ASTP Assistant Secretary for Technology Policy

ASTP Objectives, Benchmarks, and Data Updates

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October 17, 2024

21ˢᵗ Century Cures Act Requirement

For the purpose of the HITAC Annual Report, Section 4003 of the 21st Century Cures Act states that:

" …the National Coordinator, in collaboration with the Secretary, shall establish, and update as appropriate, objectives and benchmarks for advancing and measuring the advancement of the priority target areas… "

- ASTP sets the objectives and benchmarks that inform the development of the HITAC Annual Report.

- ASTP objectives and benchmarks support implementation of the *2024-2030 Federal Health IT Strategic Plan*.

- ASTP welcomes feedback from HITAC members about the objectives and benchmarks, including how they inform the HITAC target areas.

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Health Information Technology Advisory Committee
Target Areas from the Cures Act in FY23

Interoperability:
Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information

Privacy and Security:
The promotion and protection of privacy and security of health information in health IT

Patient Access to Information:
The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information
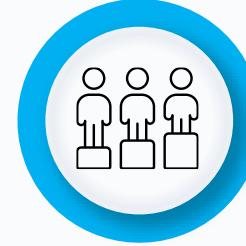
Design and Use of Technologies that Advance Health Equity:
Applying health information technology to help all people attain their full health potential regardless of social drivers of health

Use of Technologies that Support Public Health:
The facilitation of bidirectional information sharing between the clinical and public health communities

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ASTP Activities to Impacts

ASTP Activities to Impacts

ASTP is at the forefront of the federal government's efforts to support the entire health system with the use of health IT and the promotion of nationwide, standards-based health information exchange.

Vision: Better health enabled by data

Mission: To create systemic improvements in health and care through the access, exchange, and use of data

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FY 2024 Activities

# FY 2024: ASTP Health Data, Technology, and Interoperability (HTI) Rulemaking Activities

- Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing ([HTI-1 Final Rule](#)) published on January 9, 2024

- Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability ([HTI-2 Proposed Rule](#)) published on August 5, 2024

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FY 2024: ASTP Health IT Standards Activities

United States Core Data for Interoperability Version 5 (USCDI v5)

- Released USCDI v5 in July 2024

- 2 new data classes
  - Observations
  - Orders

- 16 new data elements, including:
  - Advance Directive Observation
  - Sex Parameter for Clinical Use
  - Interpreter Needed
  - Pronouns
  - Name to Use

New Data Elements for final USCDI v5

Clinical Notes	Immunizations	Medications
Emergency Department Note ↑ **H** Operative Note ↑ **H**	Lot Number 🖊 §	Route of Administration **H**

New Data Class Observations	New Data Class Orders §	Patient Demographics/Information
Advance Directive Observation **H** Sex Parameter for Clinical Use § **H**	Medication Orders Laboratory Orders Diagnostic Imaging Orders Clinical Test Orders Procedure Orders	Interpreter Needed **=** ↑ **H** Pronouns **=** ↑ § **H** Name to Use **=** ↑ § **H**

Provenance
Author **=** ↑ **H** Author Role **=** ↑ **H**

= Equity Based   ↑ Underserved   🖊 Public Health   § ONC Cert   **H** HITAC Recommended

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FY 2024 ASTP Health IT Standards Activities

USCDI+ Domains	Updates
Behavioral Health	• ASTP published a [Draft Behavioral Health Overarching Data Set](#) and [Comprehensive Care Data Set](#) • [Draft Behavioral Health Implementation Guide tested at HL7 Connectathon](#)
Cancer	• ASTP published a [Final Enhancing Oncology Model Data Set](#) • Tested the [Enhancing Oncology Model Implementation Guide](#) at an HL7 FHIR Connectathon • ASTP published the [Enhancing Oncology Model (EOM) Test Kit](#) • ASTP, NIH National Cancer Institute (NCI), CDC, CMS, and FDA hosted a two-day [USCDI+ Cancer Data Exchange Summit](#) to further explore USCDI+ Cancer use cases in a coordinated effort to advance and mature the exchange of standardized cancer data • ASTP and NCI hosted a [Post-Summit Update](#) [Webinar](#) and [USCDI+ Cancer Registry Listening Session](#) • ASTP published the [Draft Cancer Registry Data Set](#)
Maternal Health	• ASTP published a [Draft Maternal Health Comprehensive Data Set](#) • Pilot Testing Maternal Health Data List
Public Health	• ASTP and CDC published a [Draft Case Reporting Data Set](#) and a [Draft Laboratory Data Exchange Data Set](#)
Quality	• ASTP published a [Draft Quality Overarching Data Set](#) and [Draft Quality v1 Data Set](#) • ASTP coordinated with HRSA to ensure the Uniform Data System (UDS) Reporting Set was mapped to USCDI, as well as published the [UDS+ FHIR Reporting Implementation Guide](#)

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FY 2024 ASTP Health IT Standards Activities

Standards Version Advancement Process (SVAP)

- 10 SVAP approved standards for 2024
- Advanced health equity work through key patient demographic data
- Supports industry on consistent implementation of:
  - USCDI v4
  - US Core FHIR® Implementation Guide (IG) v7.0.0
  - FHIR® SMART Application Launch Framework IG v2.2.0
  - CMS Quality Reporting Document Architecture IG for Hospital Quality Reporting and Eligible Clinicians Programs
  - CDA IG for Clinical Notes Edition 3.0

FHIR®

- Published US Core FHIR® IG v7.0.0 including updates to support USCDI v4
- Released the 2024 Draft Federal FHIR Action Plan
- Supported development and/or publication of FHIR IGs including: FHIR Clinical Document, SMART Health Cards and Links, At-Home Testing, Electronic Long-Term Services and Supports (eLTSS), Prescription-Drug Monitoring Program, International Patient Summary (IPS)

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FY 2024 ASTP Health IT Standards Activities

Helios Public Health FHIR® Accelerator

- Successfully tested use of FHIR queries to obtain follow-up case information at two connect-a-thons, in support of future TEFCA functionality.

- Continued work in aggregate data track to test exchange of hospital capacity information during emergencies.

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FY 2024 ASTP Health IT Standards Activities

HHS-wide Approach on Health IT Standards Investments

- ASTP, in partnership with the Assistant Secretary for Financial Resources (ASFR), released the [HHS Acquisition Regulation (HHSAR): Acquisition of Information Technology; Standards for Health Information Technology Proposed Rule](#) on August 9, 2024

- ASTP and other HHS agencies identified a broad range of applicable grants, cooperative agreements, contracts, and rulemaking/guidance – covering public health, emergency preparedness, research, and other areas – for incorporating standard health IT language

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FY 2024 ONC Health IT Certification Program Activities

- Implemented [HTI-1 Final Rule](#) updates including:
  - Update to [USCDI v3](#)
  - "Edition-less" certification criteria, supporting a more modular and flexible approach to managing the Certification Program
  - Updates to Certification Companion Guides (CCGs)
  - Establishment of Certification Program fact sheets and other educational resources
    - DSI Resource Guide, 9 Key Functionalities Fact Sheet, and DSI Roadshow webinars

- The [HTI-2 Proposed Rule](#) includes new and revised standards and certification criteria in the ONC Health IT Certification Program. These revisions include an update to USCDI v4, as well as standards and criterion related to e-prescribing and public health exchange.

- Continued to build the Inferno Framework with [several test kits](#)
  - Da Vinci Test Kits
  - SMART App Launch 2.0
  - US Core IGs

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FY 2024 ASTP Exchange Activities

Trusted Exchange Framework and Common Agreement (TEFCA)

- 7+ QHINs live

- FHIR Roadmap for TEFCA Exchange 2.0

- Common Agreement 2.0 – Updated for FHIR® Exchange

- QHIN Technical Framework (QTF) 2.0

- Facilitated FHIR Implementation SOP (Technical Requirement)

- Published multiple Standard Operating Procedures (SOPs) for Exchange Purposes:
  Treatment SOP, Healthcare Operations SOP, Public Health SOP, and Individual Access Services SOP

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FY 2024 ASTP Exchange Activities

Information Blocking Rules

- HHS published "[21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking](#)" Final Rule

  - Rule is effective as of July 31, 2024.

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FY 2024 ASTP Exchange Activities

Information Blocking Portal Submissions by Fiscal Year
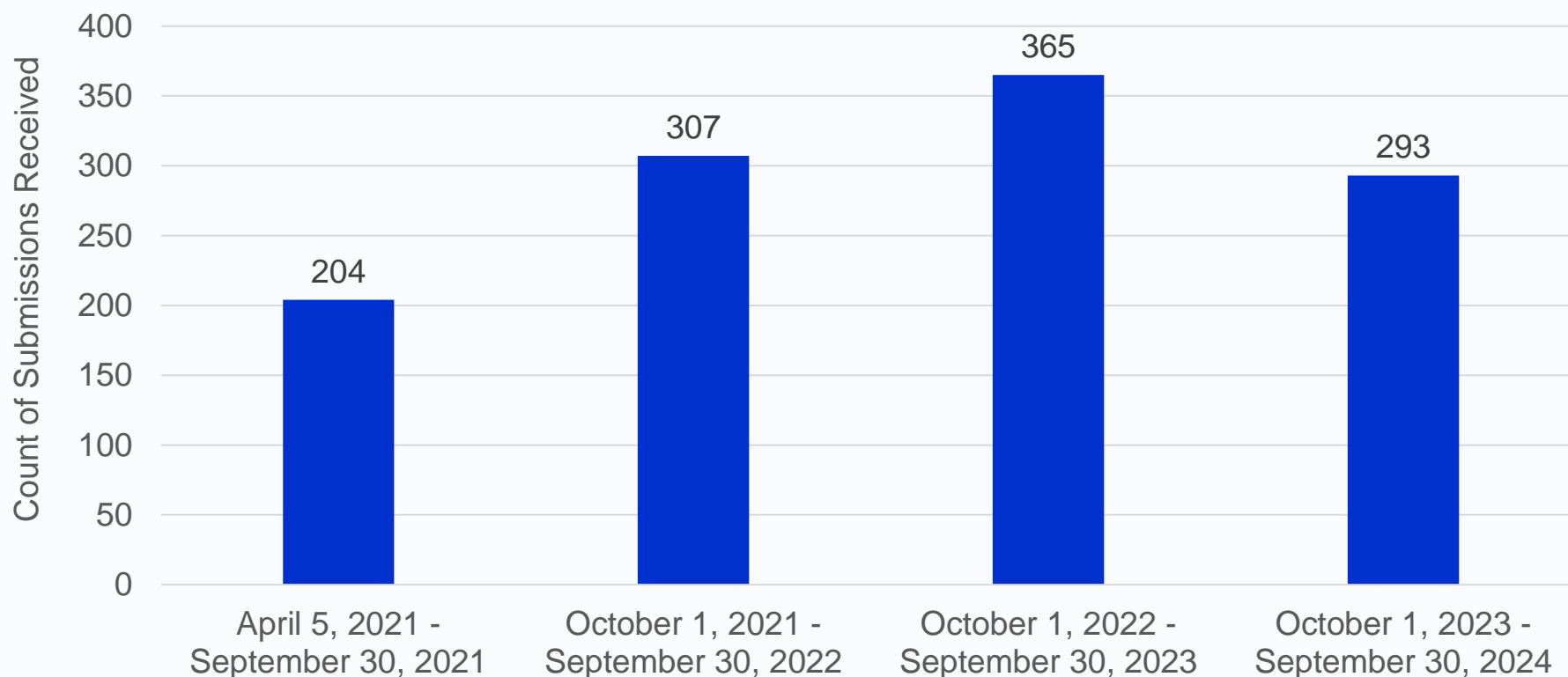
~80% of total submissions received appear to be made by a patient, or by a third party on behalf of a patient

~77% of total submissions received appear to refer to a potential health care provider actor, and

~14% appear to refer to a CHPL-listed health IT developer

NOTE: The applicability date for the information blocking regulations (April 5, 2021) was established in the ONC Cures Act Final Rule. For more information see: https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers.

FY 2024 ASTP Health IT Coordination Activities

Health Equity by Design (HEBD)

- Continued to prioritize the addition of USCDI data elements that advance health equity, including:
    - Interpreter needed
    - Pronouns
    - Name to use

- Published the [Health Equity by Design Concept Paper](#), reflecting the ASTP proposed approach for HEBD

- The Public Health Informatics & Technology [(PHIT) Workforce Development Program](#) aims to implement or expand training, certification, and degree programs in public health informatics and data science at minority serving institutions and other colleges and universities

    - The PHIT Workforce Development Program has trained 3,765 students as of September 30, 2024

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FY 2025 Plans

FY 2025 ASTP Standards Plans

SVAP
- Publish ASTP approved updated versions of health IT standards and implementation specifications via SVAP process

USCDI
- Release USCDI v6 with additional data classes and data elements

USCDI+
- Advance use cases and projects under the current domains for:
  - Behavioral Health
  - Cancer
  - Maternal Health
  - Public Health
  - Quality
  - Sickle Cell Disease

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FY 2025 ASTP Standards Plans

FHIR®

- Development and publication of US Core FHIR® IG v8.0.0 including updates to support USCDI v5

- Support standards development related to emerging FHIR® capabilities such as SMART Health Cards and Links, SMART App Launch IG granular scopes

- Ongoing development and support for FHIR® infrastructure including the FHIR® IG publisher and FHIR® validator

- Finalize Federal FHIR® Action Plan

- Lead the Global Digital Health Partnership's support and advancement of the FHIR® International Patient Summary

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FY 2025 ASTP Standards Plans

Public Health

- Incorporate USCDI+ Public Health into Standard Development Organization activities and FHIR® profile development

- Initiate production pilots for Query and Response, Bulk Query, and Aggregate Data projects

- Establish new project area for "Public Health Reporting"

- Test new Vital Records use case for "Bulk Query"

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FY 2025 ASTP Standards Plans

Leading Edge Acceleration Projects (LEAP)

2024 Awardees

The Trustees of Columbia University in the City of New York

- Area of Interest: Develop innovative ways to improve healthcare-data quality to support responsible development of artificial intelligence (AI) tools in healthcare
- Estimated Completion: Fall 2026

Oregon Health & Science University

- Area of Interest: Accelerate adoption of Health IT in behavioral health settings
- Estimated Completion: Fall 2026

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FY 2025 ASTP Standards Coordination Plans

HHS Health IT Alignment Policy

- Continue to advance technical assistance for HHS agencies and HHS funded contractors and grantees on health IT standards adoption and use

- Support HHS finalization of the *Health and Human Services Acquisition Regulation: Standards for Health Information Technology* *(ASFR proposed rule RIN:0991-AC53)*

- Explore opportunities to advance health IT standards alignment with HHS's federal, state, territory, local, and tribal partners.

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FY 2025 ONC Health IT Certification Program Plans

- Continue implementation of HTI-1 Final Rule updates, including education related to USCDI v3 and several revised certification criteria, including:
  - View, download, and transmit to 3rd party in § 170.315(e)(1)
  - Transmission to public health agencies - electronic case reporting in § 170.315(f)(5)
  - Standardized API for patient and population services in § 170.315(g)(10)

- Test tool updates

- Certification Program oversight and enforcement
  - Monitor conformance to "source attribute" requirements for decision support interventions in § 170.315(b)(11) given clarification issued September 16, 2024
  - Improve the implementation of monitoring and evaluation procedures, including coordination with ONC Authorized Certification Bodies
    - Emphasize implementation of API Conditions and Maintenance of Certification requirements by developers of certified health IT

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FY 2025 ONC Health IT Certification Program Plans

- Continued development of Inferno test kits:

  - USCDI v4/USCore 7.0.0 Inferno Test Kit

  - Standardized API for patient and population services § 170.315(g)(10) testing updates

  - FAST Security UDAP test kit update (dynamic registration, authentication and authorization)

  - Voluntary test kits to support advancement of IGs regarding payer:

    - **Accessing payer drug formulary information** as defined in the HL7 Da Vinci Payer Data Exchange (PDEX) US Drug Formulary IG (**v2.0.1**)

    - **Accessing payer insurance plan network directory information** as defined in the HL7 Da Vinci PDEX Plan Net IG (**v1.1.0**)

    - **CARIN IG for Blue Button®** IG (**v1.1.0**, **v2.0.0**)

    - **Prior authorization** support according to the HL7 Da Vinci PAS IG (v2.0.1)

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FY 2025 ASTP Exchange Plans

TEFCA

- Continue to onboard QHINs, participants, and subparticipants (including potential HHS and other federal partners)

- Increase FHIR®-based exchange via TEFCA

- Continue to expand use cases under existing Exchange Purposes (XPs), including Treatment, Health Care Operations, and Public Health

- Finalize and release Payment XP Implementation SOP

- Finalize and release Government Benefits Determination XP Implementation SOP

- Finalize and release Research XP Implementation SOP

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FY 2025 ASTP Exchange Plans

Information Blocking

- Continued coordination with OIG and CMS on Information Blocking claims

- Continued support for the Information Blocking Portal to receive information blocking claims

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FY 2025 ASTP Health IT Coordination Plans

Health Equity by Design (HEBD)

- Continue to advance the adoption and use of USCDI and USCDI+ data classes and elements that support health equity

- Continue to train 5,000 students over a 4-year period in public health informatics and technology through the Public Health Informatics & Technology Workforce Development Program

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FY 2024 Overall Data Update

A Year in Review

- Work published between October 1, 2023 – September 30, 2024
    - 15 Academic Papers
        - 8 published and 7 submitted/accepted
    - 8 [Data Briefs](#)
        - 6 published and 2 upcoming
    - 8 [ASTP Buzz Blogs](#)
        - *Decade of Data* blog series

- Topic areas

    - Hospital interoperability (progress and barriers)
    - Physician interoperability (experiences and friction)
    - TEFCA awareness and plans to participate among hospitals and health information exchange organizations (HIOs)
    - Social needs screening among hospitals and physicians

    - Patient access to data (and how it varies by cancer status and individual characteristics)
    - Use of EHR APIs among digital health companies
    - Artificial intelligence and machine learning in healthcare
    - Breadth of HIO services, use of standards, and interoperability with labs and HIO exchange

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Upcoming Activities

- American Hospital Association (AHA) 2024 IT Supplement Data
  - Use of APIs for clinical use, administrative tasks, and patient access
  - Machine Learning (ML) / Artificial Intelligence (AI) technology use
  - Hospitals' recording and use of health-related social needs data
  - Hospital awareness and plans to participate in TEFCA
  - Technology adoption and use

- Analysis and reporting of the CDC/NCHS National Electronic Health Record Survey (2024)
  - Technology adoption
  - Health information exchange

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Upcoming Activities (continued)

- Health Information National Trends Survey (HINTS) 7
  - Patient access to online medical record and immediate access to test results

- Data Collected through a Cooperative Agreement with the American Board of Family Medicine (ABFM)
  - Interoperability
  - Public health reporting
  - Social needs documentation and use

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Family Medicine Physician Interoperability Experience

Survey of Family Medicine Physician Experience

- ASTP has supported surveys of physicians using health IT for years
  - National Ambulatory Medical Care Survey
  - National Electronic Health Record Survey (2014-2024)

- 2021-2024 cooperative agreement with American Board of Family Medicine (ABFM) to measure <u>physician experience</u> using health IT
  - Partner with physician leaders and reach practicing physician to design effective questions
  - Unique design ensures high response rate

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Survey of Family Medicine Physician Experience

Family Medicine Physicians

- Over 100,000 family physicians
  - Largest primary care specialty

- Provide care continuity and coordination
  - High impact of interoperability

- Questions included on re-certification
  - Required on recurring basis
  - Avoids response bias
  - Over 7,000 respondents in 2024

Approach

- Thorough redesign of questions for 2024
  - Two expert panels to inform approach and final content
  - 20 interviews with family physicians
  - 4 focus groups with completed survey instrument

- Match respondent's mental models by focus on:
  - Specific, core information exchange
  - Where substantial exchange is occurring

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Respondent Demographics

Age	Freq.	Percent
50+	4,520	60
<50	3,053	40
Gender		
Female	3,553	47
Male	3,964	52
Other/Prefer not to answer	57	1
Ownership		
Academic health center / faculty practice	557	7
Governmental	1,161	15
Hospital / health system owned medical practice	2,608	34
Independently owned medical practice	2,220	29
Other	1,028	14
Location		
Rural	1,161	16
Urban	6,322	84
Percent Patient Panel Part of Vulnerable Group		
<10%	2,771	37
10-49%	3,171	42
>50%	1,632	22

Key Findings: Interoperability

- Few family physicians are very satisfied with EHR support for interoperability
  - Despite supportive ASTP certification criteria and CMS incentives via Promoting Interoperability

- Substantial difference in experience accessing information from organizations using the same versus different EHR
  - Parity might be one measure of success

- Limited flow of core information, including laboratory and imaging

- Few family physicians experience ideal data flow where they:
  - Often automatically obtain information
  - Easily find information
  - Easily reconcile information

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Physician satisfaction with obtaining health information from outside organizations using primary outpatient EHR

Category	Percentage
Very satisfied	11%
Somewhat satisfied	24%
Neither satisfied nor dissatisfied	15%
Somewhat dissatisfied	21%
Very dissatisfied	11%
Don't know	8%
EHR doesn't have capability	16%

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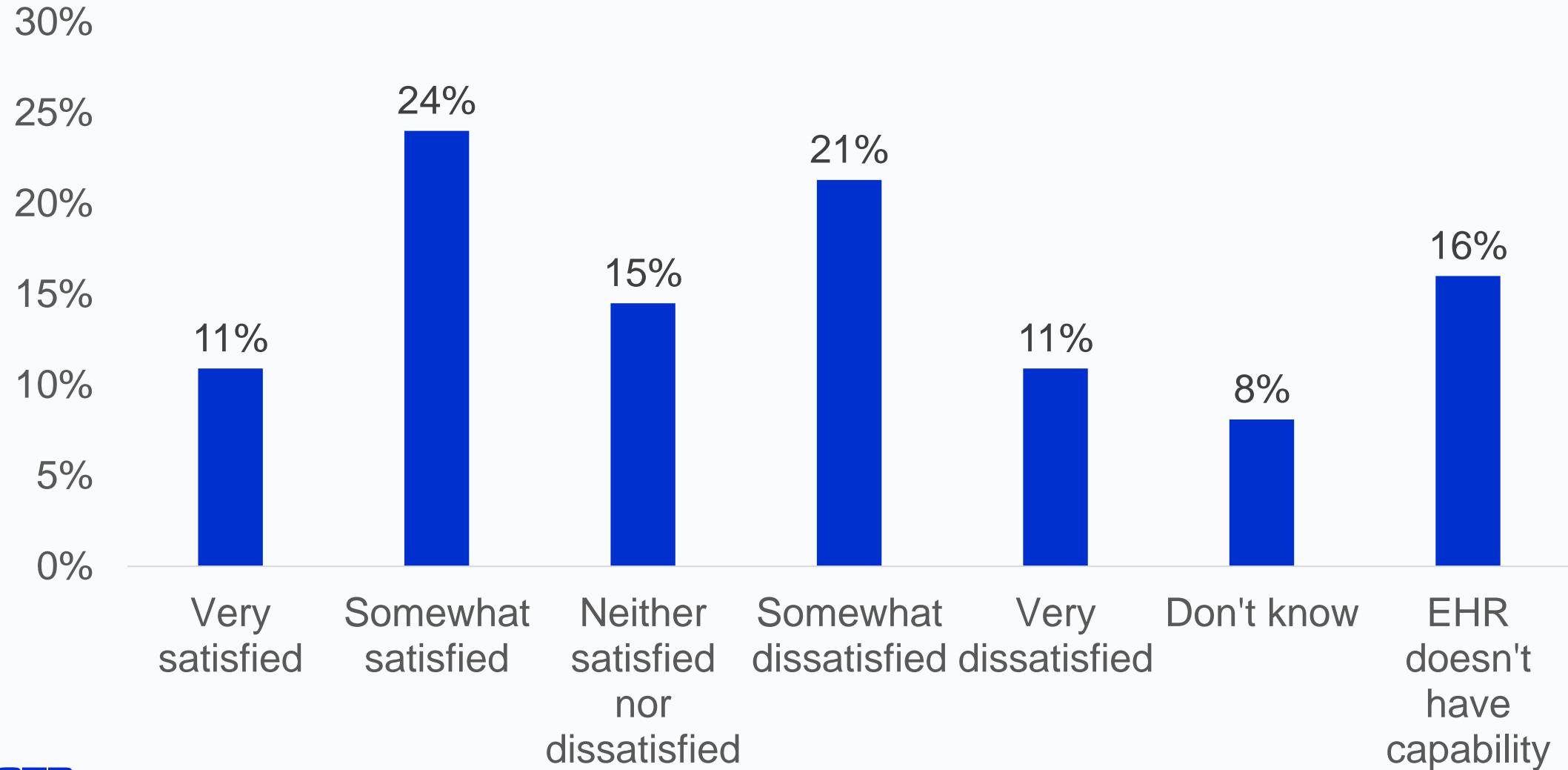
Physician satisfaction with their ability to electronically access information from organizations that use the same / different EHR vendor

Legend: ■ Same EHR Vendor ■ Different EHR Vendor

Category	Same EHR Vendor	Different EHR Vendor
Very satisfied	24%	5%
Somewhat satisfied	33%	23%
Not satisfied	9%	18%
No ability to currently electronically access	21%	38%
Don't Know	14%	16%

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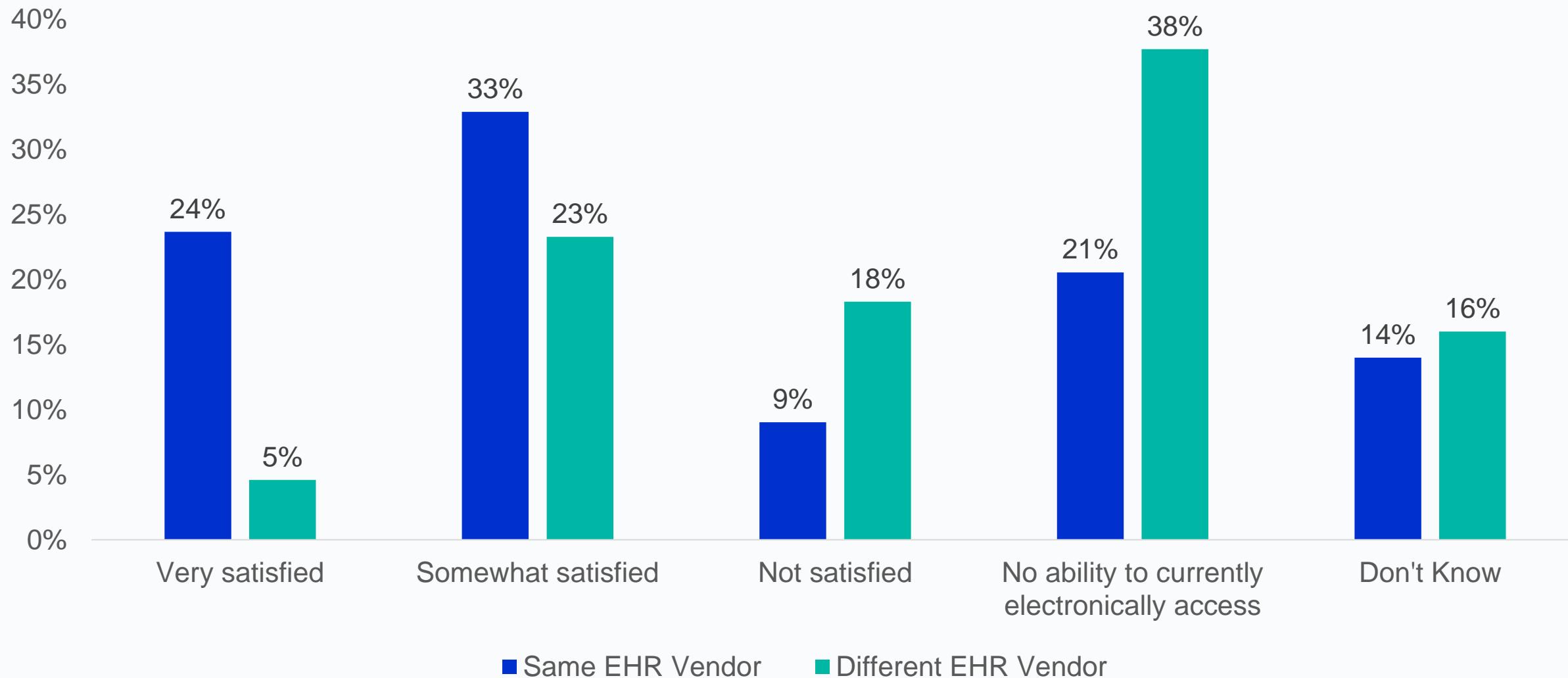
Physician experience using their EHR to obtain and review laboratory information

		Test results from commercial labs (%)
I automatically electronically obtain this information from outside organizations in my EHR	Often	32
	Sometimes	27
When I automatically electronically obtain this information from outside organizations, it includes labs ordered by other physicians for my patients	Often	24
	Sometimes	45
When I automatically electronically obtain this information from outside organizations, my EHR makes it easy to find	Often	33
	Sometimes	44
My EHR makes it easy to compare the results from outside organizations and our internal results	Often	16
	Sometimes	36

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Physician experience using EHR to obtain and use medication data from other organizations

All Respondents

32% Often automatically obtain medications in EHR

68% Do not often obtain medications

And easily find medications: 21%

33% of those that often obtain medications cannot often easily find them

But not easy to find: 11%

And easily reconcile differences with chart: 13%

38% of those that often easily find medications cannot often easily reconcile them

But not easy to reconcile 8%

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Physician experience using EHR to obtain and review imaging reports from independent imaging centers

All Respondents

26% Often automatically obtain imaging reports from independent centers in EHR

74% Do not often automatically obtain reports

34% of those that often obtain reports cannot often easily find them

And easily find the reports: 17%

But not easy to find: 9%

14% of those that often easily find reports cannot often easily find specific information within them

And easily find information in the report: 15%

But not easy to find information: 2%

Key Findings: Interoperability

- Foundational exchange of information remains a challenge that may be improved as TEFCA achieves scale

- Challenges using and reconciling information may support data quality initiatives

- Equal experience obtaining information from across organizations using same or different developers may be one measure of success

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Key Findings: Burden

- About half of physicians indicate information gathering is a substantial burden on them or their practice staff

  - Greater satisfaction with EHR support for accessing information from outside organizations associated with lower burden

- About half of physicians indicate that prior authorization is a substantial burden on them or their practice staff

 - Current EHR-based prior authorization not associated with reduced burden

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Time and effort physician or practice staff spend trying to track down health information from outside organizations (including scanning/uploading)
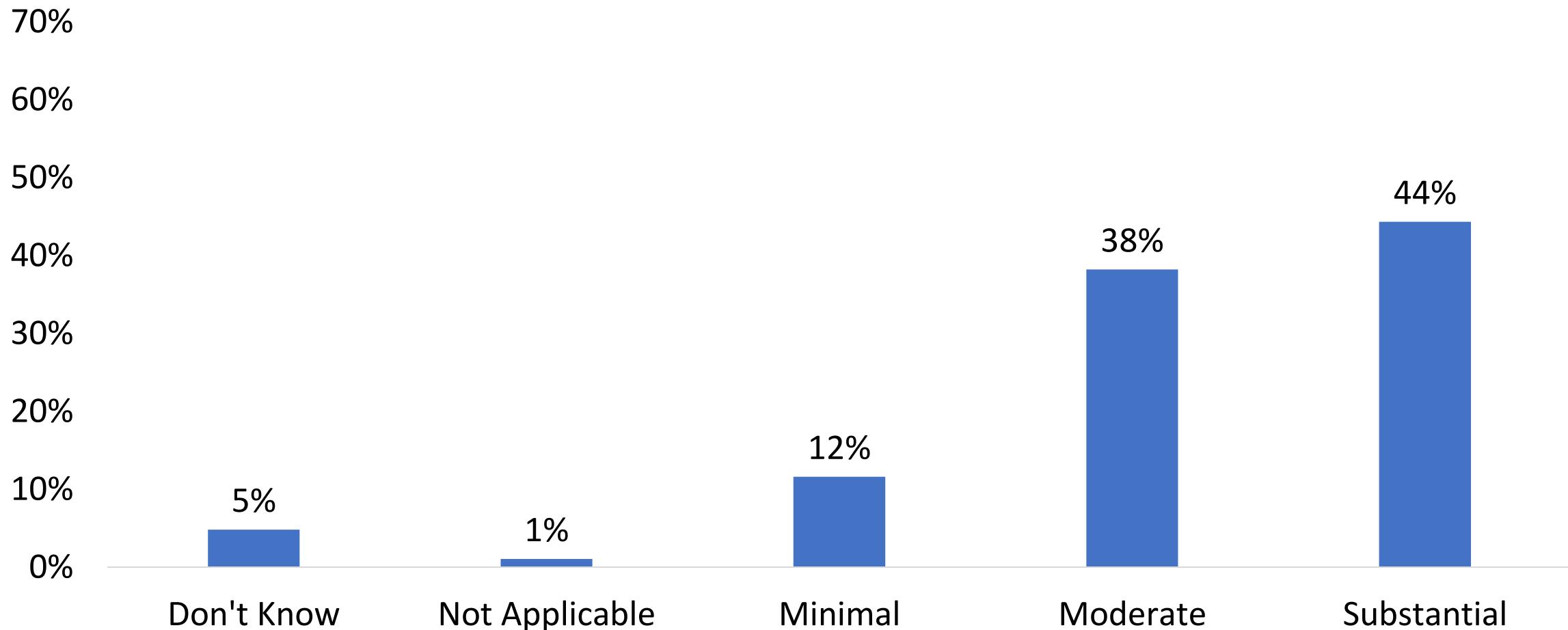
Percent of physicians reporting substantial time and effort tracking down information by satisfaction with EHR's support for accessing information from outside organizations

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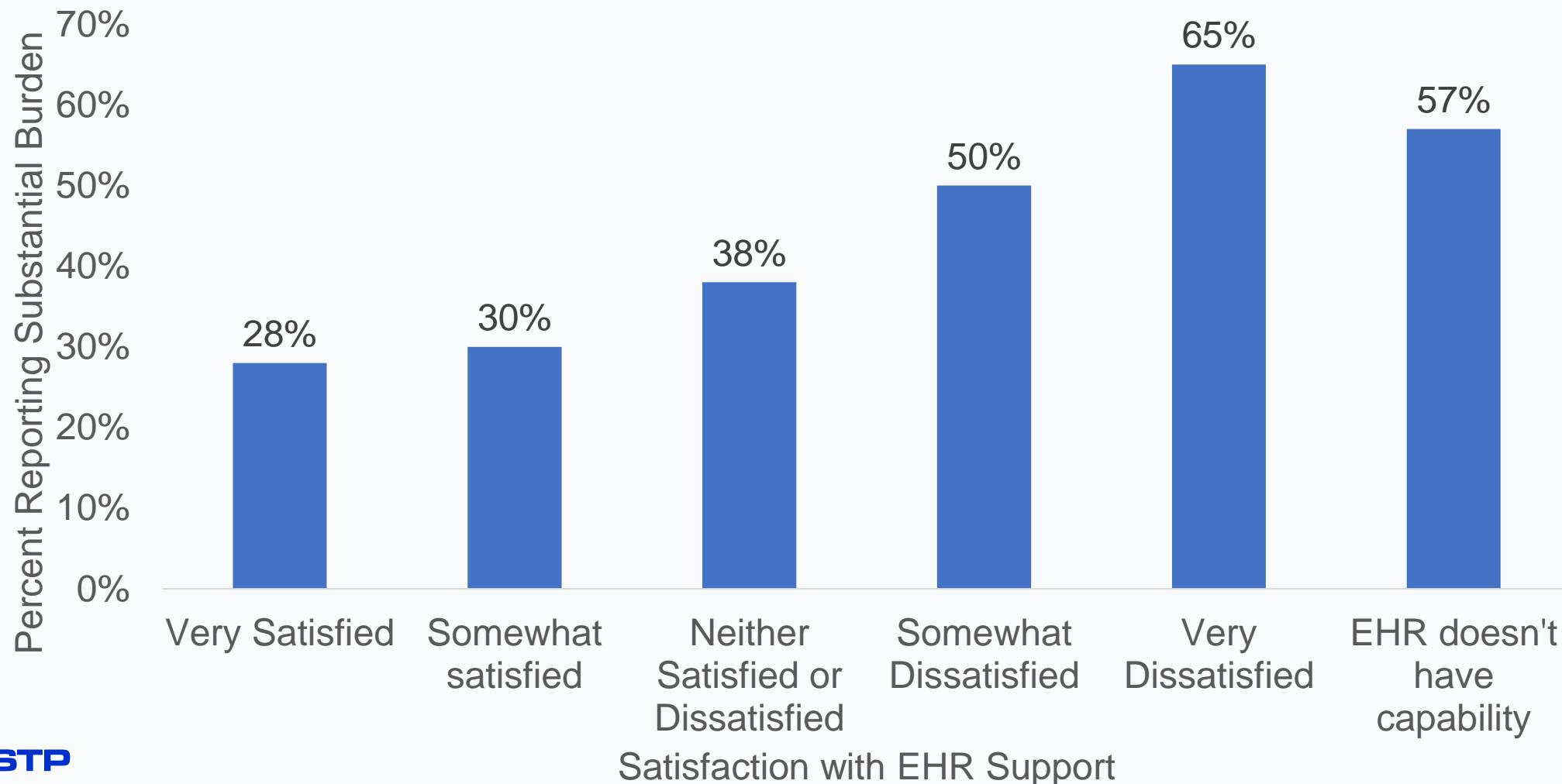
Time and effort respondent and/or practice staff spend on prior authorizations for insurance/coverage purposes?

| Category	Percentage
Don't Know	7%
Not Applicable	5%
Minimal	8%
Moderate	25%
Substantial	55%

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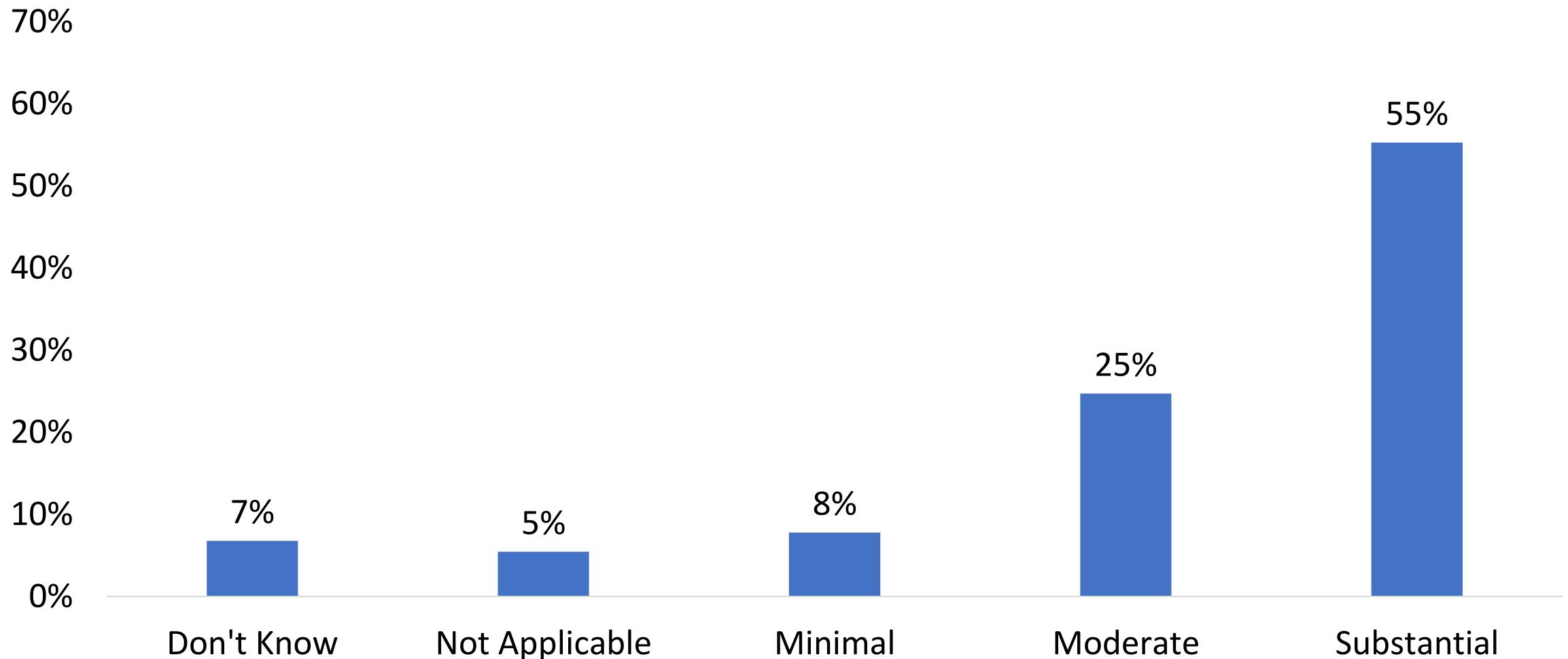
Frequency of completing all required components of prior authorization from within your primary, outpatient EHR?
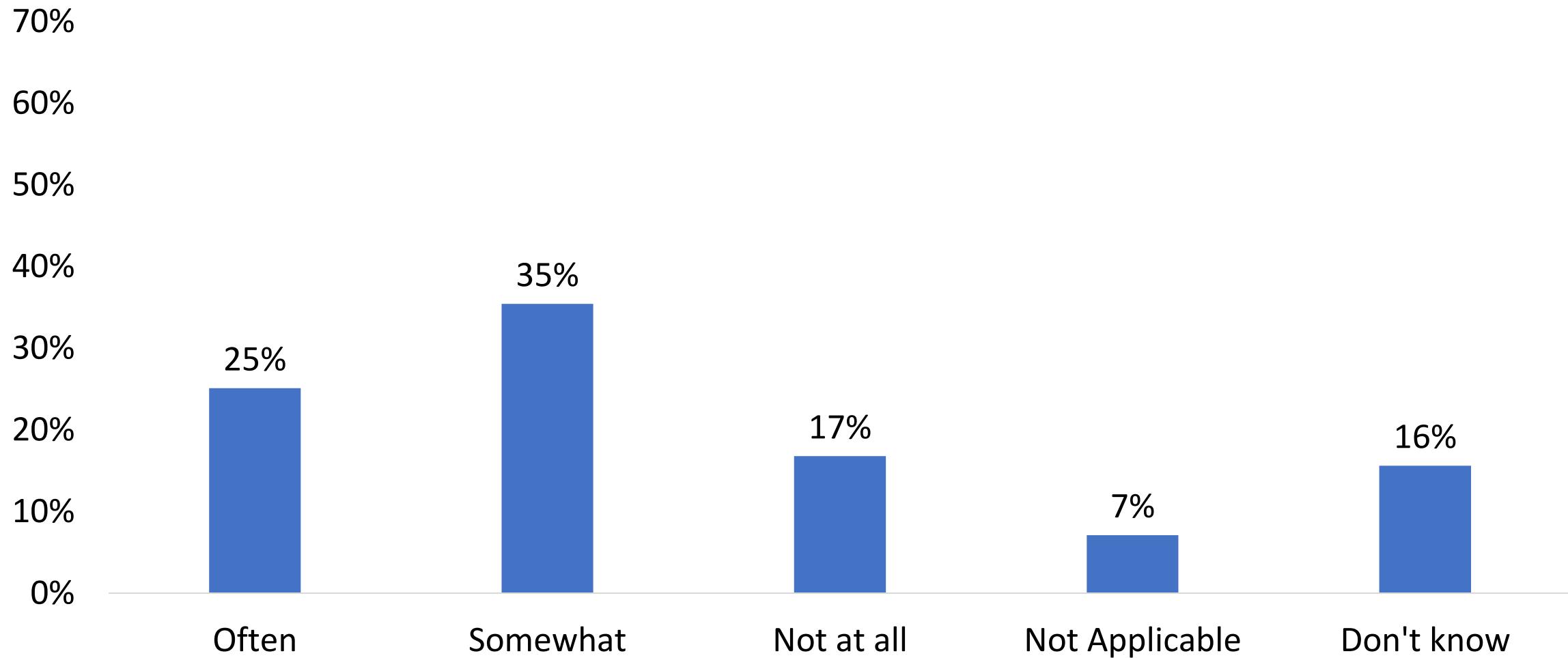
Prior Authorization (PA) burden by the ability to complete PA requirements within primary, outpatient EHR
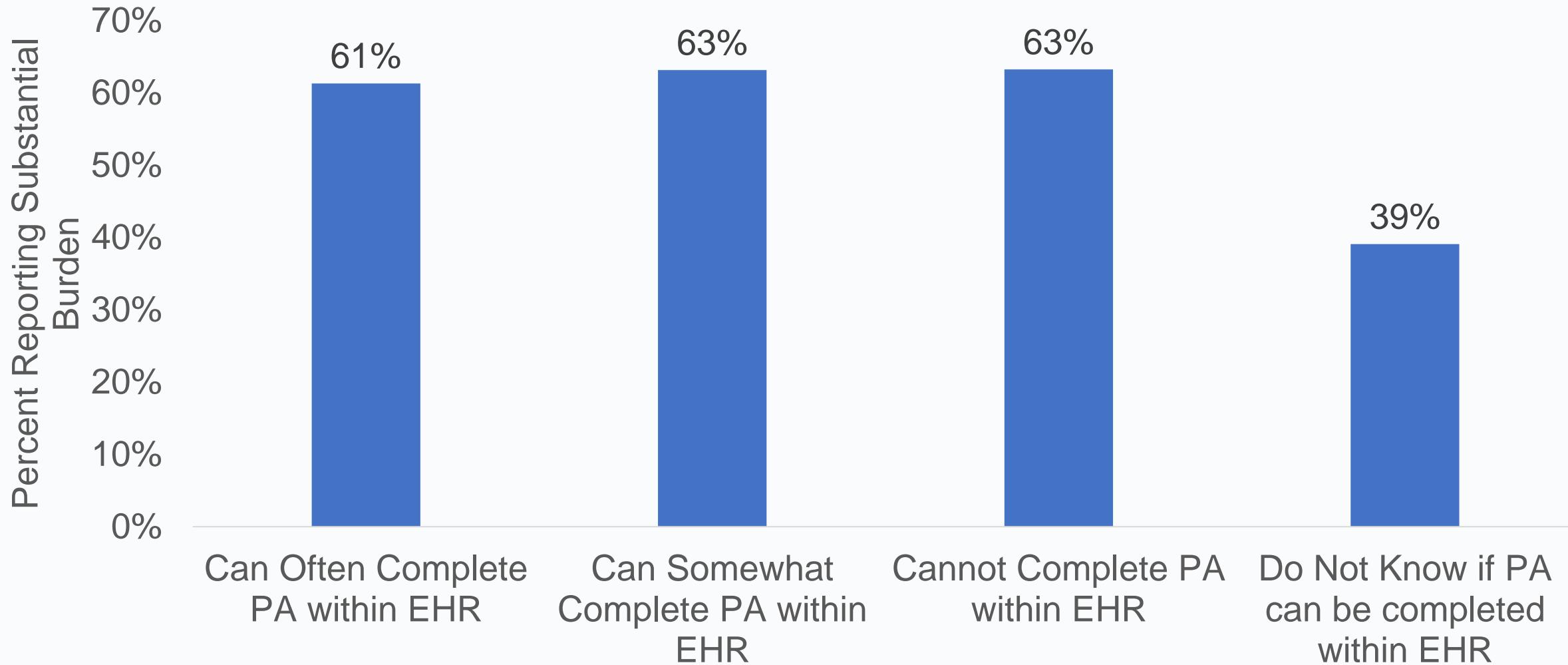
Key Findings: Burden

- Lower burden when satisfied with interoperability provides evidence for ensuring more physicians have interoperable systems

- Motivation for ongoing rulemaking to ensure standards and technology are available to simplify prior authorization is available

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Discussion