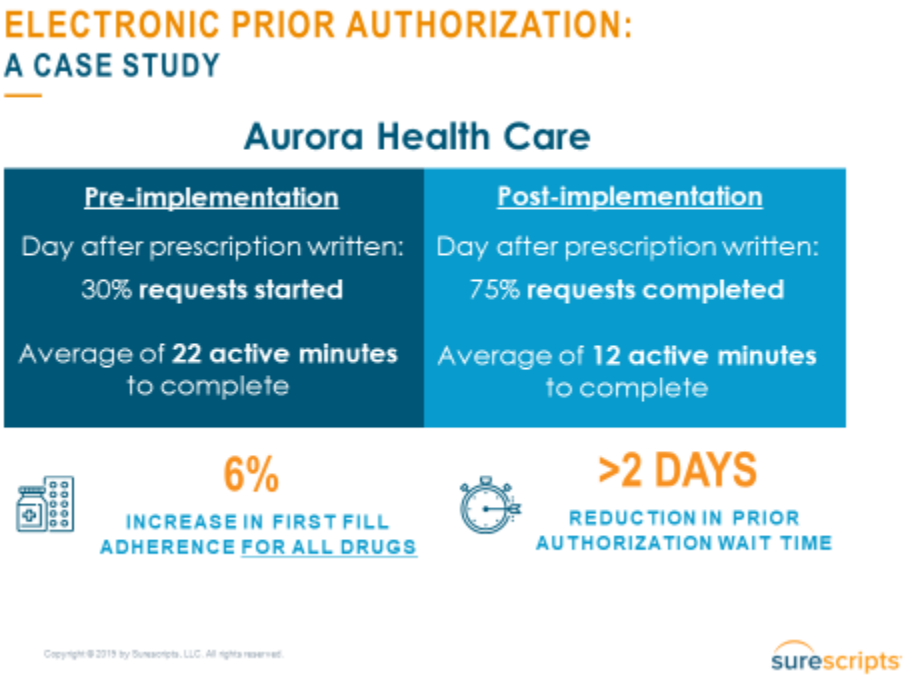
- Focus on the holistic process
- Include all patient groups
- Emphasize speed and accuracy
- Drive change in workflow

Additional evidence of rapid growth in electronic prior authorization:

- 94% of prescribers have EHRs signed on for electronic prior authorization
- 97% of patients are covered by pharmacy benefit managers using electronic prior authorization

Aurora Healthcare Case Study

Surescripts partner advocate Aurora Healthcare studied what their prior authorization process looked like before and after electronic prior authorization. The slide below highlights several of the benefits resulting from electronic prior authorization workflow improvements, such as decreased prior authorization wait times and increased first-fill adherence for all drugs.



COVERMYMEDS

Medication Access: An Overview

Kim Diehl-Boyd, VP, Industry Relations and Government Affairs
Miranda Gill, Senior Director, Provider
Liz Otley, Senior Manager, Product Management
Anna Klatt, Senior Manager, Product Management

April 28, 2020

Background

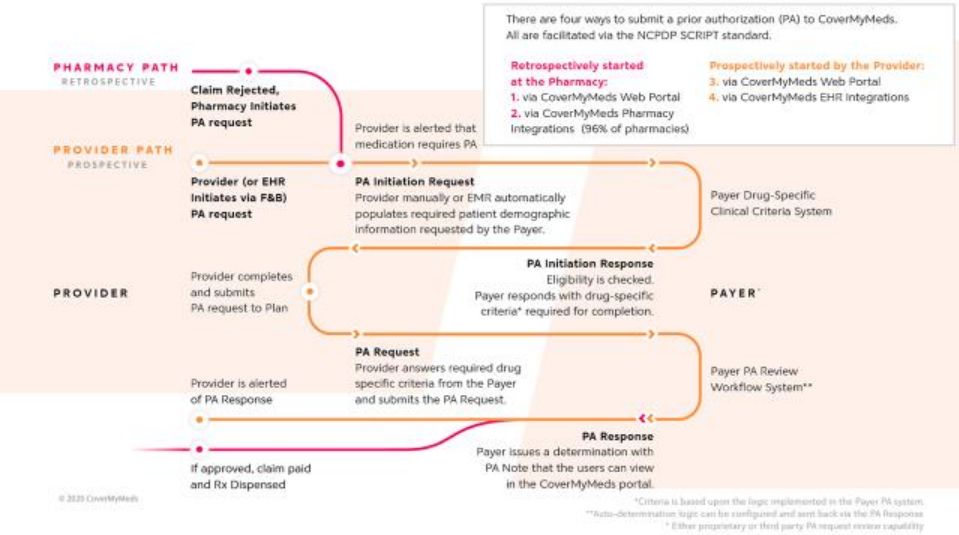
CoverMyMeds was founded in 2008 with the mission to help patients get the medication they need to live healthy lives. The co-founders set out to address prescription abandonment by developing the first all-payer, all-medication prior authorization platform that securely and electronically transmits prior authorization requests between pharmacies, providers and health plans.

Current Workflow: Overview

Attributes of the current CoverMyMeds prior authorization workflow:

- Four ways to submit a prior authorization via CoverMyMeds: all of these are facilitated via either the CoverMyMeds portal or CoverMyMeds pharmacy and EHR integration.
- Submitted to the plan or PBM via the NCPDP script standards.
- Can be done retrospectively, which is started by a pharmacy, and prospectively, which is started by a provider.

Prior Authorization Workflow



Current Workflow: What's Working Well

- Retrospective prior authorization workflow (retail ambulatory settings, medication space)
- One-stop shop for pharmacy, providers, payers with dynamic question logic
- Real-time responses
- Formulary alternatives

Current Workflow: Areas to Improve

- Prospective initiation
- Expand to medical drug prior authorization
- EMR electronic prior authorization usability
- Accuracy of formulary data
- Bi-directional data exchange

Tenants of Ideal State Workflow

- In-workflow process
- Prospectively created during e-prescribing
- Auto-populated data
- Staff completes remaining fields

CoverMyMeds presented a mock EHR prospective prior authorization workflow created in an e-prescribing workflow. Benefits include:

- Auto-populated data results in fewer keystrokes and reduced administrative burden on the provider and their staff.
- Other care team members that support that provider can become involved and help in the process.

Steps to Make Ideal State Electronic Prior Authorization a Reality for Providers

- Better eligibility and benefits data
- Helps drive a more accurate end-to-end electronic prior authorization process. Prior authorization flags in the formulary and benefit (F&B) file are not consistently completed by plans, result is that providers have a severe lack of trust in the F&B file as it stands today. Need plan-driven information that is updated in real-time.
- Additionally, Real-Time Benefit Transparency (RTBT) solutions leverage several different data sources to provide greater accuracy, mitigating false positives and offering clinical decision support in real-time.
- Continued automation of clinical data exchange
- Minimizes provider burden by leveraging information that is already present within the EHR.
- Continue to leverage the NCPDP script standard and enable coexistence with the new emerging FHIR standard.

- FHIR offers a standardized way to reach into an EHR system and get data necessary to process a prior authorization. Improves interoperability by both pulling and pushing data, creating a bi-directional data exchange between the two systems. Additionally, OAuth2 is a standardized way to authenticate allowing for faster, more efficient and more secure access to EHR resources.
- CoverMyMeds currently has a production implementation that uses these concepts, focusing on meeting the provider where they are by using FHIR-like technology to enable a preferred user experience while also leveraging the information that is already present within the EHR.
- Actively working on enabling the automation of clinical data to keep the clinician from having to key in repeated information that already exists in their system.

Recommendations to Help Drive the Industry Closer To a Fully Automated Prior Authorization Workflow

- Reduce false positives with accurate prior authorization prediction
- Update F&B file by completing prior authorization flag section of file
- Drug specific utilization logic to complete automation
- Patient-specific info available in real-time
- Auto pulling and population of data
- Leverage industry standards (SCRIPT & HL7 FHIR)

HUMANA

Prior Authorization Optimization

Patrick Murta, Principal Solutions Architect and Chief Interoperability Architect
Phil Britt, Director of Business Improvement

May 5, 2020

Background

As Humana shifts from an insurance company with elements of health to a health company with elements of insurance, it is focused on five areas of influence to help improve health and aging: primary care, home health, pharmacy, behavioral health and social determinants of health. Humana's Bold Goal is focused on addressing the needs of the whole person by co-creating solutions to address social determinants and the health-related social needs for its members and communities.

Da Vinci Project

FHIR accelerators are projects that run under the auspices of HL7 that take advantage of bold capabilities that are made available in FHIR and adjacent technologies to solve business needs and make data available at the right time in the right workflow with the right clinician.

- Da Vinci Project is one of the original FHIR Accelerators and one that focuses on payer-to-provider integration. A lot of the conversation when the project started two or three years ago was around it being a new model in value-based care.
- In that model, sharing of information is absolutely critical for the success of physicians, provider, and also for the success of payers, and, most importantly, for better outcomes for patients.
- Da Vinci Project was born of a need to share information, come together as an industry, and agree on a set of use cases and the appropriate implementations of those uses cases. Idea is to build once for all payers and EHR vendors, and have one on-ramp for each of the use cases as opposed to the classic proprietary model in which custom solutions were built, including for prior authorization.
- Uses contemporary technology and agreed-upon industry standard use cases to provide a framework for everybody to follow.
- Use cases include: cost transparency, provider data exchange or payer data exchange, clinical data exchange (payers requesting from providers), payer data exchange (providers requesting from payers), data exchange for quality measures, priority authorization support, coverage requirement discovery (CRD), and document template and rules (DTR).
- Da Vinci Project's primary goal is to facilitate the development and implementation of use cases including their associated implementation guides and reference architectures that allow payers and providers to solve real world use cases using contemporary technology.

Humana Prior Authorization Overview

- X12 278 is the Humana standard

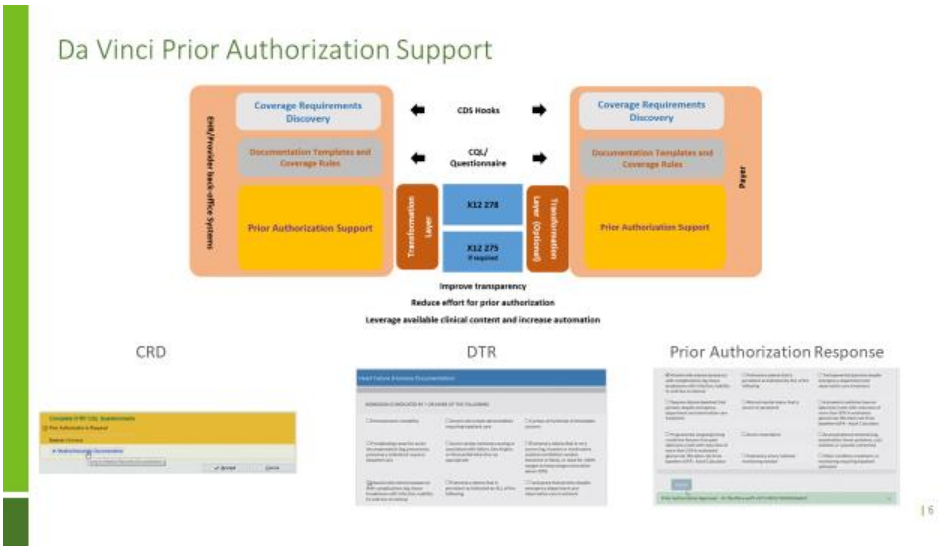
- Response is 'real-time' regardless of submission mode
- ~ 35,000 278s per day
- ~ 80% automated approval
- ~ 70% of transactions are real-time electronic, coming from business-to-business (B2B) connections or a portal

Industry Overview

- Administrative prior authorization processes have been estimated to contribute as much as $25 billion annually to the cost of health care and have been linked to negative effects on patient care and provider performance.
- While electronic prior authorization emphasis has attempted to reduce burden, adoption across the industry continues to be low with only 12% use of Form 278 in 2018.
- Industry barriers include lack of operating rules, ubiquity of payer web portals and a myriad of state laws. Also, some components of the workflow occur outside the scope of the electronic standard.
- As a 278-centric organization, Humana recognizes that prior authorization is progressive. It moves the ball forward, but is not transformative in the way we think of it today…there are other levers that can help reduce inefficient communication and provide better data integration for better efficiencies and outcomes.

Da Vinci Prior Authorization Support Use Case

The slide below depicts what the Da Vinci Prior Authorization Support Use Case looks like running in a sandbox environment.



- In the workflow, the EHR/Provider back-office systems are connected to the payer's process through clinical decision support (CDS) Hooks, the clinical language query (CQL)/Questionnaire, and the X12 278 and X12 275 (if required) standards.
- The prior authorization transaction is going from the EHR system over a transformation layer, which is a clearinghouse or intermediary.
- The clearinghouse takes all of the information, including FHIR messages, the FHIR claim, and the FHIR bundle and converts them into a HIPAA X12 278 and possibly a HIPAA X12 275, if there are medical attachments.
- Then, the prior authorization is submitted to the payer using existing modalities. In this model, because the prior authorization support transfers through an intermediary, it goes from FHIR to a 278 and then to the payer using existing 278 channels. Then, Humana, the payer, responds in real-time.
- The goal of this end-to-end process is to be able to streamline decisions and allow providers to work in their native workflow.

Broader Perspective

- Humana's broader perspective, their model, and initiatives include:
- FHIR initiatives of which prior authorization is one of the most critical.
- Connections to Fast Healthcare Interoperability Resources (FAST), Da Vinci, Argonaut, CARIN Alliance
- Additional thoughts:
- FHIR provides mechanisms that complement the X12 baseline.
- Adjacent integrations such as CRD and DTR streamline the overall process.
- Payer agnosticism is a key consideration.
- Payer rules may necessarily different but the workflow experience doesn't have to be.

REGENCE

Prior Authorization Innovation: Accelerating with FHIR

Kirk Anderson, Vice President and Chief Technology Officer
Julie Lindberg, Vice President Clinical Services
Dave Degandi, Manager Technology Strategy at Cambia Health Solutions
Heidi Kriz, Manager of Medical Policy at Cambia Regence

May 5, 2020

Background

Regence is part of a family of companies dedicated to transforming health care by delivering innovative products and services that change the way consumers nationwide experience health care.

Regence serves nearly two million members through Regence BlueShield of Idaho, Regence BlueCross BlueShield of Oregon, Regence BlueCross BlueShield of Utah and Regence BlueShield (select counties in Washington). Each health plan is a nonprofit independent licensee of the Blue Cross and Blue Shield Association.

- Regence has prioritized transforming the prior authorization process from the member experience to the provider experience. Benefits to the health care consumer include:
- Quality and safety of care (evidence-based decision making)
- Assurance of coverage (avoidance of balance billing)
- Prevention of overtreatment (medical necessity review)
- Minimization of cost-shares (appropriate level of intensity/quantity)
- Reduction in healthcare costs associated with fraud, waste and abuse

Evolution of the Prior Authorization Process at Regence

- Transformed from one with significant pain points that relied on manual process to an automated process that provides real-time responses.
- The eAuth project and strategic initiative (also called autoAuth) launched four years ago.
- eAuth involves extending automation to providers via a portal.
- While this was an improvement, there were issues that needed to be solved, so Regence identified the need to work with the Da Vinci Project to bring the automation and real-time latency that they sought to fruition.

eAuth/autoAuth Functionality

- Provider Impact: Created greater transparency, but not less work
- Goal was to create greater transparency for providers by focusing on the prior authorization check part of the process, to give providers real-time information about what does and does not require prior authorization.

- Improvements
  - Reduced waste: 65% of electronic authorization requests don't require authorization; providers can move straight into providing the service and members receive the service right away. Also reduced administrative burden for providers, Regence.
  - Shortened cycle time:
    - 87% of the authorization requests are completed ≤ 5 calendar days (vs. 69% at baseline)
    - If *all clinical info received* at time of request: 85% ≤ 2 days, 98% in ≤ 5 days
  - Auto-Approval feature creates transparency, returns instant approvals if clinical criteria are satisfied
- Limitations
  - Requires submission through separate portal (Regence currently addressing by building in vendors for prior authorizations involving imaging)
  - Auto-Authorization process adds time to providers
    - Low adoption rates, low auto-approval rates
  - Still requires attachment and review of clinical records
- eAuth has moved the needle part of the way towards improvement. But it really didn't improve the provider experience other than providers didn't have to submit an authorization that was required. They still had to exit through the EHR. They still had to send records. And the records were a bulk of records.
- FHIR standards have helped removed this barrier, they are a game changer.

Ideal State

- Providers can submit an authorization without having to leave the EHR. Exchange of clinical information occurs in an automated way: salient clinical information gets pulled in an automated way from the EHR and gets bounced up against a set of clinical criteria, again, in an automated way. If additional review is required on Regence's side, the critical clinical points get in front of the clinical staff so that they can quickly review the necessary information and render a decision. Goal is that the authorization decision is rendered before a patient leaves the office if possible, ideally even while the provider is making decisions about care.
- While pushing forward in an open standards based way using FHIR, still have to comply with current clinical data standards, including the X12 standards, 278 and, when attachments are involved, 275's, in the prior authorization workflow.
- Da Vinci use cases and the Da Vinci Project implementation guides support Regence's insertion of a bridge between FHIR end points so that Regence can continue to leverage X12 where required while having the FHIR standards in place outside of that bridge. In an ideal state going forward, Regence would not have to insert this bridge. Until then, the bridge is really critical for adoption and for Regence to be able to demonstrate the value of the future of prior authorization end-to-end with Regence's provider partners.
- Regence presented a recorded demo of the eAuth process within the Epic workflow, features of which include:
- SMART on FHIR application
- Most of the data is pre-filled; user enters servicing provider info

- Where a preauthorization is required – Regence uses MCG Health to manage their policies (MCG has a SMART on FHIR application also) – the provider launches the MCG app; it will pop into the areas specific to that procedure and diagnosis and automatically pull in any information or attachment that's needed and then, return back to the SMART app where the authorization will be submitted. And then, that goes out through Availity through the X12 translations and comes back into the app and will come back auto approved or whatever state would be determined in real-time.

AMERICAN MEDICAL ASSOCIATION (AMA)

Prior Authorization: Physicians' Recipe for Reform

Heather McComas, PharmD
Director, Administrative Simplification Initiatives
American Medical Association
ONC HITAC ICAD

May 12, 2020

Background

The AMA is a powerful ally in patient care, giving strength to physician voices in courts and legislative bodies across the nation. The AMA is dedicated to driving medicine toward a more equitable future, removing obstacles that interfere with patient care and confronting the nation's greatest public health crises.

Current State and AMA 2018 Prior Authorization Survey

In December of 2018, the AMA surveyed 1,000 practicing physicians to capture the impact of prior authorization on both patients and physicians:

- 91% report prior authorization has led to care delays.
- 75% report that prior authorization can lead to treatment abandonment.
- 91% report a significant or somewhat significant negative impact on clinical outcomes.
- 28% report that prior authorization has led to a serious adverse event for a patient in their care.
- 88% report prior authorization burdens have increased over the last 5 years. Physician practices are acutely feeling the burden:
- Volume: 31 average total prior authorizations per physician per week
- Time: Average of 14.9 hours (approximately two business days) spent each week by the physician/staff to complete this PA workload
- Practice resources: 36% of physicians have staff who work exclusively on PA

AMA presented a slide on the human face of prior authorization: A patient diagnosed with metastatic melanoma in his early 20s passed away at the age of 27; his mother reported that his quarterly scans were delayed every time during the course of his illness due to prior authorization.

AMA Consensus Statement

- Released in January 2018 by the AMA: Signatories include American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, and Medical Group Management Association.
- Five reform categories addressed:
  - Selective application of PA
  - Prior authorization program review and volume adjustment
  - Transparency and communication regarding prior authorization

  - Continuity of patient care
  - Automation to improve transparency and efficiency
- Goal is to promote safe, timely, and affordable access to evidence-based care for patients and enhance efficiency; and reduce administrative burdens
- Following release of AMA Consensus Statement in January 2018, prior authorization progress has been sluggish:
  - 86% of physicians report that the number of medical service prior authorizations required has increased over the last five years
  - Only 8% of physicians report contracting with health plans that offer programs that exempt providers from prior authorization
  - 69% of physicians report that it is difficult to determine whether a prescription or medical service requires prior authorization
  - 85% of physicians report that prior authorization interferes with continuity of care
  - Only 21% of physicians report that their EHR system offers electronic prior authorization for prescription medications; phone and fax are still the most common methods
- AMA is grateful for the task force work to date. Over the past two months, AMA has heard a broad 'sky's the limit' approach; may be ambitious to expect to accomplish everything by September.
- The task force has at times mentioned allowing multiple standards to complete an automated process and establishing both floors and ceilings for accomplishing the same tasks. AMA concern is that if plans are requiring physicians to support the different processes, use of different standards for the same process can be very cumbersome and expensive for physician practices.
  - **Prescription Drug Electronic Prior Authorization**
    - AMA heard over the past two weeks that an established standard (NCPDP SCRIPT electronic prior authorization) is in production and being used
    - Implementation is variable across EHRs and payers
    - Even with automation, electronic prior authorization vendors recommend practices have a "centralized PA team"
    - Exploration of real-time pharmacy benefit (RTPB) technology; current solutions are proprietary
  - Medical Services Electronic Prior Authorization:
    - HIPAA-mandated X12 278 adoption is weak
    - No mandated standard for exchange of supporting clinical data (attachments)
    - Strong interest in advancing technology, but projects are in prototype/sandbox environment

What Could Come Out of the Oven in September?

Ingredient	Prescription drug PA	Medical services PA
Bottom layer	• Finalize NCPDP RTPB standard	• X12 270/271, X12 278, Da Vinci CRD?
Top layer	• Support adoption of NCPDP SCRIPT ePA under Medicare Part D • Mapping of ePA questions to coded references (SNOMED, LOINC, CDA) • Standardized, USCDI-based ePA questions?	• X12 278? • C-CDA mapped to payer criteria? • Da Vinci DTR + PA Support? • Common data set request for each type of PA based on USCDI?
Icing	• Recommend that ONC coordinate pilot efforts to identify best practices for technology integration and establish path to EHR certification requirements	• Recommend that ONC coordinate pilot efforts to identify best practices for technology integration and establish path to EHR certification requirements
Recipe	• Gather baseline data (ePA volume, processing time, etc.) for major PBMs • Track progress	• Establish what data needed to support PA criteria across payers • Cross-payer pilot for a few services; results would inform future recommendations • Gather baseline data and track progress
Scalability	• Consider ROI of using common data set to map ePA questions to coded references • Evaluate path from proprietary RTPB tools to cross-PBM standardized solution	• Evaluate cost/time to practices/vendors/payers to support unique PA criteria across services/payers • Assess standard's ability to support PA volume • Consider common data set for PA requests

ONC's Physician Burden Report

A lot of the concepts (from the above slide) are included in ONC's burden report that was published earlier this year, e.g.,

- **[Clin Doc] Strategy 3:** Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.
  - Integrating payer coverage rules into EHR workflow to reduce provider burden. (bottom layer of cake)
  - Adopting standardized templates, data elements, and real-time standards-based electronic transactions for prior authorization and clinical attachments (top layer)
  - Incentivizing use and implementation of technology that streamlines prior authorization processes and reduces provider burden (icing layer)
  - Supporting/coordinating pilots of new standard approaches to prior authorization automation (icing & recipe layers)
  - Leveraging existing data to reduce the total volume of prior authorization requests that clinicians must submit (scalability layer)

Final Thoughts

- Prior authorization reform is urgent for physicians and patients.
- Urge task force to think about what concrete, immediately actionable recommendations could be acted upon in October.
  - If there is an existing viable standard, recommend its adoption and, if possible, ways to improve its implementation.
    - If there is not a clearly viable standard, reach out and get more data from payers and vendors about what is the most viable technology, i.e., what is something that everyone could use?

Final Thoughts/Considerations

- Need for PA reform is **urgent** to prevent patient harm and reduce provider burdens
- What **concrete, immediately actionable** recommendations can Task Force make?
- If there **is** an existing, viable standard:
  - Recommend adoption and actions to ensure vendor/payer support
  - Recommend enhanced implementation to further reduce practice burdens
- If there is **not** a viable standard:
  - **Research** PA data needs to ensure any solution will work across payers (e.g., models requiring attestation vs. actual clinical data)
  - Initiate cross-payer **pilot** to test a single PA workflow for a small range of services
  - **Evaluate** the time/costs to implement solution across current volume of services requiring PA
- Establish baseline **metrics** to track progress (e.g., PA volume, approval/denial rates, processing time)
- Consider how **USCDI can be leveraged/expanded** to improve PA and **other types of data exchange**
- Set **timelines** for all actions
- Beware the seductive **siren call of flexibility**
  - Multiple technology options across payers is **not a standard**
  - Without uniform process across payers, there are no efficiency gains for providers
- Keep needs of **small physician practices** in mind – especially in these challenging times

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AMA | MEMBERSHIP MOVES MEDICINE.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare Fee for Service Documentation Requirement Lookup Service (DRLS) Prototype

Ashley Stedding, DRLS Government Lead, CMS
Nalini Ambrose, DRLS Project Lead, MITRE Health FFRDC
Larry Decelles, DRLS Technical Lead, MITRE Health FFRDC

June 2, 2020

Background:

The Centers for Medicare and Medicaid Services (CMS) was created to administer oversight of the Medicare Program and the federal portion of the Medicaid Program. It also ensures that program beneficiaries are aware of the services for which they are eligible and that those services are accessible and of high quality and develops health and safety standards for providers of health care services authorized by Medicare and Medicaid legislation. CMS is also responsible for administering the State Children's Health Insurance Program (SCHIP), the Health Insurance Portability and Accountability Act (HIPAA), and several other health-related programs. CMS pledges to put patients first in all of its programs – Medicaid, Medicare, and the Health Insurance Exchanges.

DRLS Background, Context and Goals

- What CMS heard from providers and clinicians
  - Documentation requirements are too hard to find.
    - CMS heard repeated suggestions that payers should publicly disclose their requirements in a searchable electronic format and clearly communicate to prescribing and ordering providers what supporting documentation is needed
- The DRLS initiative is really one of the steps that CMS is taking toward displaying Medicare fee-for-service (FFS) rules in electronic format that will be easily accessible to providers from within their actual clinical workflow.
- What CMS is aiming for: AMA Prior Authorization and Utilization Management Reform Principles:
  - Utilization review entities should publicly disclose, in a searchable electronic format, patient-specific utilization management requirements, including prior authorization, applied to individual drugs and medical services. Additionally, utilization review entities should clearly communicate to prescribing/ordering providers what supporting documentation is needed to complete every prior authorization and step therapy

Impetus for DRLS

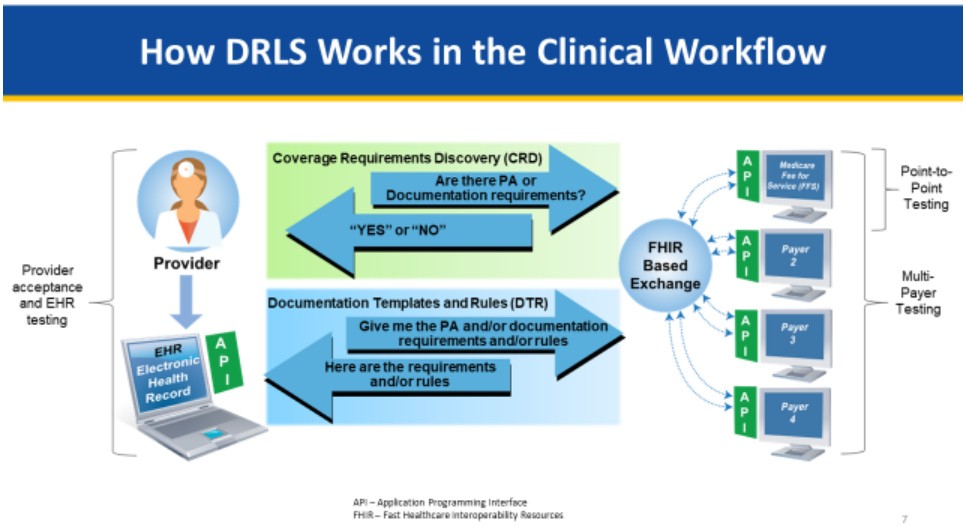
- Documentation errors or missing documentation accounted for:
  - 61.6% of Medicare Fee-for-Service (FFS) improper payments
  - 80% of improper payments for DMEPOS

- For Medicare FFS specifically, improper payment rates for DME were significantly higher than other categories:
- 31% for DME vs. 7% for overall FFS
- Oxygen and CPAP supplies led equipment types in total contribution to improper payments:
- 30% improper payment rate for Oxygen
- 33% improper payment rate for CPAP

DRLS Solution

- The Medicare FFS DRLS prototype is software that will allow healthcare providers to discover prior authorization and documentation requirements at the time of service in their electronic health record (EHR) or integrated practice management system through electronic data exchange with a payer system. It helps:
  - Reduce Provider Burden
  - Improve Provider-to-Payer Information Exchange
  - Reduce Improper Payments and Appeals

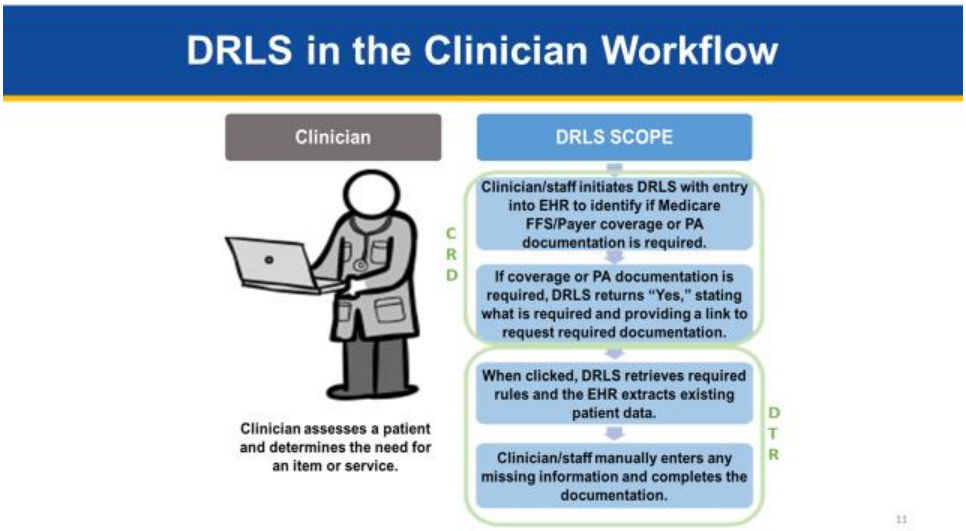
How DRLS Fits within the Current Prior Authorization Process



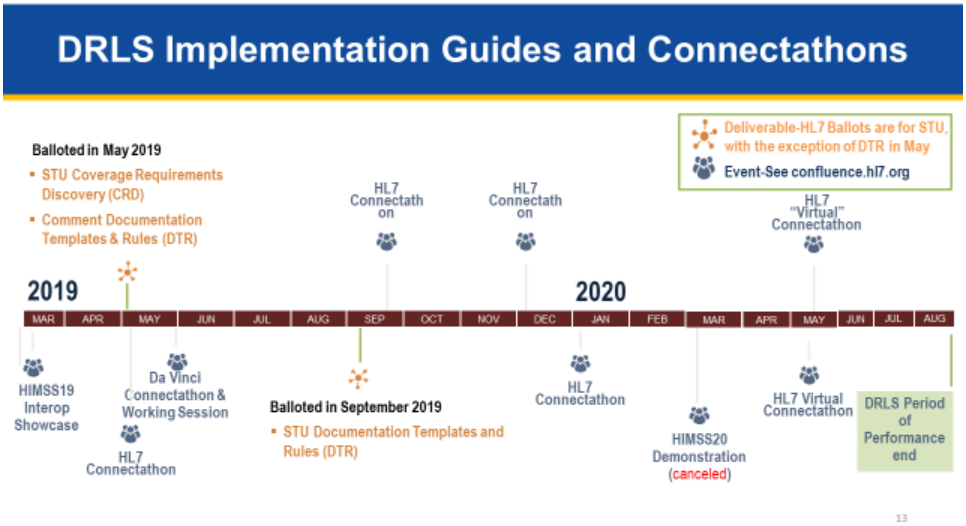
- The Da Vinci Project is a FHIR accelerator, designed to assist communities across the global healthcare spectrum in the creation and adoption of high-quality standard artifacts to move towards the realization of global health data interoperability.
- DRLS prototype is based on two use Da Vinci Project use cases:
  - Coverage Requirements Discovery (CRD) allows the provider's EHR to ask the payer's system if there are Prior Authorization (PA) and/or documentation requirements, receiving a "yes" or "no" response.

- Documentation Templates and Coverage Rules (DTR) enables the EHR to request and receive documents, templates, and rules from the payer's system. It then pre-populates required documentation.
- DRLS could be a beneficial part of the prior authorization workflow
  - Prior Authorization Support (PAS) enables the provider, at point of service, to request and receive authorization directly
- CRD and DTR are currently used by Da Vinci payers and other vendors to gather required documentation in a FHIR-based format in order to get a prior authorization number and/or X12 translation by a PAS.

Development and Testing of the DRLS Standards



Overview of Development and Testing of DRLS standards



- Tested and piloted CRD and DTR reference documentation at HL7 Da Vinci Project Connectathons and showcases.
- Both CRD and DTR use cases have their own implementation guides, weblinks, reference implementation, and confluence artifacts.

Rule Sets and Pilot Testing

- Rule sets: Specific sets of data requirements for what needs to be documented in the medical record to support coverage for a given item or service.
- DRLS rule sets for pilot testing: DRLS team is developing Medicare FFS rule sets for select topics based on improper payment rates and other factors.
- Three Types of Pilot Testing:
  - **Point-to-Point:** a single provider uses DRLS to show that the EHR (with patient test data) can 1) confirm the need for coverage documentation, 2) request specific requirements and rules from the payer's system, and 3) receive appropriate responses from the payer's system.
  - **Multipayer:** a single provider uses DRLS to communicate with more than one healthcare payer.
  - **Provider Acceptance and EHR Testing:** a provider determines whether DRLS fits into the workflow, reduces burden, and delivers the information needed.

Lessons Learned

- CMS Engagement
  - DRLS is an important first step in building interoperability between provider and Medicare FFS systems to improve identification of coverage and PA requirements. CMS could achieve data interoperability goals through DRLS, which could be leveraged across multiple CMS programs for better alignment with the standards being used.
  - As a FHIR Accelerator, the HL7 Da Vinci Project acts as a vehicle to help interoperability progress faster. CMS is a key driver, collaborator, and supporter of the standards community in this effort.
  - Establishing strong, sustained governance for the DRLS initiative is imperative to maintain momentum through industry adoption and implementation. CMS is seen as a champion for DRLS and a collaborator with industry stakeholders to build awareness and buy-in for future DRLS adoption.
  - Iterative development of the DRLS prototype (i.e., Agile philosophy and methods) allows for continuous adjustments and improvements. CMS supporting participation in collaborative forums (e.g., HL7 Connectathons, HIMSS interoperability showcase, and similar events), drives iterative development.

Lessons Learned

- Stakeholder Engagement
  - Many EHR and other health IT vendors currently do not possess the required functionality and readiness for implementing DRLS. Recent ONC and CMS interoperability rules will help drive EHR adoption of the latest FHIR standard (R4), enabling DRLS pilot testing efforts.
  - Continued pilot testing of the DRLS prototype in near-real-time settings is crucial for the future successful adoption of DRLS by industry when standards reach a full level of maturity. Early and ongoing industry stakeholder feedback is vital to help build and test the standards in a collaborative manner.
  - Clinician acceptance of DRLS within their clinical workflows is critical to its implementation. Clinician input is central to tailoring and fine-tuning DRLS to meet their needs, improve usability within their workflows, and increase their efficiency.
  - Clinicians need to understand the value proposition of the DRLS solution and be able to envision the future "return on investment" through DRLS implementation. Clinicians who understand how DRLS works in the EHR can influence their EHR vendors to develop the right user environment for easy adoption and use.

Future Work, Stakeholder Engagement

- Industry Stakeholder Engagement has been critical for building awareness and obtaining feedback from the stakeholder community on DRLS challenges and recommendations.
- CMS convenes a Quarterly DRLS Stakeholder Leadership Group (SLG)
  - 50+ members from state and federal government, commercial payers, healthcare providers, EHR vendors, DME suppliers, and associations
  - A smaller Monthly DRLS Work Group (WG) conducts focused working sessions and dives deeper into priority areas and recommends actions
  - SLG recommends and prioritizes ➔ WG develops solutions or actions ➔ SLG reviews, refines, confirms
- Continued DRLS development includes:
  - **Standards Development**: Continue developing CRD and DTR Implementation Guides and Reference Information through 2021
  - **Rule Set Development**: Identify, develop, test additional rule sets
  - **Pilot Testing**: Demonstrate the capability and readiness to deploy DRLS, and pursue end-to-end testing
  - **Stakeholder Engagement**: Continue to engage stakeholders to drive DRLS awareness and buy-in

AMERICA'S HEALTH INSURANCE PLANS (AHIP)

Prior Authorization Briefing

Kate Berry
Senior Vice President

June 9, 2020

Background & Prior Authorization Approach

- America's Health Insurance Plans (AHIP) is a national trade association representing all types of health insurers that provide healthcare coverage for millions of Americans.
- AHIP knows that prior authorization is burdensome for everyone that it touches: patients, providers, even health plans.
- AHIP has a multi-pronged approach to addressing prior authorization, which is an important tool to promote patient safety and evidence-based care:
  1) Identifying Areas of Common Interests and Opportunity for Improvements with Providers – Consensus Statement
  2) AHIP Demonstration Project on Prior Authorization Automation – Fast PATH
  3) AHIP Prior Authorization Landscape Survey
  4) Data-Driven Collaboration to Promote Evidence-Based Care
  5) Communications, Messaging, and Advocacy
     - Federal and State Advocacy
     - Message Guide
     - Resources and Talking Points
     - Op-Ed
     - Statement of Commitment
- Today's presentation focuses on (2) and (3) above:
  - AHIP's industrywide prior authorization survey conducted in late 2019
  - AHIP's demonstration project on prior authorization, a.k.a. Fast PATH.
- Sent a package of materials to task force that included a PowerPoint summarizing the survey results and infographics on Automating Prior Authorization and Use of Prior Authorization.

Prior Authorization Survey Results

- Surveyed commercial health insurance plans between September and December of 2019 (prior to Covid-19).
- Forty-four plans responded to the survey, representing 109 million commercial enrollees.
- Prior authorization is grounded in clinical evidence and selectively used.

- The report also found:
  - Health insurance providers use multiple sources of evidence-based studies, guidelines and federal standards in designing their prior authorization programs. More specifically, 98% of insurance providers use peer-reviewed evidence-based studies, and 89% use federal studies or guidelines.
- Other key takeaways:
  - The vast majority of commercial enrollees (close to 85%) are in plans that limit prior authorization to less than 10% of prescription medications.
  - Over 90% of commercial enrollees are in plans that limit prior authorization to less than 25% of medical services.
  - The vast majority of commercial health insurance providers use input from doctors.
    - 82% of health insurance providers consult specialists as needed.
    - 70% use provider-developed clinical guidelines.
  - The primary goals of health insurance providers' prior authorization programs are to improve quality and promote evidence-based care (98%), protect patient safety (91%), and address areas prone to misuse (84%).
  - The vast majority report that their programs have had an overall positive impact on quality of care (91%), affordability (91%) and patient safety (84%).
  - Prior authorization is often part of a broader strategy to improve outcomes
    - The vast majority of commercial health insurance providers (86%) use value-based provider contracts to incentivize doctors to reduce unnecessary tests, treatments and procedures
  - The majority of health insurance providers are taking steps to streamline the prior authorization process for both prescription medications (91%) and medical services (89%) and a majority (84%) reported that automation of the prior authorization process is the biggest opportunity for improvement.

Fast Path Demonstration Project

- Fast Prior Authorization Technology Highway = Fast PATH
- Demonstration project on electronic prior authorization to automate aspects of the prior authorization process, and to evaluate the impact
- Launched early 2020
- AHIP Board of Directors priority
- Coordinating with two technology companies, eight health plans, and their provider partners, as well as a couple of consultant advisors on the project.
- **Project goal:** Demonstrate health insurers' leadership and commitment to improving the [electronic prior authorization] process in a way that is standards-based, scalable, payer neutral, and as integrated as possible with provider workflow.
- Selected two vendors, Availity and Surescripts, who are addressing two very distinct use cases: prescription medications and medical surgical procedures.
  - **Prescription Medications:** Using the Surescripts technology, critical information to inform the prescribing process is available to the doctor through their EHR. Doctors can easily find out whether the medication they're prescribing requires prior authorization, and they have information to choose an alternative that may be clinically equivalent but does not require prior authorization, and may actually even be cheaper for the patient because they have access to the patient's out-of-pocket costs for the prescription.

- **Medical Surgical:** Availity technology reduces surprises for everyone. Doctors or surgeons or staff supporting them can access a multi-payer portal to figure out if what they're ordering, the surgery or procedure, requires prior authorization. If it does, they submit the information to support the prior authorization through the portal; the health plan then reviews the information and responds through the portal. This helps reduce burdensome phone calls and faxes between the plan and the provider organization.

RTI Independent Research Evaluation

- AHIP is working with a global non-profit research organization, RTI, who is performing an independent evaluation of the impact of automating aspects of prior authorization on both providers and patients.
- Point-of-Care partners serves as an expert advisor.
- Looking at two big research questions: one is focused on the provider experience, the other is focused on the patient experience:
  - Q1: How does automating aspects of the prior authorization process change the experience and administration burden on health care providers?
  - Q2: How does automating aspects of the prior authorization process change the patient experience?
- RTI is receiving data from a number of different sources: technology companies, health plans, and providers. They are also conducting a provider survey. All of the data will support the evaluation and the analysis plan.
- Timeline: Adjusted the timeline due to COVID-19, which has resulted in a lot of care deferrals and prior authorizations being waived over the last few months. Project completion and report release expected in late 2020, possibly early 2021.

PREMIER, INC.

Automating Prior Authorization

Meryl Bloomrosen, Senior Director, Federal Affairs, Premier Inc.
Scott Weingarten, MD, CEO Stanson Health
Alex Tatiyants, VP, CTO Stanson Health

June 9, 2020

- Premier is a health system-driven IT and supply chain company, while the provider of its underlying prior authorization automated technology, Stanson Health, is a provider-led, driven, and owned clinical platform company started at Cedars-Sinai in Los Angeles.
  - Stanson's clinical decision support (CDS) tools are integrated directly into the provider's EHR workflow, providing real-time, patient-specific best practices at the point of care.
- Today's discussion topics: Stanson/Premier's experience automating PA for providers within the EHR and also for payers in their utilization management systems, key lessons learned, and recommendations to the ICAD TF.

Prior Authorization

- Principal reasons to automate prior authorization:
  - **Patients:** less time spent waiting for approval; reduced delays and interruptions in care; and improved patient satisfaction.
  - **Providers:** streamlined workflows with fewer phone calls, faxes, and portals; reduced administrative costs; and reduced administrative and reporting burdens.
  - **Payers:** improved provider satisfaction; lower costs related to utilization management; and better consistency in adjudication decisions.
- Prior authorization challenges:
  - Labor-intensive source of administrative burden for providers and health plans
  - Unintended consequences for patients, plans, and providers
  - Clinical and administrative workflow disruptions and inefficiencies
  - Clinician administrative and reporting burdens
  - Need for real-time access to data within workflow and at point-of-care
  - Lack of standards adoption and implementation
  - Cumbersome and diverse PA requirements and processes
  - Lack of robust, end-to-end automation
  - Requires exchange and sharing of data among several stakeholders

There is a need for interoperability between clinical and administrative systems as the ICAD Task Force has pointed out.

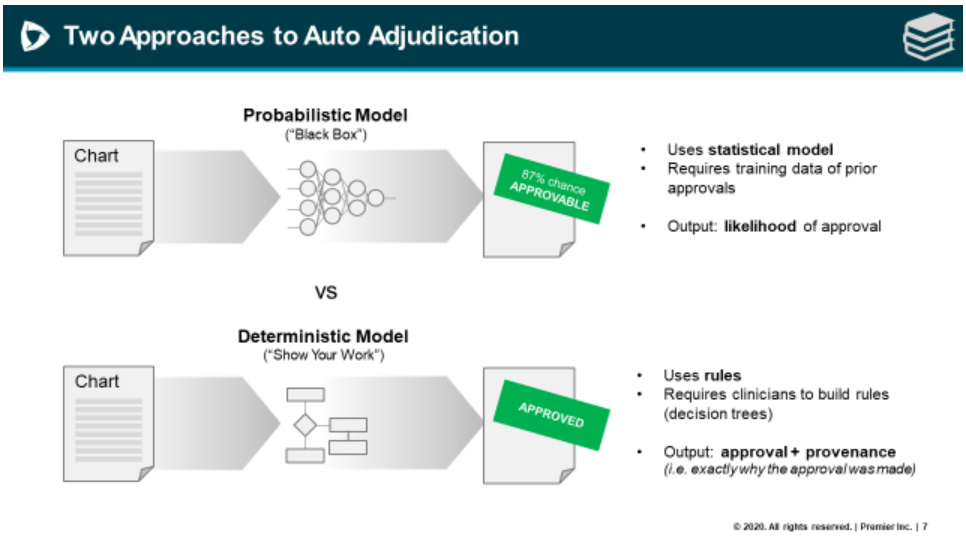
Automated Prior Authorization

- Premier has taken a provider-centric approach to automation to create a solution that is readily accepted and adopted by providers.
- Premier is focusing on one of the most difficult parts of the prior authorization process: medical necessity adjudication.

For the ideal workflow to be possible, Premier identified a set of 'table stakes,' or ground rules. They are:

- **No portals**
  - Must be embedded into provider workflow
  - Must be triggered automatically
  - Must be at the point of decision making
- **No double documentation**
  - Must use what's already on the chart (both structured and free-text)
- **No waiting**
  - Must be done in real-time (both adjudication and approval)

Auto Adjudication



- Of the two approaches to auto adjudication displayed in the slide above, Premier uses Deterministic Model – "Show Your Work" – because it uses rules, requires clinicians to build rules, and the output is Approval & Provenance.
  - Also easier for audit purposes.

Guideline Codification, EHR Data

- **Making words computable:** guideline codification is complex and time consuming but necessary for automation of prior authorization.
- **Documentation patterns vary:** Data are often incomplete (e.g., outcomes are frequently missing), patient records are fragmented, data entry errors are common, and the timeliness or currency of the data can be difficult to establish. Providers' don't always document before signing orders. Affects adjudication of medical necessity, e.g., when somebody's signing an order and they haven't captured that note until after that, you're going to be at a disadvantage because you're not going to have all the information you could have if the order were closed differently.
- **Limited structured data:** A lot of data is locked in free text. Not much is structured and cleanly documented, especially nuances of things like signs and symptoms that are very important for a lot of these guidelines.
  - In a recent survey of U.S. hospitals equipped with advanced EHRs, only about 35% of clinical data was captured in structured format and 65% in unstructured text.
  - Premier is using Natural Language Processing and machine learning to make sense of the large amounts of unstructured data and free text.
- **Notwithstanding trying to make sense of notes and free text, provider interaction is sometimes necessary:**
  - Premier built an interactive app that pops up in the EHR to assist providers in completing the adjudication process.

Benefits of Standards

- Continued adoption of standards, as well as their consistent implementation, is essential to automating the prior authorization process. Particularly CDS Hooks and FHIR.
  - **CDS Hooks**
    - Originally designed to help clinical decision support (CDS) services integrate into the EHR.
    - The EHR allows a service to register for a workflow, like signing an order. Then, whenever a provider takes that action, the EHR knows to call the CDS service, send it some data, and facilitate an interaction with the provider. This is a critical capability for automating prior authorization because it's essential to trigger when a provider is taking an action in their EHR and potentially present some sort of recommendation, in this case a recommendation around prior authorization.
  - **FHIR**
    - Creates an ability to get chart data from the EHR, both structured and pre-text, in a standard way that then can be sent up and be useful in the adjudication process.
  - **ONC and CMS Final Interoperability Rules**
    - Premier appreciates what has currently been standardized in the ONC final rules and the CMS recognition of those standards. Premier applauds the use of standards-based application programming interfaces (APIs) and the API certification criteria, which the ONC final rule made into a requirement. Both will

benefit and advance the automation of prior authorization. The implementation timelines will facilitate integration of the applications -- like those referenced in this presentation -- into providers' EHRs.

- **U.S. Core Data for Interoperability:**
  - Premier is looking forward to the evolution and the adoption of the U.S. Core Data for Interoperability (USCDI), the standardized set of health data classes and data, and its use and requirement of its use within electronic health records.
  - Also appreciative of ongoing updating of the USCDI and its related Standards Version Advancement Process (SVAP).

Utilization

- Prior authorization is a means to an end – managing appropriate utilization.
- There is another way to do this: CDS. CDS eliminates the administrative hassle and expense related to prior authorization.
  - Paired with analytics, CDS still gives health systems a way to manage utilization, but at a lower cost.

Recommendations

- Advance efforts to align and optimize existing and emerging standards and technologies
- Address interoperability between administrative and clinical data and systems
- Accelerate and expand development and adoption of open data and interoperability standards (APIs; CDS Hooks; USCDI; FHIR)
- Ensure providers and clinicians can connect and use any third-party applications of their choosing
- Facilitate real-time data access for clinicians at point of care and within workflow
- Harmonize requirements across agencies (CMS and ONC) and programs (HIPAA; CEHRT; Promoting Interoperability)
- Incentivize uses of health IT that reduce burdens and provide value to clinicians
- Recognize nuances of PA (surgeries, tests, procedures, medications)

X12

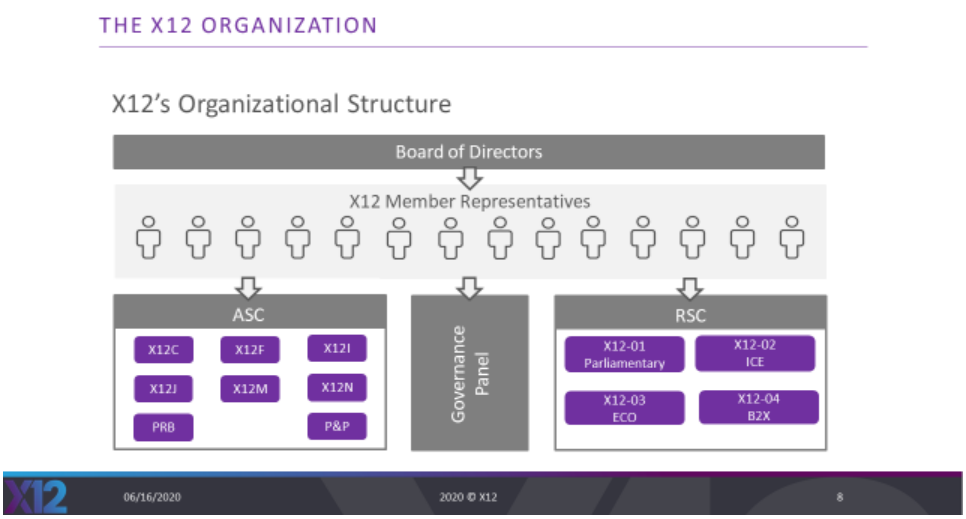
Update to the ICAD Task Force

Cathy Sheppard
Executive Director

June 9, 2020

Background

- X12 is a consensus-based ANSI-accredited National Standards Developer (ASD) focusing on the development and ongoing use of cross-industry interoperable data interchange standards
- X12's standards have proven reliable, efficient, and effective in supporting organizations and industries for 40+ years
- X12 maintains electronic messaging that supports finance, government, health care, insurance, supply chain, transportation, and other industries
- X12 is comprised of a handful of staff, hundreds of members, and more than a thousand member representatives
- Members include corporations, associations, organizations, government entities, and individuals
- X12 standards are the workhorse standards for business to business exchanges
- Many partner-to-partner "standards" are developed based on X12's intellectual property



Implementation Base

- The data exchanged in X12 transactions is well-defined and has been use-tested in production systems over many years
- X12 solutions drive business across the U.S. and internationally

- Millions of entities around the world have an established, stable, and effective infrastructure that supports X12 transactions; this infrastructure represents a significant investment that adds substantial value to implementers on an ongoing basis
- Billions of transactions based on X12 standards are utilized daily across various industries including finance, government, health care, insurance, supply chain, transportation, and others
- X12 transactions are conducted in many syntaxes including the EDI Standard, JSON, XML, and APIs, and instructions for other syntaxes will be published over the coming months

Committees

- X12's Accredited Standards Committee (ASC)
  - The ASC develops and maintains the EDI Standard and related implementation guides, including those mandated under HIPAA
- X12's Registered Standards Committee (RSC)
  - The RSC's External Code List Oversite (ECO) subcommittee develops and maintains X12's terminology, a.k.a. vocabulary, resources, excepting those defined within EDI Standard

Product Library

X12's product library includes:

- The EDI Standard, which is comprised of hundreds of transactions and internal code lists
- Technical reports, including implementation guides, describing various uses of the EDI Standard
- External code lists, a.k.a. terminology or vocabulary resources
- Schema based on the EDI Standard and implementation guides
- Other offerings designed to assist implementers

X12 Approach

- Is open-minded with vision and insight related to data exchange in both current and developing technologies
- Is responsive to needs and requirements presented by other organizations
- Collaborates enthusiastically with other SDOs, industry groups, government, and business-focused entities
- Maintains a financial model that ensures the financial health of the organization long-term by distributing costs among the entities that derive value from using the standards. When everyone pays a share, the costs are reasonable and manageable

- Focuses on collaboration meetings to drive solutions to current and future business needs not on revenue generation. Decades ago, X12 eliminated meeting fees for members and instituted a small fee to non-members to encourage participation by organizations of all sizes and individuals
- Increasing speed to market, an example of responsiveness:
  - In 2020, X12 is moving to a simplified and faster maintenance process, known as the Annual Release Cycle (ARC)
  - Responding to internal and external feedback
  - Supporting a predictable and reliable annual publication schedule
  - Reducing the burden on X12 member representatives
  - Making new functionality and additional data available in X12 products sooner (Note that this does not impact the Federal rulemaking timeline)
- Multiple collaborations illustrate X12's commitment to engagement: CAQH CORE, CARIN Alliance, Ciitizen Corp., GenRocket, HL7, IBM, NCPDP, Da Vinci Project, OpenText, Wolters Klower, WEDI

Prior Authorization

- Many groups are focused on how to increase the use of electronic prior authorizations providing more efficient processes
- Most of the issues raised are related to operationalizing the process consistently across the health care industry
  - Some payers view their prior authorization policies as a competitive differentiator and don't want to expose them publicly or standardize them
  - The industry is not aligned on the purpose or value of the prior authorization process, regardless of syntax or other technical details
- There are many different stakeholder groups, each with diverse needs, related to prior authorization functionality, the industry must identify a balance that works for all, or most, of the stakeholders or decide that one group's interests prevail over the interests of the other stakeholder groups
- X12 is currently updating the prior authorization implementation guides to enhance decision making and reporting processes
- X12 is unaware of any technical, syntactical, or implementation instruction issues that create a barrier to effective transmission of prior authorization messages
- Too often the statement is: 'The prior authorization transaction doesn't work'
- A more accurate statement might be: 'The industry's current practices don't align to support effective prior authorization data exchange'
- If we don't get the problem statement right, we won't end up with a solution that addresses the issues

What is X12 Doing?

- Publishing updates to prior authorization implementation guides that reflect decision-making and reporting functionality; available later in 2020

- Working with Da Vinci Project and CAQH CORE to ensure 278 requirements reflect the industry's current prior authorization needs and practices
- Enhancing X12 code lists to address feedback that additional codified detail would improve clarity in prior authorization transmissions
- Working to increase the number of clinical data experts and users who participate in our code list maintenance processes
- Exploring new options for connecting clinical systems to the administrative systems that support the 278 transaction

Recommendations

- Ensure that the value of X12's mature administrative data information model is harnessed in the most effective manner as groups discuss the intersection of clinical and administrative data
- Separate issues related to clinical and administrative systems not facilitating smooth movement of data from issues related to non-aligned clinical and administrative data definitions, these are different problems
- Educate implementers to bring concerns related to the 278 transaction, the prior authorization implementation guides, or X12 code sets directly to X12 so we can collaborate on solutions
- Remind collaboratives, associations, and others working to improve the exchange of prior authorization data to bring X12 into their efforts early.
- X12 wants to be a partner in those processes, not align with the findings after the analysis and recommendations are complete

AMERICAN HEALTH INFORMATION MANAGEMENT ASSOCIATION (AHIMA)

ONC Intersection of Clinical and Administrative Data Task Force

Lauren Riplinger, VP, Policy & Government Affairs, AHIMA
Alison Nicklas, Regional Director, HIM Services, Trinity Health of New England
Chantal Worzala, Principal, Alazro Consulting

June 23, 2020

AHIMA Overview

- American Health Information Management Association (AHIMA) is a global organization that represents health information and professionals that work with health data for more than a billion patients a year.
- AHIMA's mission is to empower people to impact health and its vision is a world where trusted information transforms health and health care by connecting people, systems, and ideas.
- A core tenant is that health information is human information. AHIMA-certified professionals see the person connected to the data and work to ensure that health information stays human and relevant.

Role in Coding

- AHIMA and its members sit at the intersection of clinical and administrative data: one of their roles is to translate that clinical data for standardized administrative data transactions.
  - A core focus is to ensure correctness of those claims and to keep them flowing to sustain the revenue cycle
- One of the designated Cooperating Parties for ICD-10 Coding guidance
  - With CMS, National Center for Health Statistics, and the American Hospital Association
- Participates in a variety of coding usage and standardization activities in the US and internationally
- Is a preeminent source of coding education and professional education
- Have developed standards of Ethical Coding for membership to abide by

Trinity Health Overview

- Trinity Health is a national Catholic health system. There are 92 hospitals in 22 states. Its mission as a faith-based organization is to serve together in the spirit of the Gospel as a compassionate and transforming, healing presence within the community.
- Reminded daily of the importance of living Trinity Health's core values, which include reverence, justice, commitment to those who are poor, stewardship, safety, and integrity. Very important to be considered in an environment where health models are constantly changing.

Health Models Constantly Changing

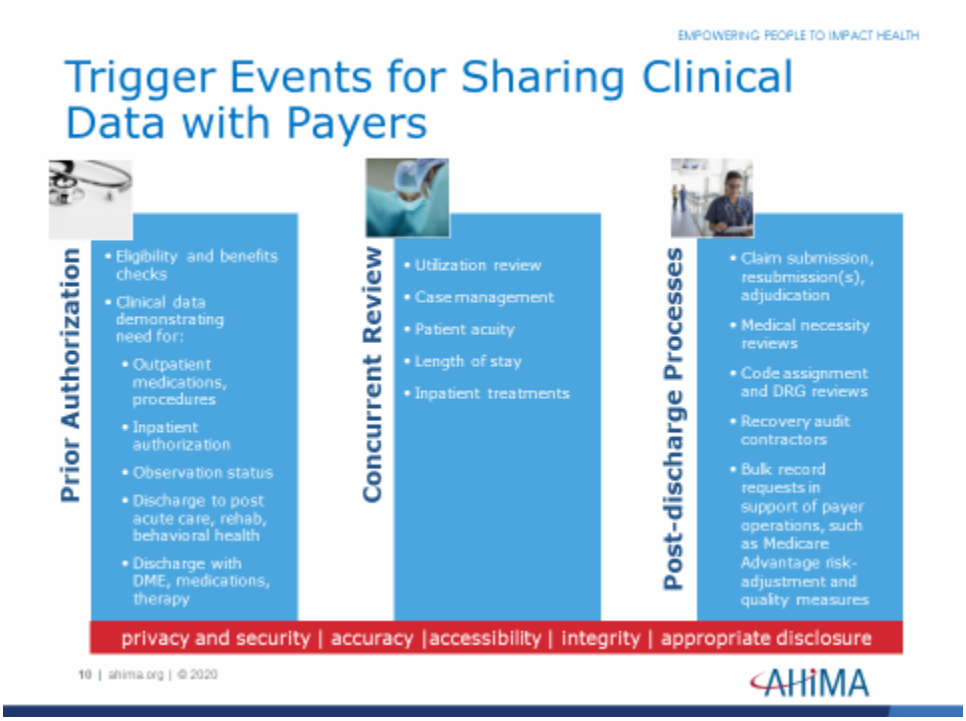
- Consumers increasingly access, generate and direct share their data
- Move from fee-for-service to value-based care to outcomes requires combining revenue cycle and quality data (eCQMs)
- AHIMA relies heavily on use clinical decision support (CDS) within each of its organizations, along with machine learning, to navigate through these changing times
- AHIMA believes that health information is the most powerful currency for change in this healthcare ecosystem

Clinical Documentation Integrity

Clinical documentation is at the core of every patient encounter. In order to be meaningful it must be accurate, timely, and reflect the scope of services provided. Clinical documentation integrity involves:

- Accurate and complete representation of a patient's clinical status that translates into coded data
- Coded data translated into quality reporting, physician report cards, reimbursement, public health data, and disease tracking and trending.

Three Swim Lanes for Sharing Clinical and Administrative Data: Prior Authorization, Concurrent Review, Post-Discharge Processes



- There are three major touchpoints in which there is sharing of clinical data and administrative data with the payers: we call them 'swim lanes.'
- What underlies all of these touchpoints/reviews is that all parties involved have to be aware of the ethical obligations in managing the patient's personal health information. Are we following HIPAA requirements while simultaneously ensuring that there is ease of access?
- From a privacy and security perspective, we need, as a provider, to ensure that the request and the requester are allowed to have the access that they are looking for. From an accuracy perspective, we have to make sure that the documentation that we are sending out is complete and accurately reflects the services that were provided. For accessibility, we have to make sure that the data is accessible in the form and the format that is being requested by that third party.
- We also have to ensure that the integrity of the provision of that information is there. If it is being sent in multiple formats, we need to make sure that the data is secure. And then we also have to make sure that the disclosure is appropriate. Is the information limited to what is minimally necessary for the purpose of the request?

Data Sharing Dilemma

The dilemma that we find we are facing is how to best manage the sharing of the data for the various clinical and administrative purposes that rely on the information:

- Content is generally payer driven
  - Information needed can vary by trigger event
  - Lack of clarity about what documentation is needed
  - May vary by plan, as well as payer
  - Rules change over time, without notice
- Formats include paper/fax, sending a CD, uploading information to a portal, using an automated HIPAA transaction (revenue cycle), or providing direct electronic access to a subset of records.
  - May use multiple formats for a single patient stay/encounter
  - EHRs vary in presentation of the record
  - Frequently involves multiple back-and-forth exchanges
- Phone calls may also be needed to check status and address questions
- Bulk record requests to support payer operations are increasing in frequency and scope
  - Inpatient and outpatient care
  - Full record requested
  - Same payer may request record for same patient multiple times

Issues Beyond Automation

Data flows with supporting administrative transactions are really just one piece of the automating prior authorization picture. Other issues if resolved can take friction out of the system for patients, for providers, and for payers. These issues include:

- Lack of standardization for business process
- Operational issues
- Technical issues
- Implications for workforce
- Alignment and accuracy of vocabulary standards themselves
    - Mapping
- Data integrity
- Privacy
- Trust and representation

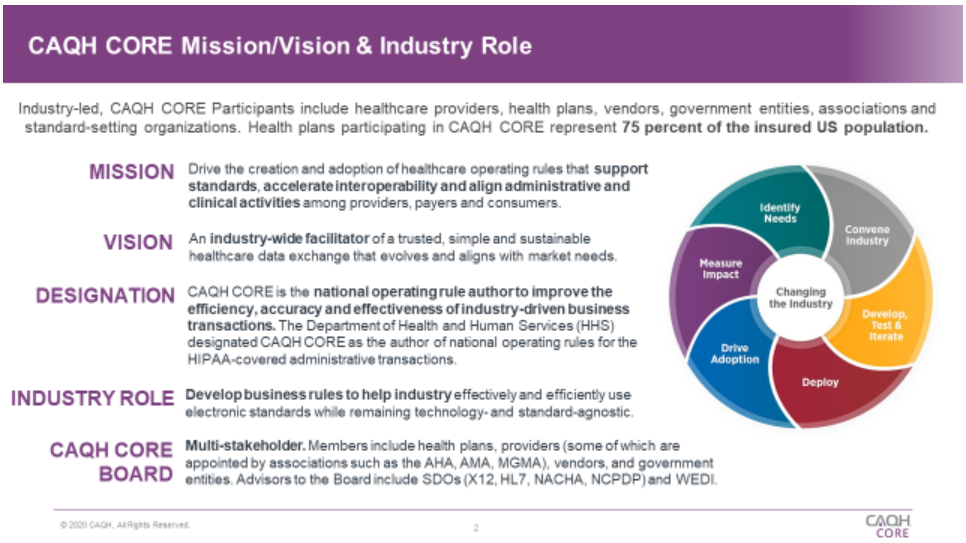
CAQH CORE

Improving Prior Authorization: Operating Rule Update

April Todd
Senior Vice President

June 23, 2020

CAQH CORE Background and Overview



Operating Rules

- Operating Rules are the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted.
- CAQH CORE is the HHS-designated Operating Rule Author for all HIPAA-covered transactions.
- Industry Use Case: Health care
  - Standard: Providers and health plans must use the ASC X12 v5010 270/271 Eligibility Request and Response transaction to exchange patient eligibility information.
  - Operating Rule: When using the eligibility transaction, health plans must return patient financial information including copay and deductible in real-time.

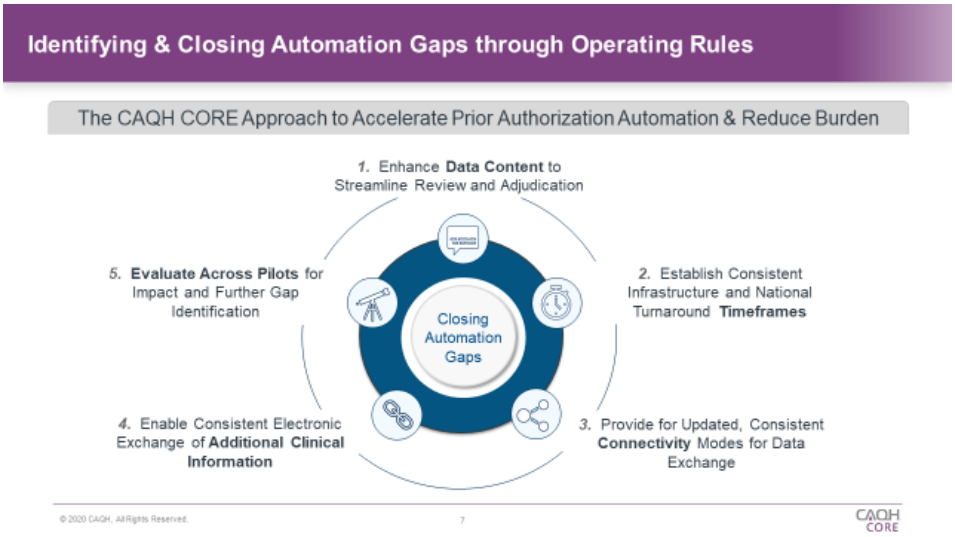
- Operating rules do not specify whether or how a payer/provider structures a business process supported by an electronic transaction. For example, operating rules do not specify when or how prior authorization is used by a health plan; if prior authorization is used, operating rules specify how information regarding that transaction is electronically exchanged.
- Operating rules are structured by different business processes. The operating rules themselves include things related to: infrastructure; data content; connectivity; and an 'other' category that includes standardization of web portals for prior authorization (the latter not recognized by CAQH CORE participating organizations as a long-term solution).

Prior Authorization: 2019 CAQH Index Report

- CAQH does an index report every year, a survey of plans and providers to gauge the adoption of electronic transactions across the industry. For a number of years, prior authorization has been very low in terms of the adoption of the electronic standard and use of portals and manual submission have seen an increase.
- Key barriers preventing full automation and auto-adjudication of prior authorization:
  - There is a lack of consistency in use of data content across industry and electronic discovery of what information is required for an authorization request to be fully adjudicated.
  - No federally mandated attachment standard to communicate clinical documentation.
  - Lack of integration between clinical and administrative systems.
  - Limited availability of vendor products that readily support the standard transaction.
  - State requirements for manual intervention.
  - Lack of understanding of the breadth of the information available in the 5010X217 278 Request and Response, and a lack of awareness that this standard prior authorization transaction is federally-mandated – particularly among providers.
  - Varying levels of maturity along the standards and technology adoption curve.

Identifying & Closing Automation Gaps through Operating Rules

Slide depicts five areas CAQH CORE is working on right now with a strong connection to ICAD task force work around administrative and clinical data.



1. Enhance Data Content to Streamline Review and Adjudication

Proposed to NCVHS: **The CAQH CORE Prior Authorization (278) Data Content Rule** targets one of the most significant problem areas in the prior authorization process: requests for medical services that are pended due to missing or incomplete information, primarily medical necessity information. The rule reduces unnecessary back and forth between providers and health plans and enables shorter adjudication timeframes and less manual follow up.

Future Opportunities:

- Operating rules can ensure consistent use of existing and emerging standards.
  - For example, operating rules can establish and maintain *common data and infrastructure requirements* across standards, giving the industry flexibility to move forward without losing sight of the need for a common approach.

2. Establish Consistent Infrastructure and National Turnaround Timeframes

Proposed to NCVHS: **The CAQH CORE Prior Authorization (278) Infrastructure Rule** specifies prior authorization requirements for system availability, acknowledgements, companion guides, and response timeframes. Rule requirements align with other federally mandated infrastructure rules.

Future Opportunities:

- CAQH CORE infrastructure requirements that apply across transactions are updated over time to align with industry maturity and technology advancements (e.g., system availability).

- Real-Time prior authorization is currently limited to requests that do not require additional documentation or complex backend adjudication processes. As standards and operating rules are identified to support the electronic exchange of attachments, new opportunities to expand real-time capabilities will emerge.

3. Provide for Updated, Consistent Connectivity Modes for Data Exchange

The CAQH CORE **Connectivity Rule vC3.1.0** establishes a Safe Harbor connectivity method that drives industry alignment by converging on common transport, message envelope, security and authentication standards. CAQH CORE proposed to NCVHS that the CAQH CORE Connectivity Rule vC3.1.0 replace current regulations mandating support for CAQH CORE Connectivity Rules vC1.1.0 and vC2.2.0 for the eligibility and benefits, claim status, and electronic remittance advice transactions in addition to prior authorization to promote uniform interoperability requirements across administrative transactions.

Under Development:

- The CAQH CORE Connectivity Work Group is currently updating the CAQH CORE Connectivity requirements to support administrative and clinical data exchange, including RESTful APIs to serve as a bridge between existing and emerging standards and protocols.

Future Opportunities:

- Once a single Connectivity Rule is established across all CAQH CORE operating rule sets, CAQH CORE Participants will continue to update the rule to align with current interoperability, privacy and security standards.

4. Enable Consistent Electronic Exchange of Additional Clinical Information

Under Development:

- CAQH CORE is launching an Attachment Subgroup in July to draft operating rules to reduce administrative burden associated with the exchange of additional documentation/clinical information.
- Rule requirements will align seamlessly with existing prior authorization data content and infrastructure operating rules.
    - Initial focus will be solicited attachments to support the complete adjudication of a prior authorization request either using the X12 275 or without the X12 275 (e.g. HL7 C-CDA).

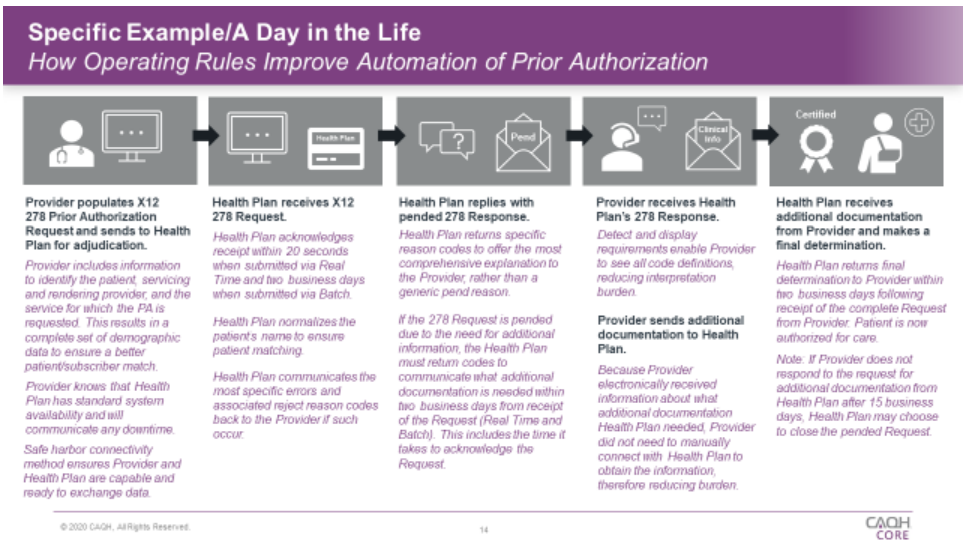
Future Opportunities:

- The Attachments Subgroup will address claim attachment use cases after prior authorization.

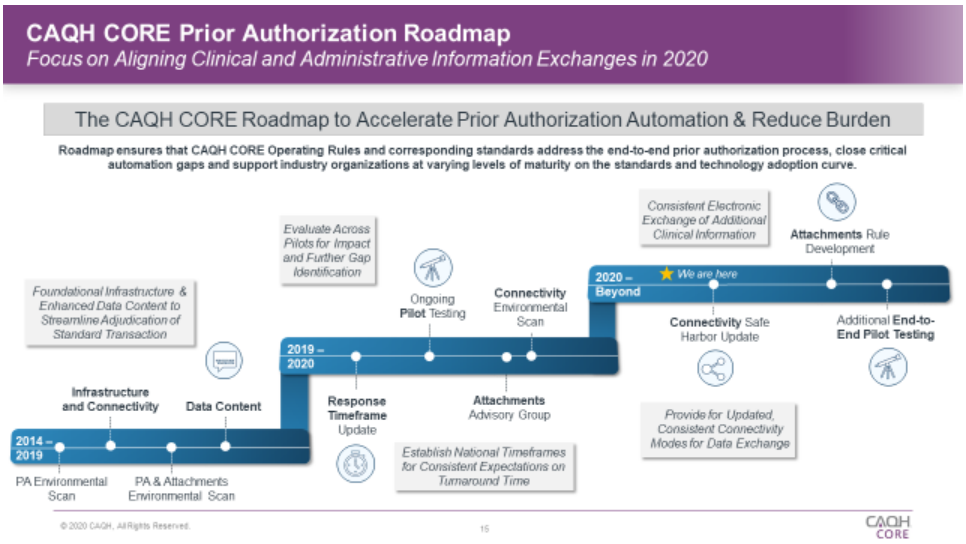
5. Evaluate Across Pilots for Impact and Further Gap Identification

Initiative Vision: Partner with industry organizations to measure the impact of existing and potentially new CAQH CORE prior authorization operating rules and corresponding standards on organizations' efficiency metrics.

How Operating Rules Passed Today will Help Improve Automation of Prior Authorization, Sample Workflow



The CAQH CORE Roadmap to Accelerate Prior Authorization Automation & Reduce Burden



ELECTRONIC HEALTH RECORDS ASSOCIATION (EHRA)

Presentation to HITAC Intersection of Clinical and Administrative Data Task Force

Hans Buitendijk
Chair, EHRA Executive Committee

July 7, 2020

Background

- The EHR Association's 30 member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States.
- Core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

Why Electronic Prior Authorization?

- EHRA agrees that there is a need to streamline the prior authorization process.
- Clients frequently tell us that the process, the steps, the documentation – all the things that are needed to get prior authorization for the items that are being ordered, considered, and otherwise – are taking a lot of time and effort, and this has a number of challenges in a variety of different ways.

Current State

- EHRA likes to make a distinction between prior authorization for medications and for everything else. In the medication area, EHRA is very pleased by how far they have been able to collectively get. In the area of other services, we have clearly been collectively lagging.
    - Electronic Prior Authorization for prescription medications is more widespread due to integration with payers through CoverMyMeds and Surescripts
- CMS moving toward adoption of v2017071 of the NCPDP SCRIPT standard for Part D plans
- ePrior Authorization for all other medical services has been lagging

Challenges

- Level of detail at which prior authorization is required, e.g., procedures, tests, DME, services
- Lack of standard data requirements and granularity across payers (federal, state, commercial)
- Lack of efficient data-exchange technology by payers

  - Attempts at using X12 and infrastructures that were in place just did not enable us to integrate the flow and the data as easily into the workflows with minimum impact on the user. Delays and lags occurred because the technologies were not there to have a smooth interaction.
- Data capture and workflow integration
  - How to ensure that data fits in the right spot, in the right place has been challenging with the variety of data requirements that are needed.

Some of the challenges that we recognize and hear about are about the level of detail at which prior authorization is required. So, it needs to be done for individual procedures, individual tests, individual DME, and individual services where that may be required. The data requirements and the need for them

Electronic Prior Authorization and EHRs

- EHRs capture much of the relevant data for prior authorization, but:
  - Need for prior authorization often not known at time of order
  - Prior authorization often requires additional documentation beyond what is needed for treatment
  - Need for additional documentation often not known at time of order
  - Relevant data may be in a different system or format, such as relevant PDF or C-CDA documents
  - Potential lags in accessing and exchanging with payer systems
- Challenges are frequently projected onto the EHR rather than on the source requiring further documentation

Recommendations

- Establish authorization at a higher level than procedure/service/test/DME
  - Shift from fee-for-service to value-based payments has helped.
  - Are there opportunities by which there is effectively no need for authorization to be embedded as deeply into the workflows and at each individual procedure, service, et cetera? What can be done there so that it's not needed?
- Integrate electronic prior authorization process within EHR workflow; avoid reliance on separate payer/third-party portals
  - All working proactively to integrate electronic prior authorization into the EHR workflow will reduce reliance on separate payer third-party portals to get access to that information. Da Vinci is one of several areas being explored to make that happen.
  - There is still a fair amount of work to be done, but if electronic prior authorization can be integrated, it will be key if that can be done with the least amount of documentation requirements, data capture, and offline interaction with the payer.
- Automate data capture and prior authorization requests
  - If not, it adds to burden.
- Adoption of technologies/standards better suited to real-time interactions across systems, e.g., CDS Hooks, RESTful, HL7, FHIR, and SMART
  - Let's all be looking at the technology standards that are better suited to real-time interactions across systems. With recent developments around CDS Hooks, RESTful, HL7 FHIR, and SMART, there is a toolkit that is starting to become available that has the opportunity to establish the level of integration and interaction that makes it more viable than what was available before.

APPENDIX 4: Compendium of Landscape Artifacts

1. **Task Force Presentations and Demonstrations**
    a. April 28, 2020
        i. Surescripts: https://www.healthit.gov/sites/default/files/facas/2020-04-28_ICAD_TF_Prior_Automation_Surescripts_508.pdf
        ii. CoverMyMeds: https://www.healthit.gov/sites/default/files/facas/2020-04-28_ICAD_TF_CoverMyMeds_508.pdf
    b. May 5, 2020
        i. Humana: https://www.healthit.gov/sites/default/files/facas/2020-05-05_ICAD_Prior_Auth_Humana_508_0.pdf
        ii. Regence: https://www.healthit.gov/sites/default/files/facas/2020_05-05_ICAD_Taskforce_Regence_508.pdf
            1. Demo: https://www.healthit.gov/hitac/events/intersection-clinical-and-administrative-data-task-force-meeting-8
    c. May 12, 2020
        i. AMA: https://www.healthit.gov/sites/default/files/facas/2020-05-12_ICAD_TF_AMA_Presentation_508.pdf
    d. June 2, 2020
        i. CMS: https://www.healthit.gov/sites/default/files/facas/2020-06-02_CMS_DRLS_Support_508.pdf
    e. June 9, 2020
        i. AHIP: https://www.healthit.gov/sites/default/files/facas/2020-06-09_AHIP_Presentation_508.pdf
            1. AHIP 2019 Prior Authorization Survey Results and Infographics: https://www.ahip.org/ahip-survey-prior-authorization-grounded-in-clinical-evidence-and-selectively-used/
        ii. Premier: https://www.healthit.gov/sites/default/files/facas/2020-06-09_Premier_Presentation_508_0.pdf
    f. June 16, 2020
        i. X12: https://www.healthit.gov/sites/default/files/facas/2020-06-16_X12_Presentation_508.pdf
    g. June 23, 2020
        i. AHIMA: https://www.healthit.gov/sites/default/files/facas/2020-06-23_AHIMA_Presentation_508.pdf
        ii. CAQH CORE: https://www.healthit.gov/sites/default/files/facas/2020-06-23_CAQH_CORE_Presentation_508.pdf
    h. July 7, 2020
        i. EHRA: https://www.healthit.gov/sites/default/files/facas/2020-07-07_EHRA_HITAC_ICAD_ePA_Presentation_508.pdf

2. **Industry Recommendations**
    a. AHIMA Policy Statement on Integrating Clinical and Administrative Data, 8/3/20 https://journal.ahima.org/ahima-policy-statement-on-integrating-clinical-and-administrative-data/

    b. Premier Letter to ONC on Additional Recommendations to HITAC ICAD Task Force, 6/23/20

    Letter to HITAC ePA_06_05_2020.pdf

    c. AMA Prior Authorization Proposed Pilot for Medical Services Prior Authorization, Sent to Task Force Co-Chairs 6/2/20

    Prior Auth Pilot for ICAD TF - FINAL

3. ***Strategy on Reducing Regulatory and Administrative Burdens Relating to the Use of Health IT and EHRs* Final Report, February 21, 2020**
    a. Report: https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs
    b. HHS Press Release: https://www.hhs.gov/about/news/2020/02/21/hhs-issues-strategy-improve-care-for-patients-by-reducing-clinician-burdens.html
    c. ONC Blog Post: https://www.healthit.gov/buzz-blog/health-it/final-report-delivers-a-strategy-to-reduce-ehr-burden

4. **ONC Annual Meeting, January 27-28, 2020**
    a. Day 2 Breakout Session: Prior Authorization: A Public and Private Sector Update: https://www.healthit.gov/sites/default/files/page/2020-03/MasonModeratorSlidesPAPanelforONCAnnualMeeting.pdf
        i. Jocelyn Keegan; Payer Practice Lead/Da Vinci Program Manager, Point of Care Partners
            1. Standards; Medical and Pharmacy Prior Authorization; Da Vinci Project
        ii. Alexandra Mugge; Deputy Chief Health Informatics Officer, Centers for Medicare & Medicaid Services
            1. Patients Over Paperwork; Document Requirement Lookup Service via FHIR-based API; (DRLS); ePrior Authorization via FHIR-based API
        iii. Kate Berry; Senior Vice President, America's Health Insurance Plans
            1. Prior Authorization Survey Preliminary Results, Fast PATH Project (Automating Prior Authorization)
        iv. Miranda Gill, MSN, NEABC, RN; Senior Director, Provider Services & Operations, CoverMyMeds

5. **CAQH Resources**
    a. CAQH CORE Approves Two-Day Rule to Accelerate Prior Authorization Process, CAQH Press Release, February 4, 2020: https://www.caqh.org/about/press-release/caqh-core-approves-two-day-rule-accelerate-prior-authorization-process
    b. 2019 CAQH Index, January 21, 2020: https://www.caqh.org/explorations/caqh-index-report-0
    c. 2018 CAQH Index, January 16, 2019: https://www.caqh.org/sites/default/files/explorations/index/report/2018-index-report.pdf

6. **NCVHS Full Committee Meeting, November 13-14, 2019:** https://ncvhs.hhs.gov/meetings/full-committee-meeting-2/
    a. November 13, 2019 (Day 1) Meeting Transcript: https://ncvhs.hhs.gov/wp-content/uploads/2019/12/Transcript-Full-Committee-Meeting-November-13-2019.pdf
        i. X12 Updated and Enhanced Implementation Guide Processes, Cathy Sheppard; **Transcript, p. 66**
        ii. Predictability Roadmap, Alix Goss & Rich Landen; **Transcript, p. 104**
        iii. NCVHS and ONC/HITAC Prior Authorization Collaboration, Don Rucker; **Transcript, p. 143**
        iv. Expert Panel on Prior Authorization; **Transcript p. 152**
            1. Expert Panel: Heather McComas – AMA; Kate Berry – AHIP; April Todd – CAQH CORE; Mary G. Greene – CMS; Jay Eisenstock – WEDI; Pam Dixon – World Privacy Forum)
            2. Topics: Updates on prior authorization work since March 2019 HITAC meeting; Challenges in reducing provider and patient burden; Industry survey efforts with themes and gaps preliminarily identified
            3. Heather McComas AMA Update: https://ncvhs.hhs.gov/wp-content/uploads/2019/12/Presentation-Prior-Authorization-AMA-Update-Heather-McComas.pdf
            4. Follow-up Discussion with NCVHS and ONC, **Transcript, p. 239**
                a. Future of Convergence of Administrative and Clinical Data

7. **3/20/19 HITAC Meeting on Prior Authorization**
    a. Patient/Clinician Perspective
        i. Andrew Robie MD, Family Medicine Physician, Anacostia Community Health Center, Unity Health Care
        ii. Heather McComas, PharmD, Director, Administrative Simplification Initiatives, American Medical Association (remote): https://www.healthit.gov/sites/default/files/facas/2019-03-20_Patient_Clinician_Perspective_AMA_Heather_McComas_508.pdf
    b. Interoperability and HIPAA Administrative Simplification Considerations
        i. Daniel Kalwa, Policy Advisor, Division of National Standards, Centers for Medicare and Medicaid Services: https://www.healthit.gov/sites/default/files/facas/2019-03-20-Interoperability_HIPAA_Administrative_Simplification_Considerations_CMS_Daniel_Kalwa_508.pdf
    c. Industry Standards Perspective
    Industry Administrative Transaction Data
        i. April Todd, Senior Vice President, CAQH CORE, CAHQ Index Data Report: https://www.healthit.gov/sites/default/files/facas/2019-03-20-Industry_Administrative_Transaction_DataCAQH_Index_Deck_April_Todd_508.pdf

Medication workflow (NCPDP SCRIPT)

i. Anthony Schueth, CEO, Point of Care Partners: https://www.healthit.gov/sites/default/files/facas/2019-03-20_Industry_Standards_Perspective_Medication_Workflow_%28POCP%29-_Anthony_Schueth_508.pdf
ii. Margaret Weiker, Director of Standards Development, National Council for Prescription Drug Programs: https://www.healthit.gov/sites/default/files/facas/2019-03-20_Industry_Standards_Perspective_Medication_Workflow_%28NCPDP%20SCRIPT%29-_Margaret%20Weiker_508.pdf

Non-medication workflow (Durable Medical Equipment, Referrals, Imaging, Procedures)

i. John Kelly, Principal Business Advisor, Edifecs, Chair, Work Group for Electronic Data Interchange (WEDI) Prior Authorization Council: https://www.healthit.gov/sites/default/files/facas/HITAC%20WEDI%20Deck.J.Kelly_508.pdf
ii. Robert Dieterle, EnableCare, CEO, Program Management Office HL-7 Da Vinci Project: https://www.healthit.gov/sites/default/files/facas/2019-03-20_Da_Vinci_Prior-Authorization_Support_Robert_Dieterle_508.pdf

CDS Hooks

i. Ken Kawamoto, MD, Associate Chief Medical Information Officer, Director, Knowledge Management and Mobilization, Vice Chair for Clinical Informatics, Department of Biomedical Informatics, University of Utah: https://www.healthit.gov/sites/default/files/facas/2019-03-20_Industry_Standards_Perspective_CDS_Hooks-Kensaku_Kawamoto_508.pdf

d. Public and Private Payer Perspective
   i. Kate Berry, Senior Vice President Clinical Affairs and Strategic Partnerships, American's Health Insurance Plans (AHIP): https://www.healthit.gov/sites/default/files/facas/2019-03-20_Public_and_Private_Payer_Perspective_AHIP_Kate_Berry_508.pdf
   ii. Melanie Combs-Dyer, Director, Provider Compliance Group, (Medicare Fee for Service) Center for Program Integrity, Centers for Medicare and Medicaid Services: https://www.healthit.gov/sites/default/files/facas/2019-03-20_State_of_PA_in_Medicare_FFS_Program_Melanie_Combs_Dyer_508.pdf
   iii. Sagran Moodley, Senior Vice President, Clinical Data Services, United Healthcare, Chair Steering Committee DaVinci Project, Co-Chair Documentation Requirement Lookup Service (DRLS) (remote)
e. 3/20/19 HITAC Meeting Transcript https://www.healthit.gov/sites/default/files/facas/2019-03-20_HITAC_InPerson_Transcript_508.pdf
f. 3/20/19 HITAC Meeting Notes https://www.healthit.gov/sites/default/files/facas/2019-03-20_HITAC_Meeting_Notes_508.pdf

8. **NCVHS 13th Report to Congress, March 14, 2019**: https://ncvhs.hhs.gov/wp-content/uploads/2019/03/13th-Report-to-Congress.pdf

Percent Industry Implementation of Seven Transaction Standards[1]	2013	2018	2019[2]
Health Care Claim Submission	90%	96%	96%
Eligibility for a Health Plan	65%	85%	84%
Coordination of Benefits	NR	80%	86%
Health Care Claim Status	48%	71%	70%
Claim Payment	50%	63%	70%
Remittance Advice	43%	48%	51%
Prior Authorization	NR	12%	13%

Source(s): 2018 CAQH Index, 2019 CAQH Index
[1]Table original included six transaction standards; table above added prior authorization standard
[2]Added 2019 CAQH data

9. **2020 CoverMyMeds Publications**
   a. **Sixth Installment of ePA Report, September 23, 2020:** https://www.covermymeds.com/main/insights/articles/epa-report-findings-prospective-pa-decreases-time-to-therapy/
   b. **Medication Access Report, March 2020** https://www.covermymeds.com/main/medication-access-report/
      i. **Executive Summary:** https://assets.ctfassets.net/2in405srp47m/4SyH0ZdIFQwuAuCzhuAmTo/973d7b3266a843c94c074fce698de9ea/CMM_36517_MARExecutiveSummary_Digital.pdf

10. **WEDI Industry White Paper on Prior Authorization Burden, February 5, 2019:** https://www.wedi.org/2019/02/05/wedi-releases-industry-white-paper-authored-by-newly-chartered-prior-authorization-council/

11. **eHealth Initiative Report, February 2019: Prior Authorization: Current State, Challenges, and Potential Solutions** https://www.ehidc.org/sites/default/files/resources/files/Prior%20Auth%20Comprehensive%20Report%20Feb%202019.pdf

12. **AMA Resources (Additional)**
    a. Consensus Statement on Improving Prior Authorization: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf
    b. Letter to Seema Verma re: Da Vinci Project, September 19, 2019: https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FFINAL-STAKEHOLDER-SIGN-ON-HR-3107-090919.pdf
    c. Prior Authorization and Utilization Management Reform Principles, June 2019: https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf
    d. 2018 Physician Survey on Prior Authorization, February 2019: https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf

13. HL7 FHIR Da Vinci Project

a. Clinical Advisory Committee Guiding Principles for Da Vinci Implementation Guides, Published January 20, 2020: https://confluence.hl7.org/display/DVP/Da+Vinci+Clinical+Advisory+Council+Members?preview=/66940155/66942916/Guiding%20Principles%20for%20Da%20Vinci%20Implementation%20Guides.pdf
b. Prior Authorization Support Use Case, September 2019: http://hl7.org/fhir/us/davinci-pas/2019Sep/usecases.html
c. Da Vinci Deep Dive, March 11, 2020: Document Requirement Lookup Service (DRLS) Burden Reduction:
    i. Slide Deck https://confluence.hl7.org/download/attachments/39160937/HIMSS%202020%20DRLS%20presentation_508compliant_03-09-2020.pdf?version=1&modificationDate=1583936478372&api=v2
    ii. Recording https://transcripts.gotomeeting.com/#/s/4b0939fbfd542123f4db5062779a852f46daa57750e4f9cac4e7af6f3d34b6b5

14. Selected Industry Trade Press

a. AHIP Survey: Prior Authorization Grounded in Clinical Evidence and Selectively Used, June 9, 2020: https://www.ahip.org/ahip-survey-prior-authorization-grounded-in-clinical-evidence-and-selectively-used/
b. Expanding How CoverMyMeds Helps Patients Access Their Medications, March 27, 2020: https://www.drugchannels.net/2020/03/expanding-how-we-help-patients-access.html
c. WEDI Shares Results of Prior Authorization Survey in Testimony to NCVHS, WEDI Press Release, January 23, 2020: https://www.wedi.org/2020/01/23/wedi-shares-results-of-prior-authorization-survey-in-testimony-to-ncvhs/
d. New Fast PATH Initiative Aims to Improve Prior Authorization for Patients and Doctors, AHIP Press Release, January 6, 2020: https://www.ahip.org/new-fast-path-initiative-aims-to-improve-prior-authorization-for-patients-and-doctors/
e. Momentum Builds to Fix Prior Authorization, Modern Healthcare, October 2019: https://www.modernhealthcare.com/insurance/momentum-builds-fix-prior-authorization
f. Health Care Leaders Collaborate to Streamline Prior Authorization and Improve Timely Access to Treatment, AHIP Press Release, January 17, 2018: https://www.ahip.org/health-care-leaders-collaborate-to-streamline-prior-authorization-and-improve-timely-access-to-treatment/