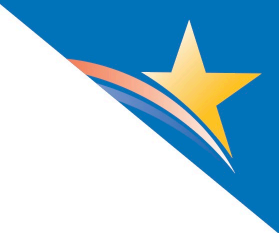


# Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

## FINAL REPORT

As Required by the 21st Century Cures Act

Public Law 114-255, Section 4001



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# A Message from the Secretary of Health and Human Services

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This report, as required by the 21st Century Cures Act, addresses specific sources of clinician burden that will require coordinated action on the part of a variety of stakeholders across the health care system, including federal, state, local, territorial, and tribal government entities, commercial payers, clinical societies, electronic health record (EHR) developers, various health care provider institutions, and other service providers.

As part of its definition of interoperability, the 21st Century Cures Act describes “the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user.” This definition reflects a key insight: that interoperability will not be achieved for users until their experience with electronic health information and technology has been made seamless and effortless, and, as a result, truly interoperable. The Department of Health and Human Services (HHS), including the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS), are committed to a vision for interoperable health information exchange that centers on the experience of clinicians and patients.

HHS believes that the types of electronic health record (EHR) and health information technology (health IT)-related burden identified in this report hinder the achievement of this vision of interoperability. These sources of burden increase the time and expense which clinicians must invest to interact with electronic health information, reducing the value of that information and diverting precious clinical and financial resources from patient care. As health care providers across the health care continuum seek to improve the ways they deliver care by incorporating beneficial new information technologies, these sources of burden can impede further innovation, ultimately limiting potential gains in improved quality of care for patients and patient safety.

In its roles as a payer and regulator, we believe there are many steps HHS can take to reduce burden by reassessing and revising different regulatory and operational aspects of federal programs, and with effective leadership on the key challenges of health IT-related burden. For instance, targeted action by CMS through its reporting and payment programs can impact the significant number of health care providers that participate in the Medicare and Medicaid programs, as well as set a direction for the rest of the health care sector. CMS has been leading by example with its recently released payment rules designed to put patients and their needs first, ease provider burden, and make significant strides in modernizing Medicare through effective and efficient use of technology. ONC can help to lead the health IT industry towards common solutions that result in reduced burden for clinician users by promoting common standards for health IT systems that support greater efficiency and interoperability, as well as best practices for usability of these systems.



Since the passage of the 21st Century Cures Act, HHS and other federal partners have worked diligently to begin implementing the Act's many important provisions around interoperability, such as proposing a framework for trusted exchange among health information networks and improving the effectiveness of ONC's Health IT Certification Program.

We view the strategy outlined in this report as a vital complement to the programs mandated under the 21<sup>st</sup> Century Cures Act. The HHS strategy and recommendations for burden reduction described here encompass a range of incremental changes to allow clinicians to enjoy the benefits of greater interoperability while producing benefits for patients and the health care system overall. We look forward to feedback about these recommendations from the health care community.

**Alex M. Azar II**  
**Secretary of Health and Human Services**



# A Message from the National Coordinator for Health Information Technology

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We are on the verge of realizing the incredible potential of health IT to interact with clinical care in a radically different way than what we have seen thus far. This will have a more profound impact on reducing clinician burden than we may fully anticipate today. The introduction of big data and machine learning along with the integration of disparate data sources will enable clinicians to have a more comprehensive view of the patient. Through this HHS strategy, we look forward to advancing the premise of how to accurately model and support the clinical cognitive process in the EHR—a shift away from a strictly linear, logic-based model to a more sophisticated design that supports the complex pattern recognition inherent in the diagnostic and treatment process. New health care-specific software design elements will help produce software tailored to the clinical workflow. We envision a time when clinicians will use the medical record not as an encounter-based document to support billing, but rather as a tool to fulfill its original intention: supporting the best possible care for the patient. Secondary purposes such as billing should occur behind the scenes of the EHR and health IT systems—in a manner that fully utilizes the scope of software technologies now available. Similarly, quality reporting should be seamless, accessible through the metadata in the EHR, and available through high-quality application programming interfaces (APIs), which will reduce the need to separately submit data.

We see a future where those best suited to define the required content of a clinical note for billing or quality reporting purposes—the clinical specialty societies, professional boards, and clinicians themselves—do so, rather than the federal government. Like quality reporting, we see an environment where public health syndromic data is also made available to public health authorities at the local, state, and federal levels, without direct and separate actions by the clinician, during the day-to-day care of their patients. We look forward to health IT continuing to improve every use case found in health care. Too often we look at “the house of medicine”<sup>1</sup> in a simple, standardized way, when in fact “the house of medicine” really encompasses multiple clinical disciplines with disparate workflows and health IT needs.

The recommendations in this report represent the best next steps to address the growing problem of clinician burden related to their use of health IT and EHRs. We recognize and are deeply grateful to all of the extremely hard-working clinicians in this country, who work long hours and deal with increasingly complex administrative requirements, all while maintaining their singular desire to provide the best care for their patients. We will all be patients at some point in our lives and owe it to our dedicated clinical colleagues to improve the administrative, regulatory, and technological environment in which they work. We are excited to put forward the HHS strategy and recommendations to help clinicians get back to what they do best—the healing arts.

**Donald W. Rucker, MD**

**National Coordinator for Health Information Technology**





# A Message from the Administrator of The Centers for Medicare & Medicaid Services

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At CMS, we are empowering patients, and moving to break down silos of patient information that deprive patients of access to the best quality and most affordable care. Sustaining our exceptional health care depends, now more than ever, on driving down costs. reveals a variety of information about a beneficiary's health, including type of Medicare coverage, drug prescriptions, primary care treatment, and claims data. By giving beneficiaries the ability to share their claims data electronically, CMS has enabled use of data with a wide range of applications.

We at CMS are deeply committed to programs, policies, and systems that put patients and their needs first. It is 2020—most doctors use electronic health records and most patients have access to the Internet and a smartphone, providing them with many ways to view their own health care data securely. Patients' information should automatically follow them to all of their health care providers, so that everyone on their care teams stays informed and provides the best treatment.

Moving toward this goal, we believe that providers should be able to focus on delivering care to patients instead of spending far too much time on burdensome and often mindless administrative tasks. Providers particularly identify burdens associated with the use of health IT such as EHR system design, regulatory and administrative burdens associated with the use of EHRs during care delivery, required reporting activities, and documentation of claims for payment.

With the passage of the 21<sup>st</sup> Century Cures Act, CMS and the White House Office of American Innovation launched the MyHealthEData initiative in March 2018, an initiative designed to empower patients by ensuring that they can access and use their health information to make better informed decisions about their care. Many providers still fax patient records, some medical staff manually enter results into EHRs, and some hospitals hand out data to patients on CD-ROMs. The MyHealthEData initiative aims to help bridge these interoperability gaps by providing patients electronic access to their medical records and bring the best of American innovation to health care by ensuring America's patients receive the medical information they need to make the best decisions for themselves and their families, while simultaneously reducing burden on clinicians.

An important part of the MyHealthEData initiative is CMS's BlueButton 2.0, a developer-friendly, standards-based application programming interface (API) that allows Medicare beneficiaries to connect their claims data to applications and services they trust. Blue Button 2.0 provides access to up to four years of Medicare Parts A, B, and D data for approximately 53 million Medicare beneficiaries enrolled in Medicare fee-for-service and Part D. Medicare beneficiaries have full control over to whom and for what they provide access to their data, with identity proofing and the authorization process controlled by MyMedicare.gov. This data





reveals a variety of information about a beneficiary's health, including type of Medicare coverage, drug prescriptions, primary care treatment, and claims data. By giving beneficiaries the ability to share their claims data electronically, CMS has enabled use of data with a wide range of applications.

As an example of how CMS is working to increase interoperability, CMS released the Interoperability and Patient Access proposed rule in which we proposed to require all payers regulated by CMS to share health claims data as well as other important information electronically with their patients through an API, similar to what we did with Blue Button 2.0. CMS also released the Discharge Planning Final Rule requiring hospitals to provide patients access to information about post-acute care (PAC) provider choices, putting patients in the driver's seat of their care transitions. The rule also advances CMS's historic interoperability efforts by mandating that hospitals ensure each patient's right to access their medical records in an electronic format, as well as requiring the seamless exchange of patient information between healthcare settings, and ensuring that a patient's healthcare information follows them after discharge from a hospital or PAC provider. It requires the discharge planning process to focus on a patient's goals and treatment preferences.

Additionally, CMS overhauled the Medicare and Medicaid Promoting Interoperability Programs (formerly known as the EHR Incentive Programs) and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category to focus on interoperability, improve flexibility, relieve burden, and emphasize measures that require the electronic exchange of health information between health care providers and patients, including providing patients with electronic access to their health information. The overhaul of the programs was the first step in achieving our interoperability objectives and addressing the recommendations in this report that also seek to enhance agency goals of interoperability and reduced EHR-related burden across the health care community.

Recommendations in this report seek to enhance the goals of interoperability of health information and reduce the EHR-related burden across the health care community. We look forward to continuing our partnership with ONC on the EHR-related burden reduction initiatives described in this report. We want to help providers improve the already high quality of care they deliver to patients.

We look forward to hearing feedback from you, members of the health care community, to enhance collaborative efforts about these recommendations.

**Seema Verma, MPH**

**Administrator, Centers for Medicare & Medicaid Services**





# Executive Summary

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## STATUTORY REQUIREMENT

Section 4001 of the 21<sup>st</sup> Century Cures Act (Cures Act)<sup>2</sup> amended the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act,<sup>3</sup> to add section 13103, “ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.” It requires HHS to articulate a plan of action to reduce regulatory and administrative burden relating to the use of health IT and EHRs. Specifically, the Cures Act directs HHS to: (1) establish a goal for burden reduction relating to the use of EHRs; (2) develop a strategy for meeting that goal; and (3) develop recommendations to meet the goal.

Section 13103 identifies a number of areas which should be prioritized for consideration as potential sources of burden to be addressed as part of the strategy. These include recent federal programs that have provided incentives for the adoption and use of EHRs, including the Medicare and Medicaid EHR Incentive Programs (now known as the Promoting Interoperability Programs), established under the HITECH Act, and the Merit-based Incentive Payment System (MIPS), established under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The statute also identifies for prioritization burden associated with value-based payment models, including: initiatives recognized as alternative payment models (APMs) under MACRA; the Hospital Value-based Purchasing program; and other value-based payment programs, as deemed appropriate by the Secretary. Finally, the statute requires HHS to prioritize the burden associated with the alignment and simplification of quality measures across federal and non-federal payer quality initiatives.

In addition to these programs, section 13103 requires HHS to prioritize several areas directly related to health IT, including: the certification of health IT; the implementation of standards within health IT products; how health IT is used to provide individuals with access to their electronic health information; and activities related to the privacy and security of electronic health information.

Section 13103 also requires HHS to prioritize EHR-related burden that may arise related to reporting clinical data for administrative purposes. The statute considers other areas of the health care enterprise, which may include EHR-related burden: specifically, public health and clinical research. Besides these enumerated areas, section 13103 permits the Secretary to determine other areas for prioritization as appropriate.

Finally, section 13103 requires HHS to address actions that improve the clinical documentation experience, patient care, and are deemed appropriate by the Secretary’s recommendations. The statute notes that these actions may be taken by the Secretary and by other entities.

HHS has prepared this report to fulfill the statutory requirements of section 4001 of the Cures Act.







## INTRODUCTION

Providers of health care in the United States have identified regulatory and administrative burden as a key contributor to a number of challenges facing the health care delivery system. Today, physicians and other health care providers, administrators, and institutions must comply with an ever-increasing, wide-ranging, and often poorly coordinated body of requirements to deliver and receive payment for patient care. Stakeholders argue that the cost of compliance with these requirements, and longer term effects such as increased physician burn-out, are a significant obstacle in making the health care system more efficient, increasing quality of care for patients, and improving patient safety.

Stakeholders frequently cite the use of health IT, such as EHRs, as one aspect of the burden problem. Over the past several decades, health IT use has dramatically changed the practice of medicine and clinical care in the United States. These tools have offered physicians unprecedented access to information about patients and enabled clinicians in other health disciplines across the health care system to increase efficiency when electronic solutions have replaced cumbersome paper-based processes. Yet there is a growing consensus that, while it has made an unprecedented amount of information about patients available to them, technology has yet to make the practice of medicine easier for physicians and other health care professionals.

Although clinicians and other health care providers point to the implementation, use, and regulation of health IT and the EHR as a key support tool for care delivery, it remains a source of ongoing frustration. They argue that the EHR has introduced new challenges or failed to address existing ones despite intending to improve the practice and experience of medicine. We have heard from health care providers, practice managers, and hospitals that they experience challenges with EHR system design and the regulatory and administrative burdens associated with the use of EHRs during care delivery, required reporting activities, and documentation of claims for payment. These challenges affect productivity, increase organizational cost, and detract from patient focus, resulting in negative experiences using health IT.

## BURDEN REDUCTION GOALS

This report outlines three primary goals informed by extensive stakeholder outreach and engagement for reducing health care provider burden:

- 1) Reduce the effort and time required to record information in EHRs for health care providers during care delivery.
- 2) Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations.
- 3) Improve the functionality and intuitiveness (ease of use) of EHRs.

While different types of administrative burden can affect all participants in the health care system, this report is specifically focused on health care providers directly involved in the delivery of care: frontline health care providers, including physicians, nurses, and other clinical staff; practice managers and other administrators immediately engaged in the management of care delivery; and care delivery institutions, such as hospitals.





## BACKGROUND

Federal policy related to health IT has evolved considerably over the past decade. The HITECH Act, enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA), established incentive payments for the adoption and meaningful use of certified EHR technology by health care providers in the Medicare and Medicaid programs. To receive these incentive payments (or to avoid a downward payment adjustment in the Medicare program in later years), the law required eligible professionals and hospitals to demonstrate “meaningful use” of certified EHR technology.

Over the course of subsequent rulemakings, HHS defined three progressive stages of “meaningful use” requirements, including measures designed to directly gauge the use of health IT and the reporting of electronic clinical quality measures (eCQMs) using an EHR. Since the enactment of the HITECH Act, these programs have provided more than \$37 billion in incentive payments to eligible professionals and hospitals participating in the programs.<sup>4</sup>

HITECH also established a framework for the certification of health IT, including EHRs, which health care providers must use to qualify for these incentive payments. Under this authority, ONC established a certification program for health IT that uses HHS adopted standards, implementation specifications, and certification criteria (e.g., for the electronic exchange of health information), and performs certain functions (e.g., clinical decision support capabilities) consistent with its certification. To date, ONC has published three “Editions” of these certification criteria to reflect the continued evolution of health IT.<sup>5</sup> To be certified to a particular Edition, health IT must be tested and found compliant with that Edition’s applicable standards, implementation specifications, and certification criteria.

The Patient Protection and Affordable Care Act (ACA),<sup>6</sup> enacted in 2010, further emphasized the use of health IT, particularly within new value-based payment initiatives. Some new payment and service delivery models designed and tested under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center) in CMS have introduced model design elements for the use of health IT as well as electronic reporting of clinical quality measures as requirements for participants.

In 2015, MACRA significantly restructured programs focused on quality and value for physicians paid under Medicare Part B. Through the new MIPS, MACRA combined for physicians, in a single framework, the existing Medicare EHR Incentive Program, Physician Quality Reporting System (PQRS), and Physician Value-based Modifier programs. It also added a new component around completing “improvement activities” which contribute to higher quality care and better outcomes for beneficiaries. Performance scores across the MIPS categories contribute to a single score, which determines whether a MIPS-eligible clinician receives a positive, neutral, or negative payment adjustment. MACRA also included incentives under Part B for clinicians to participate in Advanced APMs, which are APMs that require participants to use certified EHR technology, provide payment for covered professional services based on quality measures comparable to those used in the MIPS quality performance category, and either: (1) be a Medical Home Model expanded under CMS Innovation Center authority or (2) require participants to bear a more than nominal amount of financial risk.

By bringing these three programs together under a single framework, MACRA provided an opportunity to streamline how clinicians under Medicare were rewarded based on quality performance. In subsequent program rulemakings, CMS has continued to explore ways to reduce burden under MIPS, especially with respect to the Promoting Interoperability performance category, formerly known as the Advancing Care





Information performance category, which incorporated many of the health IT requirements of the Medicare EHR Incentive Programs. For instance, these efforts include final policies established in the CY 2019 Physician Fee Schedule final rule that increased alignment between the Promoting Interoperability performance category under MIPS for eligible clinicians and the policies for hospitals under the Promoting Interoperability Program that were established in the FY 2019 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule. These rules also reduced burden in other ways, such as significantly simplifying the scoring structure for the MIPS Promoting Interoperability performance category. In addition, both rulemaking efforts emphasized a smaller set of measures that require the exchange of health information between providers and patients and incentivize providers to make it easier for patients to obtain their medical records electronically from both clinicians and hospitals.

## FINDINGS IN THIS REPORT

This report describes sources of EHR-related burden, as well as strategies and recommendations that HHS and other stakeholders can pursue to achieve the burden reduction goals stated above. In order to better understand sources of EHR-related burden, HHS reviewed stakeholder input from a wide range of stakeholders (e.g. payers, health care professional societies, health care clinicians, hospital representatives, health IT developers, and health informatics associations). HHS received input through a variety of channels, including: in-person meetings with stakeholder representatives; formal written input provided as part of the rulemaking process and in response to specific requests for information; dedicated channels used to receive stakeholder feedback and complaints; literature reviews; virtual and in-person listening sessions; and others. The draft report was released for public comment in November 2018. Over the next 60-day public comment period, ONC received 208 individual comment letters from a broad spectrum of stakeholders as referenced above. This feedback represented over 1,400 pages of written documentation which ONC made available online for the health IT and clinical community to review. Those comments helped shape the revisions enclosed in this finalized report to Congress.

## ISSUES AND CHALLENGES

Based on a review of this input, HHS established four workgroups which included representatives from across HHS, including ONC, CMS, and other federal offices. Each of these workgroups focused on a different aspect of EHR-related burden, specifically:

- 1) Clinical Documentation
- 2) Health IT Usability and the User Experience
- 3) EHR Reporting
- 4) Public Health Reporting

The first section of this report, entitled “Issues and Challenges,” describes the findings of these workgroups in more detail in order to identify the mechanisms by which EHR-related burden impacts health care providers today.

### Clinical Documentation

This section considers how clinicians use EHRs to capture clinical documentation required for administrative purposes. While billing and audit requirements may impose administrative burdens



regardless of EHR usage, the implementation of these requirements within EHRs may add additional burden, particularly where health IT systems have failed to address clinical/administrative processes that would benefit from greater automation and standardization. For instance, stakeholders have long noted that documentation required to bill for patient visits (e.g., evaluation and management codes) may add burden to clinical day-to-day practices, such as capturing the information directly and separately in the EHR. This section also addresses prior authorization requirements for certain items and services, and potential opportunities to ease related clinician burden through improved health IT-enabled processes.

### **Health IT Usability and the User Experience**

This section focuses on how usability challenges within EHR and health care IT products can increase clinician burden. Clinicians often associate additional burden with the EHR when the EHR is seen as disrupting or slowing clinical workflows. For instance, poor design of electronic clinical decision support (CDS) tools such as pop-up alerts can require excessive interaction and hamper clinicians' ability to efficiently review patient safety alerts. Likewise, suboptimal information presentation, such as the poor implementation of electronic summary of care documents, can result in excessive, unnecessary information included in documents supporting care transitions.

This section identifies several areas where EHR and health care IT products can be improved to reduce burden experienced by clinicians using these products, including: alignment of health care IT (e.g., EHR) with the clinical workflow; improvements to the graphical user interface (GUI); increased standardization around presentation of clinical content within the EHR, such as medication ordering and laboratory result displays; and improved processes around the configuration and implementation of EHRs, which proactively engage the end user.

### **EHR Reporting**

This section looks at the EHR-related burden associated with federal programs that require health care providers to report performance data using health IT, particularly the Promoting Interoperability Programs, formerly known as the Medicare and Medicaid EHR Incentive Programs, and MIPS.

The current design and administration of these programs may impose burden on clinicians in a variety of ways. For instance, regulatory requirements and timelines are often misaligned across programs and subject to frequent updates, which require significant investments from clinicians to ensure annual compliance. Government requirements are often also poorly aligned with the reporting requirements across many of the federal payer programs in which clinicians may participate, thus, requiring additional work on the part of the health care provider.

Features of the current approach for developing eCQMs may also contribute to burden. Long timelines combined with limited transparency for stakeholders into aspects of the measure development process can lead to a climate of uncertainty for physicians, hospitals, and the health IT developers that support them. A number of physicians and hospitals expressed concern about the relevance and applicability of quality and health IT measures to their own clinical workflows and to patient care. The current process may also discourage innovation around new electronic measures, a key priority for many stakeholders seeking measurement options that are more meaningful to their practices.

Health care providers also face challenges in utilizing their EHRs to meet reporting requirements due to ongoing problems with accessing and extracting data from systems supporting reporting. While third party



organizations may be able to facilitate reporting for practices, these services may be prohibitively expensive for small practices or unavailable in certain areas.

### Public Health Reporting

This section explores several areas in which federal and state requirements associated with public health infrastructure may impose EHR and health IT-related burden on health care providers. The primary burden in this section relate to: insufficient interoperability between state prescription drug monitoring programs (PDMPs) and EHRs; burden related to electronic prescribing of controlled substances (EPCS); and a lack of automated, standards-based public health reporting requirements across federal programs.

## STRATEGIES AND RECOMMENDATIONS

Based on the issues and challenges described, the report lays out a series of strategies and recommendations that HHS is considering taking to mitigate EHR-related burden for health care providers. In order to ensure strategies are both high impact and feasible, HHS is focused on strategies which meet the following criteria:

- Strategies should be achievable within the near to medium term, roughly 3–5 year window.
- HHS should be able to either implement these strategies through existing or easily expanded authority, or should have significant ability to influence the implementation of these strategies.
- Strategies should include actions that improve the clinical documentation experience and improve patient care.

### Clinical Documentation

These strategies seek to mitigate the EHR-related burden associated with a variety of administrative processes. We are considering how reforming certain administrative requirements or optimizing out-of-date requirements for health IT-enabled health care provider workflows can reduce the burden of clinical documentation. We also consider administrative processes like prior authorization, which are widely perceived as burdensome and could benefit from more focused IT automation.

We first consider EHR-related burden associated with documentation requirements for patient visits—especially the guidelines for evaluation and management visit codes used by most payers. In both the CY 2019 and CY 2020 Physician Fee Schedule final rules, CMS has taken a number of steps to update and streamline documentation requirements for office and outpatient evaluation and management (E/M) visits. Efforts to reduce the overall burden associated with E/M documentation guidelines can impact EHR-related burden. We also consider how recent CMS policy changes can help to leverage data already stored in the EHR, reducing the need for redundant documentation. In implementing these policy changes, HHS should continue to obtain robust stakeholder input to ensure that health IT solutions are supporting these new opportunities for burden reduction. Finally, HHS could consider ways to exempt clinicians participating in APMs from certain documentation requirements.





We have heard that current ad hoc approaches to documentation within the EHR contribute to many of the burden issues in this area. In addition to policy changes, HHS could continue working collaboratively with stakeholders to disseminate best practices for documentation. For instance, limited appropriate use of the “copy and paste” and auto-populate functions within the EHR can ensure records do not become overloaded with extraneous information.

Clinicians have also identified documentation requirements for items and services associated with prior authorization and ordering for certain items and services as significant sources of burden. HHS can play a role in helping to evaluate and address process and clinical workflow factors contributing to the burden associated with prior authorization. EHRs and other health IT solutions can also help to mitigate this burden, but prior authorization processes suffer from a lack of standardization and common approaches. Consistent with the HIPAA rules, HHS could expand on current work to identify common data elements and standardized templates that can be implemented by health IT developers to support more automation around these processes. HHS could also explore ways to incentivize clinicians to adopt and use technology certified to conduct these transactions according to recognized standards. Testing these new approaches is important, and HHS could engage a wide variety of payers, health care providers, and other third-party intermediaries in working toward robust standards-based automation of these transactions.

Finally, HHS should work closely with standards development organizations, commercial payers, and others to support coordination of multi-stakeholder efforts to advance new standard approaches supporting prior authorization. Medicare fee-for-service is already engaged in the Da Vinci Project, which is a private sector initiative led by the standards development organization Health Level 7 (HL7®). Through the Da Vinci project, Medicare fee-for-service is working with several other payers, EHR vendors, providers, and ONC to help find ways to reduce provider burden related to prior authorization requirements and related documentation requirements.

### Health IT Usability and the User Experience

Recommendations in this area directly address how improvements in the design and use of health IT systems can reduce EHR usability-related burden for clinicians. Implementing these recommendations will require collaboration across a range of stakeholders, including clinicians who best understand how to reduce burden within their own processes, health IT developers and other vendors who must implement these changes within their products, and HHS and other institutional stakeholders who can help to develop and disseminate best practices.

Improving the usability of health IT systems is a key priority for reducing clinical burden, specifically through better alignment of the EHR with optimal workflows for care delivery, clinical decision making, and other tasks. As today’s clinical decision support tools are often difficult to use and can lead to clinician fatigue, widespread adoption of a robust framework for effective CDS, as recently outlined by the National Academy of Medicine,<sup>7</sup> could be impactful. Many clinicians encounter challenges in using the EHR for basic

### CLINICAL DOCUMENTATION STRATEGIES

**Strategy 1:** Reduce regulatory burden around documentation requirements for patient visits.

**Strategy 2:** Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements.

**Strategy 3:** Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.





documentation purposes. Other health providers face similar challenges with their health IT systems. There are areas in which developers, clinicians, and other stakeholders can work together to promote best practices that reduce the burden associated with these tasks. Finally, EHR developers can improve information presentation and display to minimize information overload for the end user.

There are several ways improvements to the user interface can improve health IT system usability, efficiency, user experience, and end user satisfaction. Health IT developers should consider implementing common approaches to basic clinical operations across EHRs, so that clinicians do not have to utilize a significantly different interface each time they switch between systems. The industry should also consider options to develop and adopt health care-specific GUI design components (such as flowsheet list generation and navigation components suitable to the busy clinical environment) that could better support the clinician's cognitive process and the clinical workflow. Health IT developers can ensure that the user interface is consistent throughout an entire product, and health care institutions can consider limiting customization that significantly changes this user interface. Finally, a better design of the physical environment can reduce EHR-related burden by making it easier for clinicians to interact with health IT systems in ways that better align with existing clinical workflows.

#### HEALTH IT USABILITY STRATEGIES

**Strategy 1:** Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools.

**Strategy 2:** Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.

**Strategy 3:** Promote harmonization surrounding clinical content contained in health IT to reduce burden.

**Strategy 4:** Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.

While much has been done in recent years to standardize the clinical content contained in health IT, variation in key areas continues to cause frustration and burden for clinicians. Key priorities for harmonization across EHR systems center around: standardizing medication information across EHR systems (e.g., consistent use of generic drug names and presentation of medication instructions such as dose and frequency); standardizing order entry content so that order names, care activities, and order set components are presented consistently; and developing agreed upon conventions and common user interface (UI) components for the display of results.

Finally, promoting better implementation decisions in the deployment of health IT systems can improve clinician efficiency and satisfaction and lower burden. Health IT stakeholders have suggested to ONC in discussions that developers and institutions that manage system deployment can increase end user engagement and training to ensure that the product purchased by an organization will meet the needs of its end users and their desired workflows. In a related recommendation, developers and institutions can minimize clinician burden associated with system log-on through thoughtful workflow integration, while emerging technologies such as facial recognition tools can be explored in greater depth. Greater transparency and thoughtful planning around budgeting for health IT investments can ensure adequate resources are available for critical training and ongoing support. Broader, nationwide strategies to improve interoperability will have a positive impact on usability and burden reduction.





## EHR Reporting

This report outlines a set of strategies designed to address many of the programmatic, technical, and operational challenges raised by stakeholders to reduce EHR-related burden associated with program reporting.

There are specific requirements that increase EHR-related burden in federal programs utilizing health IT within the Promoting Interoperability performance category of the Quality Payment Program for clinicians and the Promoting Interoperability Programs for hospitals, formerly known as the EHR Incentive Programs. CMS is working to simplify requirements for these programs. Through the CY 2019 Physician

Fee Schedule final rule and the FY 2019 IPPS/LTCH PPS final rule, CMS actively worked to increase flexibility and reduce burden, whenever possible. For instance, in the CY 2019 Physician Fee Schedule final rule, CMS reduced the number of required measures as well as simplified the scoring methodology for the Promoting Interoperability performance category under MIPS by eliminating the base, performance, and bonus scores and established a new scoring methodology focused on clinician performance at the individual measure level.

Simplifying requirements within these programs and exploring alternative approaches to rewarding performance can contribute to reduced burden for health care providers. Specifically, as these changes are implemented, CMS could continue to explore new incentives within these programs that reward the innovative use of health IT and increased interoperability, while continuing to invest in technical assistance for health care providers to improve understanding and overall success within these reporting programs, such as through the Quality Payment Program-Small Practice, Underserved, and Rural Support (QPP-SURS).<sup>8</sup>

Reducing EHR-related burden in these programs will require collaboration between HHS, health IT developers, and other health IT vendors, in order to take advantage of the potential of health IT to improve the technical infrastructure available for reporting. Stakeholders could work together to develop and adopt industry-wide best practices for data mapping that can improve data accuracy and reduce burden when reporting from EHRs, as well as standards that improve the ability to access and extract data from health IT systems. Improved technical standards in these domains can reduce the cost and labor associated with reporting by encouraging more competition among entities that facilitate reporting.

Finally, a strategy for improving the value and usability of eCQMs and realizing the potential of electronic measurement and reporting creates possibilities for reducing burden. To address the technical issues which often accompany deployment of new measures and serve as a source of frustration for clinicians, CMS could establish a first-year test reporting approach for new eCQMs. Building on the work of its existing eCQM Strategy Project, HHS could expand its strategic focus on the future of eCQMs and how to ensure

### EHR REPORTING STRATEGIES

**Strategy 1:** Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.

**Strategy 2:** Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.

**Strategy 3:** Improve the value and usability of electronic clinical quality measures while decreasing health care provider burden.







health care providers increasingly transition to electronic measurement and reporting. Finally, HHS could further explore innovative approaches to electronic quality measurement that leverage emerging technologies, while incentivizing clinicians to help develop these approaches.

## Public Health Reporting

These strategies look at a set of topics linked to federal, state, local, territorial, and tribal government policies and public health programs, with a specific focus on EPCS and use of PDMPs. Where EHR-related burden remains a key barrier to progress in these areas, there are several recommendations for how stakeholders can advance these burden reduction goals related to public health.

The first strategy looks at ways federal stakeholders can work with states to increase provider PDMP query for the retrieval of medication history from state PDMPs by promoting improved integration of health IT into health care provider workflows. Specifically, federal agencies could work with states to adopt common industry standards that can better facilitate integration and to explore potential sources of federal financing to support this work. HHS is also implementing section 5042 of the SUPPORT for Patients and Communities Act, which provides for a 100 percent federal Medicaid matching percentage for certain state expenditures related to PDMPs, if certain conditions are met, including that the PDMP must facilitate the integration of medication history information into provider workflows.

The second strategy seeks to accelerate adoption of electronic prescribing of controlled substances, including through implementation of SUPPORT Act provisions requiring use of EPCS. The third strategy looks at how to mitigate burden associated with the volume and variability of public health reporting and data collection requirements which utilize data from health IT systems. HHS could develop a process to convene key stakeholders to assess and inventory public health reporting requirements. This inventory could help HHS to better understand the complexities of harmonization across federally funded public health programs, in order to identify programs that use the same or similar EHR data and promote use of common standards for these processes.

Finally, this area looks at how HHS could address EHR-related burden associated with confidentiality requirements and issue additional guidance regarding federal privacy and confidentiality protections to enable electronic exchange in compliance with these requirements.

### PUBLIC HEALTH REPORTING STRATEGIES

**Strategy 1:** Increase provider PDMP query for the retrieval of medication history from a state PDMP. Improve health care provider workflow for conducting the query by integrating the PDMP with health IT.

**Strategy 2:** HHS should increase adoption of electronic prescribing of controlled substances (EPCS) with consideration for provider-specific preferences, workflow, and use of available standards.

**Strategy 3:** Develop a process to address the issue of inconsistent data collection by federal, state, and local programs.

**Strategy 4:** HHS should expand upon existing guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorders (SUDs) health information in order to better facilitate electronic exchange of health information for patient care.

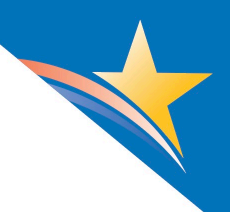




## STRATEGIES AND RECOMMENDATIONS

	STRATEGIES	RECOMMENDATIONS
<p><b>Clinical Documentation</b></p>	<p><i>Reduce regulatory burden around documentation requirements for patient visits.</i></p>	<ul style="list-style-type: none"> <li>● Continue to reduce overall regulatory burden around documentation of patient encounters.</li> <li>● Leverage data already present in the EHR to reduce redocumentation in the clinical note.</li> <li>● Obtain ongoing stakeholder input about how to effectively implement documentation policy changes using health IT.</li> <li>● Waive documentation requirements as may be necessary for purposes of testing or administering APMs.</li> </ul>
	<p><i>Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements.</i></p>	<ul style="list-style-type: none"> <li>● Partner with clinical stakeholders to promote clinical documentation best practices.</li> <li>● Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models.</li> </ul>
	<p><i>Leverage health IT to standardize data and processes around ordering services or equipment and related prior authorization processes.</i></p>	<ul style="list-style-type: none"> <li>● Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.</li> <li>● Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers and payers.</li> <li>● Incentivize adoption and/or use of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.</li> <li>● Work with clinicians, suppliers, payers and other intermediary entities to support pilots for standardized electronic ordering of services/items.</li> <li>● Coordinate efforts to advance new standards approaches supporting prior authorization.</li> </ul>





	STRATEGIES	RECOMMENDATIONS
<p><b>Health IT Usability and the User Experience</b></p>	<p><i>Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation.</i></p>	<ul style="list-style-type: none"> <li>● Better align EHR system design with real-world clinical workflow.</li> <li>● Improve clinical decision support usability.</li> <li>● Improve clinical documentation functionality.</li> <li>● Improve presentation of clinical data within EHRs.</li> </ul>
	<p><i>Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.</i></p>	<ul style="list-style-type: none"> <li>● Harmonize user actions for basic clinical operations across EHRs.</li> <li>● Promote and improve user interface design frameworks specific to health care delivery.</li> <li>● Improve internal consistency within health IT products.</li> <li>● Promote proper integration of the physical environment with EHR use.</li> </ul>
	<p><i>Promote harmonization surrounding clinical content contained in health IT to reduce burden.</i></p>	<ul style="list-style-type: none"> <li>● Standardize medication information within health IT.</li> <li>● Standardize order entry content within health IT.</li> <li>● Promote best practice and user interface design frameworks for results display within health IT.</li> </ul>
	<p><i>Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.</i></p>	<ul style="list-style-type: none"> <li>● Increase end user engagement and training.</li> <li>● Promote understanding of budget requirements for success.</li> <li>● Optimize system log-on for end users to reduce burden.</li> <li>● Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.</li> </ul>





STRATEGIES	RECOMMENDATIONS
<p><b>EHR Reporting</b></p> <p><i>Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.</i></p>	<ul style="list-style-type: none"> <li>● Simplify the scoring model for the Promoting Interoperability performance category and Medicare Promoting Interoperability Program.</li> <li>● Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.</li> <li>● Reduce burden of health IT measurement by continuing to improve current health IT measures and developing new health IT measures that focus on interoperability, relevance of measure to clinical practice and patient improvement, and electronic data collection that aligns with clinical workflow.</li> <li>● To the extent permitted by law, continue to provide states with federal Medicaid funding for health IT systems and to promote interoperability among Medicaid health care providers.</li> <li>● Revise program feedback reports to better support clinician needs and improve care.</li> </ul>
<p><i>Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.</i></p>	<ul style="list-style-type: none"> <li>● Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting.</li> <li>● Adopt additional data standards that make access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals.</li> <li>● Implement a secure standards-based API approach to HHS electronic administrative systems to promote integration with existing health IT products.</li> </ul>
<p><i>Improve the value and usability of electronic clinical quality measures while decreasing health care provider burden.</i></p>	<ul style="list-style-type: none"> <li>● Consider the feasibility of adopting a first-year test reporting approach for the newly developed electronic clinical quality measures.</li> <li>● Continue to evaluate the current landscape and future directions of electronic quality measurement and provide a roadmap toward increased electronic reporting through the eCQM Strategy Project.</li> <li>● Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.</li> </ul>





STRATEGIES	RECOMMENDATIONS
<p><b>Public Health Reporting</b></p> <p><i>Increase provider PDMP query for the retrieval of medication history from a state PDMP. Improve health care provider workflow for conducting the query by integrating the PDMP with health IT.</i></p> <p><i>HHS should increase adoption of EPCS with consideration for provider-specific preferences, workflow, and use of available standards.</i></p>	<ul style="list-style-type: none"> <li>Federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and applicable laws including the HIPAA Rules.**</li> <li>Promote standards-based API emerging technologies to support improved access to and use of opioid prescription histories for Opioid Use Disorder (OUD) prevention and treatment.</li> <li>HHS should increase adoption of electronic prescribing of controlled substances with consideration for provider-specific preferences, workflow, and use of available standards.</li> </ul>
	<p><i>Develop a process to address the issue of inconsistent data collection by federal, state, and local programs.**</i></p> <ul style="list-style-type: none"> <li>HHS should convene key stakeholders, including state and local public health departments and community health centers, to inventory reporting requirements from federally funded public health programs.**</li> <li>HHS should continue to work to harmonize reporting requirements across federally funded programs.</li> </ul>
	<p><i>HHS should expand upon existing guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorders (SUDs) health information in order to better facilitate electronic exchange of health information for patient care.</i></p> <ul style="list-style-type: none"> <li>HHS should continue to work to harmonize reporting requirements across federally funded programs.</li> <li>HHS should expand upon existing guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorder health information in order to better facilitate electronic exchange of health information for patient care.</li> </ul>

\*\* = Strategy or recommendation shortened from report





# Issues and Challenges

## CLINICAL DOCUMENTATION

Documentation is primarily for the purpose and use of clinicians providing care, but it can also provide patients with a narrative which increases their understanding of their overall health. In addition to documenting information for clinical care, health care providers must complete a range of documentation tasks to satisfy administrative and billing-specific requirements. The EHR could enable a clinician experience that decouples documentation required for the clinical care of the patient from documentation required for administrative purposes, seamlessly extracting information captured in the process of care delivery, and utilizing that information for other tasks as needed. In practice, however, these systems and the way clinicians interact with them to complete documentation tasks often add to administrative burden.

Many existing documentation requirements were crafted with paper-based systems and acute or chronic single-system medical problems in mind. They have not been updated to account for the current integration of health IT systems, increased complexity of patients and treatment options, and the increased need for longitudinal, coordinated care. At the same time, health IT solutions have not adequately addressed a range of administrative processes health care providers face—for example, prior authorization processes, where effective electronic automation could significantly reduce physician and organizational burden. This misalignment between administrative health care processes and the health IT tools clinicians have at their disposal adds to overall frustration with the increasing amount of time health care providers must devote to paperwork, at the expense of time and resources that could be better directed to patient care.

ONC, in partnership with CMS, met with a diverse group of stakeholders including clinical professional societies and individual practitioners to establish strategies, recommendations, and goals for the reduction of burden related to clinical documentation. This section identifies EHR-related burden associated with clinical documentation to fulfill administrative requirements, as well as documentation for prior authorization of medications, items, and services.

While many of these administrative processes are important for accurate payment and program integrity, targeted reforms to optimize guidance and a move toward more effective health IT-enabled processes could have far reaching effects on the EHR-related burden clinicians experience as part of these tasks.

### Clinical Documentation Required for Physician Visits

Stakeholders have often identified the evaluation and management (E/M) visit documentation guidelines that are used by CMS and other payers as being clinically outdated and a source of EHR-related burden.

Responding to specific stakeholder concerns, CMS has engaged in rulemaking in both the CY 2019 and CY 2020 Medicare Physician Fee Schedule (PFS) final rules to address policy concerns around E/M documentation. HHS believes these policies can help to enable EHRs to support efficient care, while giving physicians more time to spend with their patients, especially those with complex needs, rather than on paperwork.





These significant changes to documentation rules for E/M outpatient and office visits, including changes already in effect and others which will take effect starting in 2021, will simplify, streamline, and offer flexibility in documentation requirements for E/M outpatient and office visits.

Clinicians use a series of CPT codes that distinguish level of complexity, site of care, and the differences between new and established patients in order to bill Medicare and other payers for E/M visits in outpatient, inpatient, and other care settings. Because there are multiple levels of visits and codes (for example, level 1 is the least complex visit and level 5 is the most complex visit for office or outpatient E/M visit codes), clinicians must distinguish and justify the level of complexity of the visit to ensure appropriate payment when billing these codes. Historically, the CPT codes, which are maintained by the American Medical Association, have distinguished the code levels according to how extensive three key components of the service are: history of present illness (or history), physical exam (exam), and medical decision making (MDM).

Clinicians have used three sets of guidelines (one set existing within the American Medical Association CPT codebook, another established in 1995,<sup>9</sup> and another version revised in 1997<sup>10</sup>), to determine how to document information in these three categories and to support reporting of a given code.

Ideally, EHRs should help reduce the burden associated with physician documentation, providing a number of features to help busy clinicians ensure documentation is sufficient and completed efficiently. Structured templates within EHRs help ensure that clinicians are capturing all the information required, and clinicians can easily carry forward, or “copy and paste,” prior entries into the record to save time, especially when the same description of a patient’s history has been previously recorded.

However, stakeholders have noted that using these features has created additional challenges beyond the administrative burden already associated with meeting the E/M visit documentation guidelines. In response to a comment request in the CY 2018 Medicare Physician Fee Schedule proposed rule,<sup>11</sup> stakeholders noted that EHRs have complicated E/M code selection at the same time that they have “amplified” flaws in the existing E/M guidelines.<sup>12</sup> Driven by the need to quickly complete documentation, concerns about audit risk, or the need to justify a specific coding level, clinicians frequently use the EHR to enter excessive or overly detailed documentation such as irrelevant details about patient history, unaffected systems, or unrelated physical exam elements. This clutters the EHR for any particular patient and makes it difficult to find pertinent information in the EHR.

Furthermore, time spent complying with these documentation requirements means clinicians are often unable to finish all required clinical documentation during clinic hours. Clinicians indicate that this cuts into personal and family time, increasing clinician frustration and, ultimately, physician burnout, which has been noted as a growing problem. CMS has heard from many clinicians that copying and pasting contributes to meaningless data accumulation within the medical record and in some cases presents program integrity issues.

The result of this excessive documentation, sometimes referred to as “note bloat,” can contribute to an unwieldy patient record that may satisfy billing requirements, but is clinically outdated and fails to convey effectively the most relevant patient information and to document evidence-based decisions related to actual patient care—the very information that is critical to improving health care quality and outcomes. As the American College of Physicians has noted, this practice increases burden on downstream clinicians,





who must take the time to sift through “long, verbose, repetitive, and difficult-to-read notes” to glean information needed to inform clinical decision-making.<sup>13</sup>

Historically, EHRs have largely based documentation templates around the 1995 and 1997 E/M documentation guidelines. This adherence to a paper-based, clinically outdated documentation paradigm has helped to ensure billing requirements are met, but unfortunately limits the EHR’s potential to improve documentation efficiency through innovative software design. The templates are also often centered on face-to-face visits for acute or chronic problems, instead of being designed to account for other kinds of care management and integration services that are increasingly critical and have been recognized as discrete services in recent years.

Another source of burden and frustration related to the electronic documentation tools found in EHRs is the problem of over-standardization. In many cases, a “one size fits all” suite of documentation tools and templates is rolled out to clinical staff. In a larger institutional setting, the clinical staff, made up of a variety of medical specialties and sub-specialties, often run into problems trying to adapt these documentation workflows and templates to their unique clinical workflows. Smaller practices often struggle with a similar issue when a particular workflow that the practice normally follows must be adapted to fit existing over-standardized product functionality. For example, some practices cited this as a roadblock in trying to provide chronic care management services.<sup>14</sup> Poor usability features within EHRs can further exacerbate this issue of documentation over-standardization, as clinicians find it difficult to navigate long records within the EHR interface. As discussed in the “Health IT Usability and the User Experience” section of this report, EHR design improvements can play an important role in reducing EHR-related burden associated with documentation requirements.

The recent regulatory changes pursued by CMS will create opportunities to revisit sub-optimal EHR design features related to the previous guidelines. In the CY 2019 Medicare Physician Fee Schedule (PFS) final rule, CMS finalized a number of documentation, coding, and payment changes to reduce administrative burden and improve payment accuracy for office/outpatient E/M visits over several years.<sup>15</sup> For CYs 2019 and 2020, CMS implemented several documentation policies to provide immediate burden reduction. These included:

- Removal of potentially duplicative requirements for notations in medical records that may have been previously included in the medical record by residents or other members of the medical team for E/M visits furnished by teaching physicians;
- Expansion/clarification of current policy for history and exam, such that certain data already present in the medical record need not be re-documented but rather can be reviewed, updated, and signed off on by the billing practitioner; and
- Elimination of the need to document the medical necessity of a home visit in lieu of an office visit.

In the CY 2019 final rule, CMS also finalized a series of additional payment, coding, and documentation changes for payment for implementation beginning in the 2021 calendar year. CMS sought to engage in further discussions with the public to refine further the policies for CY 2021. Subsequently, the AMA established the Joint CPT/RUC Workgroup on E/M to develop an alternative approach to key policies in the rule and the workgroup’s recommendations were subsequently adopted by the CPT Editorial panel.







In the CY 2020 PFS Final Rule, CMS adopted changes made to E/M coding by the AMA CPT Editorial Panel for office/outpatient E/M visits beginning for CY 2021. The CPT coding changes retain 5 levels of coding for established patients, reduce the number of levels to 4 for office/outpatient E/M visits for new patients, and revise the code definitions. The CPT coding changes include performance of history and exam with E/M services only as medically appropriate, and allow clinicians to choose the E/M visit level based on either medical decision making or time.

CMS also adopted the AMA RUC-recommended values for the office/outpatient E/M visit codes for CY 2021 and a new add-on CPT code for prolonged service time. The AMA RUC-recommended values will increase payment for office/outpatient E/M visits. The RUC recommendations reflect a robust survey approach by the AMA, including surveying more than 50 specialty types, and demonstrating that office/outpatient E/M visits are generally more complex and require additional resources for most clinicians.

CMS also simplified, consolidated and revalued the add-on codes and payment amounts for office/outpatient E/M visits for primary care and non-procedural specialty care that it finalized in the CY 2019 PFS final rule. CMS adopted a single add-on code describing the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition. This will also be implemented in CY 2021.

CMS believes these policies will allow practitioners greater flexibility to exercise clinical judgment in documentation, so they can focus on documenting what is clinically relevant and medically necessary for the beneficiary. These and other changes in the CY 2020 PFS rule build on the CY 2019 policies by paying clinicians for the time they spend treating the growing number of patients with greater needs and multiple medical conditions, through increasing the value of E/M codes for office/outpatient visits and providing enhanced payments for certain types of visits. CMS is investing in the critical thinking required to evaluate a patient, which will help improve outcomes. This is especially important to clinicians that spend significant time managing patients with multiple co-morbidities, such as diabetes and heart disease.

In addition to documentation requirements associated with routine E/M care, payers may have additional unique documentation requirements associated with other visit types which must be implemented within the EHR. Non-ambulatory care settings (such as inpatient care) require documentation of other parameters, such as patient status or admission orders, to support payment. Finally, private payers also have varying documentation requirements associated with payment and clinical processes that add complexity to documentation burden, such as patient care plan documentation requirements.

### **Documentation for Prior Authorization of Medications, Items, and Services**

Prior authorization or preauthorization generally refers to rules imposed 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. Medicare and other payers have programs under which providers and suppliers complete or include clinical documentation when ordering a range of services and items provided to beneficiaries that require prior authorization, from durable medical equipment to repetitive, scheduled non-emergent ambulance transports. In addition to gathering detailed clinical information necessary to support payment for the





ordered item or service, documentation may need to be exchanged with other health care providers and suppliers involved in delivering items and services to the beneficiary.

Stakeholders have identified the documentation requirements associated with completing prior authorization requests for payers as increasingly burdensome. In a 2018 survey of 1,000 practicing physicians, respondents reported per-physician average of 31 prior authorization requests completed each week, consuming an average of 15 hours of practice time.<sup>16</sup> Each payer has different requirements and different submission methods, and clinicians report finding it burdensome and time-consuming trying to determine whether prior authorization requirements exist for a given patient, diagnosis, insurance plan, or state. Medicare Advantage plans and Prescription Drug Plans, Medicaid managed care plans, and private health insurance plans may have different prior authorization requirements than Fee-For-Service Medicare, which has implemented or piloted prior authorization programs for a number of items and services in recent years, including certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), and repetitive scheduled, non-emergent ambulance transports.

This administrative burden is exacerbated by a lack of standardization and effective technology solutions to automate these processes. Clinicians continue to rely on cumbersome processes to complete prior authorization requirements, including payer-specific web-based portals, facsimile exchange (fax), and telephone-based processes, which divert valuable time and resources away from direct patient care. Stakeholders have also raised concerns that these processes can interrupt or delay necessary treatment and can inadvertently lead to negative patient outcomes. A wide group of clinical stakeholders have identified this lack of automation as a key contributor to the burden associated with prior authorization, arguing that these processes should be standardized and made electronic throughout the industry to promote conformity and reduce administrative burdens.<sup>17</sup> At the same time, stakeholders have noted that process improvements must be complemented by efforts to reduce the overall volume of required prior authorization transactions, for instance, through more targeted application of these requirements.

Better standardization of prior authorization processes and use of health IT to support more streamlined workflows around these processes has been difficult to achieve thus far. Payers and health IT developers have generally addressed prior authorization in an *ad hoc* manner, implementing unique interfaces to facilitate documentation and sharing of information that reflect their own technology considerations, lines of business, and customer-specific constraints. Utilizing these unique interfaces (for direct data entry) is time consuming for clinicians and often disruptive to their workflows. Varying state and local regulatory requirements can also impact how prior authorization is deployed. This environment has contributed to clinicians not being able to access accurate, patient-specific, up-to-date coverage and formulary information that includes prior authorization and step therapy requirements in EHR systems at the point-of-care.

As part of listening sessions focused on the reduction of clinician burden, CMS and ONC have heard repeated suggestions that payers publicly disclose, in a searchable electronic format, a payer's requirements (including prior authorization requirements and patient cost-sharing information) for coverage of medical services. Stakeholders have called for more effective payer collaboration to make these requirements transparent to enable potential solutions to reduce burden.

The standards currently exist and must be used by HIPAA covered entities because they were adopted by HHS through the rulemaking process for electronic prior authorization transactions (that is, the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide





Version D, Release 0 (Version D.0) for retail pharmacy and the ASC X12N 278 Healthcare Services Review Request for Review and Response transactions for medical services benefits). EHR developers and payers have the opportunity to widely implement these standards, as there are recent modifications adopted through rulemaking to improve the standards based on industry feedback, including a modification to the requirements for the use of the D.0 standard in January 2020 (85 FR 4236). Further, HHS is currently developing a proposed rule that would adopt standards for health care attachments transactions, which would assist in implementing electronic prior authorization transactions. Recent data from CAQH shows the percentage of fully automated electronic exchanges for prior authorization slightly increased from 12 percent in 2018 to 13 percent in 2019, while the percentage for partially automated exchanges (primarily via payer portals) increased from 36 percent to 54 percent, and the percentage of fully manual exchanges (e.g. phone, mail, fax) decreased from 51 percent to 33 percent.<sup>18</sup> We do not have complete standards and processes for fully automating prior authorization of medical services, which clinicians have indicated leads to increased burden. In addition, though the NCPDP standard has been proposed<sup>19</sup> for Medicare part D, the standard has not been proposed for non-Part D pharmacy transactions.

New standards, such as HL7® Fast Healthcare Interoperability Resources (FHIR®), hold promise in solving many of the current prior authorization workflow challenges. This international standard is finding strong support from EHR developers in solving interoperability problems. Medicare fee-for-service is a member of the Da Vinci project, a private sector initiative led by HL7® which seeks to bring together payers, EHR vendors, and providers to help find ways to reduce provider burden through FHIR-based solutions. The Da Vinci team has identified 17 use cases to date. Four Da Vinci use cases involve prior authorization either directly or indirectly:

- “Coverage Requirement Discovery,” will make prior authorization requirements and other documentation requirements electronically accessible to health care providers at the point-of-care in EHRs and/or practice management systems.
- “Electronic Health Record Exchange,” focuses on making it easier for a provider to send medical records to another provider or to a payer. For example, payers often request medical records from providers during the prior authorization process.
- “Prior Authorization Support,” aims to simplify the actual prior authorization workflow between a provider/supplier and a payer.
- “Documentation Templates and Coverage Rules” specifies how payer rules can be executed in a provider context to ensure that documentation requirements are met.

These use cases can be integrated into clinician workflow through the use of “CDS hooks,” a technology approach through which an EHR application triggers external decision support services, in this case, certain prior authorization tasks, while remaining within the clinician’s EHR.

Medicare fee-for-service has begun developing a Documentation Requirement Lookup Service that will use the FHIR® standard for Coverage Requirement Discovery and Documentation Templates and Coverage Rules. More information on this lookup service can be found at [go.cms.gov/MedicareRequirementsLookup](http://go.cms.gov/MedicareRequirementsLookup).

To support these and other efforts, ONC has established the FHIR® At Scale, or “FAST,” taskforce to help pilot, test, and spread FHIR® solutions nationwide. This workgroup addresses issues that may impact the broad adoption of FHIR-based solutions. This is the first time payers, providers, suppliers, and EHR vendors





have worked side-by-side to address health care delivery problems in a manner that will improve coordination of care and reduce the administrative burden on providers.

New standards are also available to support improved prior authorization processes for medications. As discussed in a recent proposed rulemaking,<sup>20</sup> CMS is seeking to support the use of technology and standards in the Part D e-prescribing program through the proposed adoption of an updated industry standard for that program that is capable of conveying prior authorization transactions electronically in real time. If finalized, the proposed rule would update the Part D e-prescribing program by adopting standards that ensure secure transmissions and expedite prior authorizations.

A variety of other efforts are also important to highlight in addressing current gaps in our approach to prior authorization. For instance, over the past several years, CMS's Center for Program Integrity has published electronic clinical templates and suggested data elements for a number of high priority documentation processes, such as ordering power mobility devices and home health services. By incorporating these templates or data elements into the EHR, health IT vendors can better equip health care providers to complete necessary documentation components for a given task.

Implementation of common data elements and templates supports better data interoperability, so that health care providers and suppliers can electronically share documentation to prepare claims for submission or satisfy prior authorization requirements. HHS has specifically focused on enabling these transactions through the Electronic Medical Documentation Interoperability (EMDI) initiative, which identifies the technical specifications and interoperability standards needed to move administrative documentation between health care provider/supplier systems electronically. This effort is currently working with a number of pilot sites across the country to test exchange of documentation.

In addition to sharing documents between health care providers/suppliers, the transmission of clinical documentation required for audit compliance also imposes burden on clinicians/suppliers as this transmission often takes place via fax or mail.

Another HHS initiative, Electronic Submission of Medical Documentation (esMD), has allowed an increasing number of clinicians/suppliers to respond to documentation requests from CMS review contractors by submitting records electronically. Most recently, HHS has enhanced the esMD system with the capability to send these documentation requests electronically on behalf of clinicians/suppliers, and also to receive medical records generated according to common standards for EHRs. Allowing health care providers and suppliers to submit requested records directly from their own systems promises to further reduce the burden associated with these processes.

Finally, stakeholders have identified a number of new technology solutions that may hold promise for reducing EHR-related burden, such as artificial intelligence approaches and natural language processing.

## **HEALTH IT USABILITY AND THE USER EXPERIENCE**

As EHR adoption has increased in health care settings, so too have concerns about the user experience.<sup>21</sup>The user experience is often closely related to the usability of a health IT product. Poor usability can be a significant contributor to clinician burden. Usability, however, is not the only driver of clinician burden. As shown in other sections of this report, many other factors contribute to burden, including





regulatory and payment related factors, such as documentation requirements. A highly usable product can still be burdensome if the administrative requirements associated with its use are severe. Likewise, a health IT product with poor usability can render even minimal administrative requirements burdensome.

Before delving into the connection between usability and clinician burden, it is important to define two key concepts: usability and user-centered design. The National Institute of Standards and Technology (NIST) defines usability as “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.”<sup>22</sup> In short, usability is concerned with how well users can learn and use a product to achieve their goals. User-centered design deals more with the design of the actual product. Usability.gov defines user-centered design as “Design based upon an explicit understanding of users, tasks, and environments that is driven and refined by user-centered evaluation and addresses the whole user experience.”<sup>23</sup> The principles underlying usability and user-centered design can guide the development of health IT to more effectively match the product to the clinical task at hand. When done well, it can reduce clinician burden and increase efficiency. Perhaps more importantly, it can help to improve patient safety,<sup>24</sup> as more research is starting to show.<sup>25</sup>

As part of the effort to reduce clinician burden by increasing usability, certain 2015 Edition certification criteria require the application of safety-enhanced design.<sup>26</sup> Those criteria require that developers employ user-centered design principles and perform usability testing on certain functionalities of the software, including clinician order entry, problem list functionality, electronic prescribing, and other user tasks. The developer is required to submit a description of the usability testing method and results during the certification process. Currently, ONC certification criteria do not specify which usability principles must be employed in the design of health IT products, only that an approach must be selected and employed, and a report must be generated describing the testing and its outcomes.

ONC also works closely with other federal agencies, including the Agency for Healthcare Research and Quality (AHRQ) and NIST, on matters concerning health IT usability. Among other projects, AHRQ maintains a health IT portfolio<sup>27</sup> focused on funding research that will improve the safety and quality of health IT. NIST has a long history of collaboration with ONC in the health IT space and works toward improving standards and interoperability. NIST has produced multiple usability-related resources.<sup>28</sup> ONC also monitors multiple private sector collaboratives (the Electronic Health Records Association Clinician Experience Workgroup,<sup>29</sup> The Pew Charitable Trusts Health Information Technology Project,<sup>30</sup> the ECRI Institute Partnership for Health IT Patient Safety,<sup>31</sup> and the Bipartisan Policy Center’s Health Project<sup>32</sup>) focused on improving health IT and usability to keep up with developments in the field. In 2016, ONC released its *Report on the Safe Use of Pick Lists in Ambulatory Care Settings*,<sup>33</sup> which focused on improving medication safety in the outpatient setting through a number of methods, including optimizing the usability of medication ordering functionality. ONC updated its *SAFER Guides*<sup>34</sup> in 2016, which are a set of nine interactive guides that organizations can use to optimize the safety and safe use of their EHRs. In 2018, ONC released its *Usability Change Package*<sup>35</sup> — a resource for small- to medium-sized health care institutions aimed at optimizing the usability of their EHR systems.

Health IT developers are also working on ways to improve usability in their products. The Electronic Health Records Association (EHRA), an industry association comprised of companies that design and market EHRs, recently released *Design Patterns for Patient Safety*,<sup>36</sup> which includes guidance on how to improve the usability of certain EHR workflows, including medications, lab results, handling alerts, and minimizing alert fatigue and screen element design through the use of various text, color, and other design elements.





Despite efforts to improve health IT usability, multiple challenges exist in the pursuit to improve the user experience. These challenges can be grouped into four broad categories that align with the clinical environment. They are: (1) EHR system support for the clinical workflow, (2) design of the screen and integration with the clinical physical environment, (3) standardization of order entry and results display, and (4) design, development, and implementation decisions affecting usability.

### **EHRs and Cognitive Support for Clinical Workflow**

EHRs have evolved into more than just serving as an electronic patient chart; they have become an important tool that can facilitate a myriad of clinical and administrative tasks. In addition to maintaining copies of a patient's clinical documentation, EHRs also serve as an interface to laboratory, imaging, and other diagnostic study results, a correspondence medium serving as a dedicated clinical e-mail system, and, importantly, a powerful tool for initiating clinician orders. As EHRs continue to evolve, it is imperative that they support the workflows that have been established in clinical practice so as not to add to clinician burden. While EHRs have improved some aspects of the clinical workflow—for example, a patient's medical history is now available at a glance and electronic prescribing is widely regarded as a success story—areas for improvement still remain.

In an EHR system, there may be instances where the workflow reflected by a particular EHR does not mirror the clinical environment.<sup>37</sup> In these instances, end users are often forced to alter their clinical workflows to align with an EHR system's workflow. This can lead to frustration and increased burden, and sometimes results in less efficient clinical care. Another area where EHRs may fail to match the clinical workflow is when EHRs lack functionalities needed to support specialized clinical workflows. In some clinical sub-specialties, users develop workarounds to meet their needs.<sup>38</sup> This is often the case when an EHR is purchased and implemented as a "one size fits all" solution for a variety of clinical specialties that have differing, and, often, specialized workflows. In some cases, a health care institution decides to customize an EHR to try to better fit its workflow needs. Customization may alleviate some workflow issues for an institution, but can also inadvertently create other usability and efficiency issues as the software has been modified from the original version designed by the developer.<sup>39</sup> Customization is often expensive, and can be a large financial burden for smaller practices.

EHRs are also used to aid clinical decision making for both clinicians and patients using CDS tools. A common example of a CDS component is the medication-allergy interaction warning. When a prescriber electronically orders a medication to which a patient has a listed allergy, a pop-up window will appear warning the user about the allergy and suggesting alternative actions for the prescriber. While in theory EHR alerts can help clinicians deliver higher quality care, in practice clinicians are often inundated with pop-up alerts ranging from very minor interactions to truly critical risks. This can lead to "alert fatigue"—a phenomenon where the user, faced with many lower level alerts, starts to ignore all alerts and thereby misses critical alerts that can impact patient health and safety.<sup>40</sup> Thus, a potentially life-saving tool, when implemented without considering usability, can become an additional source of burden to EHR end users.

Another area contributing to burden is information overload. As EHR adoption has increased, electronic patient records have grown in size due to the vast amounts of information incorporated from a variety of sources. If not properly organized and managed by the EHR system, a clinician may have to spend time searching through large amounts of information for the piece that is needed to perform a clinical task.<sup>41</sup> For example, patients often transition from one care environment to another in the course of their health care. To provide continuity of care, each clinician involved with a patient needs access to that patient's clinical





history. EHR documentation is often transferred electronically from one EHR system to another using a common file format so that different EHR systems can “talk” to each other. A transfer file, known as the Continuity of Care Document (CCD), is typically used to transfer patient information between EHRs.<sup>42</sup> There are multiple types of CCDs. The version that substitutes for what formerly was described as a hospital discharge summary is difficult to recreate digitally. Stakeholders have expressed frustration when they receive all of the EHR content from an inpatient admission versus receiving key findings and observations associated with the hospitalization and recommended plans for future care. Stakeholders have also provided feedback that the resulting discharge CCDs as described can represent voluminous pages of documentation that are both difficult to digest for subsequent EHRs and even more difficult in clinical settings where they are portrayed as pdf documents or printed files. We believe there are opportunities to solve some of these problems. ONC in collaboration with HL7® [administered a prize competition on C-CDA rendering](#), which showcased the modern ways CCDs could be presented to users.

The problem of information overload is exacerbated because often there is no way for the user to easily retrieve information in a context- or user-driven manner from an EHR system. Typically, more of a patient’s information is displayed than is needed in a particular clinical situation, rather than having it tailored to what is needed by the end user at a particular point in time.<sup>43</sup> For example, a respiratory therapist may need to view the patient’s respiratory status and inhaler treatments over the last 48 hours, while an emergency department physician must be able to quickly find a patient’s last imaging study and consult notes from the treating specialist. Locating pieces of information quickly within the massive data store of EHRs can be challenging if the EHR is not designed with the user in mind, increasing the burden on clinicians.

A related aspect of information overload is how information is presented in EHRs from a chronological standpoint. EHRs have been designed largely to support the episodic nature of the encounter-based, fee-for-service payment system, and they often do not provide a comprehensive longitudinal view of a patient’s health history. This makes it difficult for clinicians to get the full picture of a patient’s health history, especially when reviewing information for a new or referred patient. In addition to the large amount of data that resides within a single patient record, clinicians are constantly receiving additional patient data from other health care institutions and from patients themselves, which takes time and effort to review, reconcile, and incorporate into the existing patient record. EHR systems offer varying degrees of support for organizing and reconciling information, but often clinicians must spend time with the EHR after business hours to locate and organize the relevant information, which can be burdensome and frustrating.<sup>44</sup>

Clinical documentation tasks in EHRs present another major challenge to clinician workflow.<sup>45</sup> EHRs are the primary vehicles for clinicians to document what has happened during the course of care. Clinical documentation has traditionally taken the form of a written narrative that includes history, findings, assessment, and a plan of care. EHRs have added features to aid clinician documentation: document templates; “smart” features, such as click buttons that help dynamically generate text; and the incorporation of medications, laboratory results, vital signs, and other clinical information found elsewhere in EHRs. Unfortunately, these features can create documents that read more like completed check lists than comprehensive histories, making it difficult for health care providers to locate the information they need. Similarly, use of copy-and-paste functionality as part of the documentation process can make it easy for physicians to fail to update or correct copied information and continue to propagate outdated or false information.<sup>46</sup>





## Design Decisions: EHR Graphical User Interface and Physical Clinical Environment

The design of a graphical user interface (GUI) can significantly impact the usability of a system for end users.<sup>47</sup> One key challenge for health IT usability is that, regardless of how good an individual EHR's GUI may be, different products are designed with different screen layouts.<sup>48</sup> The variation in GUI design among EHRs, while understandable, is particularly burdensome for clinicians who work at multiple health care institutions using different EHRs. It would be similar to every car manufacturer having different driver controls for each car—not only would the driver have to relearn the mechanics of driving in each vehicle, the potential for error could be fatal. Likewise, the absence of alignment between EHR GUIs raises the burden on end users by increasing their cognitive load (the amount of mental activity imposed on working memory)<sup>49</sup> and potentially risks patient safety. Another challenge with EHR GUI design is that products have been designed typically with user interfaces that support a linear and logic-based thought process, rather than the complex clinical pattern recognition that occurs during the diagnostic and treatment process.

There is a substantial amount of research and literature that can inform best practices of EHR GUI design. Private sector groups and federal institutions such as AHRQ and NIST have created resources detailing best practices in user-centered software design, and in NIST's case, have even made recommendations for health IT in particular.<sup>50</sup> A common complaint of end users regarding the GUI is that there are too many clicks required to achieve a specific goal when using an EHR. A 2013 study from the American Journal of Emergency Medicine found that during a busy ten-hour shift a clinician could make almost 4,000 mouse clicks completing routine clinical workflow tasks.<sup>51</sup> While there are certain scenarios in which multiple confirmation steps are desirable to increase safety (e.g., confirming patient identification prior to ordering a medication), usability of a product could be improved by reducing the number of clicks required to complete a task.

Another design issue involves the integration of EHRs into the clinical physical environment. In an ambulatory clinic, access to EHRs is generally provided through laptop, desktop, or tablet computers. In many cases, the desktop computer is positioned so that the clinician must turn away from the patient to view the screen, resulting in a loss of eye contact. Patients and clinicians have reported that the interruption in eye contact interferes with the therapeutic relationship.<sup>52</sup> There is research indicating design and behavior changes can positively impact the patient's clinical encounter while the clinician uses an EHR,<sup>53</sup> but these practices are not always employed.

## Standardized Order Entry and Results Display

EHRs can also create burden for clinicians when they enter orders for medication, treatment, and diagnostics. Clinical end users who place medical orders are routinely confronted with lengthy drop-down menus that are not standardized and may be difficult to navigate. This is particularly evident when ordering medications.<sup>54</sup> In addition to the frustration inherent in trying to find the correct medication from an extensive drop-down list, medication selection also presents patient safety issues as the names of medications may be similar and only differ by a few letters.<sup>55</sup> Compounding this issue, medications in the United States are typically referred to by both their brand and generic names. The formulation, dosage, and schedule information can also appear differently depending on the EHR system. Each of these issues adds an additional layer of cognitive load on the end user, increasing burden.

Treatment, laboratory test, and diagnostic imaging orders present similar issues. Frequently, ordering clinicians are presented with long lists of possible choices with display values that are very similar and only differ by a few characters.<sup>56</sup> Moreover, the information presented in these lists does not always





appropriately align with the medical product or service requested.<sup>57</sup> This may result in order mistakes, with either the wrong test being carried out or extra communication required between the ordering clinician and laboratory or radiology staff to determine which test was initially intended. Similarly, the display of laboratory test results can also cause confusion.<sup>58</sup> Laboratory results for a patient are typically displayed in a tabular fashion similar to a spreadsheet, with test names displayed as rows and result dates displayed as columns. The actual result value is found in the appropriate cell of the table. Different EHRs, however, lay out the laboratory results table in different configurations, most notably with regards to chronology. Some systems display the oldest results to the left, others display the newest results to the left, and still other systems allow the end user to configure this as an option. Results screens that a user is unfamiliar with can increase the likelihood of error.<sup>59</sup>

There are design features that could reduce burden, increase safety, and help clinicians find the appropriate option more quickly. Features such as screen emphasis, typography, and color choices can make it substantially easier for a user to locate the correct medication or diagnostic order.<sup>60</sup> For example, by writing part of a drug's name in upper case letters to help distinguish look-alike drugs from one another (“tall man lettering”),<sup>61</sup> end users would be able to more quickly identify the appropriate medication, thus reducing health care provider burden. There is currently no certification requirement that health IT designers use a standardized design format.

### Configuration and Implementation of EHR Systems

Decisions that impact the usability of a health IT product do not only take place in the design and development stage.<sup>62</sup> After an institution or office selects a product, the health care organization must incorporate the product into their environment—a series of actions usually referred to as the implementation phase. During implementation, a number of decisions are made by the health care organization, in concert with the health IT developer, regarding configurable options of the health IT product. In larger health care systems, these decisions can be complex and plentiful. Some examples of clinical content implementation decisions include default medication list content, document template structure, and CDS rules. User authentication can also affect usability. During the course of a typical clinical shift, clinicians must log into an EHR system many times, because clinicians are often mobile and work in many spaces throughout a facility in a single shift. There are various authentication technologies available for implementation that could ease this burden, but unfortunately they are not implemented universally. The decisions made during the implementation phase can significantly affect the user experience and have patient safety implications once the system is up and running.<sup>63</sup>

Implementation decisions made concerning integration with other health IT systems affect the degree of system interoperability, the ease of access to outside information by clinical end users, and ultimately the quality of care of the patient. End users consistently report issues achieving interoperability between various systems<sup>64</sup> and find that it is difficult to access information from other clinical sites. At times, this difficulty integrating data from other systems requires data to be entered multiple times. In addition to increasing economic costs through redundant data entry, this lack of true interoperability increases clinician burden and frustration as clinical data existing elsewhere is not easily located or transferred.<sup>65</sup>

Therefore, in terms of improving usability, it is critical that end users be regularly involved in the implementation phase.<sup>66</sup> Prior to implementation, clinical end users can also inform institutional acquisition staff which features will best support clinical workflows. Unfortunately, end users and experts are not always involved at each stage and may only be consulted when the system has been selected and contracts are

underway. Currently, there is a wide variation of clinical end user involvement, with some institutions supporting a very active feedback structure, while others do not devote adequate resources to ensuring ongoing feedback and involvement.

Another issue affecting usability, specific to the implementation phase, occurs when institutional management teams view EHR implementation as a discrete event and cost rather than an ongoing process. In such cases, training of end users is limited to a few days which, unsurprisingly, fails to achieve the desired goal of producing end users who have a high-degree of comfort or proficiency with the new product. Thorough training is a crucial part of a comprehensive strategy to ensure high user satisfaction in EHR systems.<sup>67</sup> Problems attributed to poor usability may actually stem from inadequate or short-term training. System maintenance and integration with other electronic clinical systems also requires adequate resources (e.g. budgetary and technical staff support) to ensure that the EHR system facilitates the best possible user experience.

## EHR REPORTING

Under the EHR Reporting area, HHS focused on evaluating regulatory, administrative, financial, and other burdens for physicians and hospitals related to participation in and use of health IT as part of federal quality reporting, valued-based payment, APMs, and EHR programs. The HITECH Act and MACRA created multiple incentives for physicians, hospitals, and other health care providers to utilize EHRs for reporting data as part of programs that assess quality of care. Through the Quality Payment Program, under both MIPS and Advanced APMs, as well as the Promoting Interoperability Programs, formerly known as the EHR Incentive Programs, physicians and hospitals report electronic data collected through the EHR on both quality and health IT measures. Under these programs, the reporting of this electronic data can result in positive and/or negative payment adjustments for physicians and hospitals depending on both the extent of reporting and individual or organizational achievement on particular measures.

Electronic measurement can be an impactful component for improvement in any health care setting, and EHR reporting is an important part of HHS's evaluation strategy in establishing necessary metrics for organizational care and quality improvement. Physicians, hospitals, and other industry stakeholders have expressed a number of challenges associated with effective participation in programs that utilize health IT through a series of listening sessions, stakeholder engagement meetings, conference settings, and leadership discussions. They are categorized as follows: eCQM infrastructure and implementation, technical challenges, and program requirements.

### eCQMs, Infrastructure, and Implementation

Physicians and hospitals frequently cite significant challenges associated with eCQMs, including issues related to their availability and issues with collection and calculation of the measures. As they are generally the newer of the available CQMs and involve health IT, these issues are increasingly prominent for eCQMs. Inaccuracies in eCQMs can have a direct impact on health care organizations and business models because HHS increasingly continues to shift from more traditional paper-based, chart-abstracted quality measurement to electronic measurement and reporting, and because quality performance is increasingly publicly reported (through websites such as Physician Compare and Hospital Compare) and fee-for-service payment is increasingly tied directly to achievement on quality measurement relative to peers (through programs such as Quality Payment Program).



A number of studies have identified significant variations in the accuracy of eCQM measure calculations,<sup>68</sup> with at least one estimate of between 39 percent and 65 percent of the data required for accurate measure calculation residing in non-standardized electronic fields or outside of the EHR itself.<sup>69</sup> Further, the interfacing of certified health IT products with other certified and non-certified IT products can lead to data mapping issues that prevents standardized data needed for accurate calculation from being populated in the appropriate areas for measurement. Because of these challenges, many organizations are unable to fully automate the collection of eCQM data, which significantly adds to the burden of quality measurement.

The capture of data for eCQMs can have a negative impact on clinical workflow even in instances where measure calculation and data mapping do not present issues. In a 2016 response letter to CMS, the Healthcare Information Management Systems Society (HIMSS) noted the particular burden of collecting and entering additional data specific to quality measures, and urged CMS and ONC to work jointly in developing eCQMs in such a way that data can be collected as part of the normal workflow of health care delivery.<sup>70</sup>

All of the above issues have been cited as concerns, especially for newly developed eCQMs, which often have not been widely tested and present issues with workflow, calculation accuracy, standardization, and data mapping. In a 2016 public comment letter to CMS, the American Medical Informatics Association (AMIA) noted these issues and urged CMS to not only consider workflow implementation as part of new eCQM development, but also to develop more rigorous quality testing and assurance for measures, including test data representing different patient populations and clinical workflows.<sup>71</sup> AMIA also recommended a one-year discretionary period on reporting new measures.

The availability of eCQMs and the lack of a long-term strategy for eCQM adoption and development also present challenges for a number of physicians and hospitals. The eCQMs that are currently available through HHS reporting programs are not universally relevant to all physicians, with many specialties underrepresented or not represented at all. This has resulted in situations with previous reporting programs where physicians are either exempted from quality reporting or report quality measures without value—both of which can significantly disadvantage physicians in comparative programs that impact fee-for-service payment adjustments.

Hospitals frequently struggle with competing requirements in separate programs that necessitate the collection of information both electronically (through the Promoting Interoperability Programs for Hospitals, formerly known as the Hospital EHR Incentive Programs) and through traditional, paper-based chart-abstraction (through the Hospital IQR Program), which adds burden in quality measurement. Because of this, a number of hospitals have urged a faster transition to full electronic reporting. Organizations such as HIMSS have suggested a transparent strategic approach to eCQM development and transition, with the adoption of eCQMs that provide a clear value to patient care and quality improvement for health care providers. CMS worked to better align programs and facilitate less burdensome EHR reporting through policies finalized in the FY 2019 IPPS/LTCH PPS final rule. Specifically, beginning with the reporting period in 2020, CMS removed 8 of the 16 eCQMs in the Promoting Interoperability Program, consistent with CMS' commitment to producing a smaller set of more meaningful measures and in alignment with the Hospital IQR Program.

A number of challenges related to participation in quality and health IT measurement reporting programs are fundamentally technical in nature and are related to infrastructure, timelines, and data accessibility. As





noted above, stakeholders cite the lack of standardization in the current infrastructure as a barrier to system integration.<sup>72</sup> Rapidly shifting certification requirements and short implementation timelines pose particular challenges for the health care industry: frequent updates to certification of health IT, frequent program updates that require new eQMs or significant modification to existing measures, and limited implementation timelines for all certification and programmatic changes. Finally, access to quality and related data within certified health IT itself can present significant challenges for many health care organizations, which can impact program participation and accuracy of the data submitted.

Many stakeholders point to a lack of standardization across electronic infrastructure that has led to a comparatively slow integration of systems. This lack of interoperability impacts not only data exchange between health care providers, but integration of data within shared health IT systems. Health care providers have increasingly turned to third-party vendors, such as registries and data warehouses, to overcome these technical limitations. However, use of these vendors often comes at a financial cost for physicians and hospitals. While there is a robust health IT marketplace, the marketplace is not always self-motivated to move toward a more standardized electronic health landscape with readily available data exchange among multiple systems.<sup>73</sup>

Short eQm implementation timelines also cause issues for physicians and hospitals. Short implementation timelines for the use of new, not widely tested eQMs pose additional financial and operational challenges for health care providers and clinicians.<sup>74</sup> A number of developers and health care providers note that the current approach to certifying measures forces development to adhere to an unsustainable timeline. Within approximately a year of finalization within regulation, health IT measures must be specified, developed within IT products by vendors, and rolled out to new and existing customers, who must then implement the measures as part of their health care workflow. This requires further effort by health care providers and clinicians to perform data mapping, ensure that correct data entry is retained in its intended structured format, and implement workforce training. Implementation of health IT measures can be further complicated by those that add additional product functionality (e.g., secure messaging), which necessitates additional certification by health IT developers, adding to the timeline and the financial cost for health care providers.<sup>75</sup>

As part of the eQm Strategy Project burden reduction recommendations, CMS is working with measure development contracts to increase transparency of testing results and will provide a transparent workspace in which stakeholders can comment on new measures' workflows and testing. Finally, there are significant challenges in accessing, extracting, and integrating data from one or more health IT sources.<sup>76</sup> The widespread use of a large number of vendors, and an absence of standardized elements and transfer protocols, promotes a fragmented system containing many data silos that cannot always effectively exchange data. Additionally, many health care providers report difficulties in retrieving or extracting data from their existing health IT systems, with many health care organizations forced to commission custom data reports or extractions in order to access data necessary for quality and health IT program reporting. These custom solutions only add to the already existing financial and human resource burden of health IT use for health care organizations. While the adoption of proposed API technology standards as part of ONC's *2015 Edition Health IT Certification Criteria* should help alleviate some of these issues, the actual adoption of API technology was not yet prevalent enough at the time of the writing of this report to make a significant impact on data accessibility. In addition, a number of stakeholders expressed concerns about the security of patient information when using API technology for both reporting and providing access to electronic information.





## Program Requirements

Beyond regulatory requirements, eCQMs, and technical issues related to infrastructure and implementation, physicians and hospitals have noted program requirements themselves as being excessively burdensome. Scoring models of individual reporting programs, such as MIPS and the Hospital Promoting Interoperability Program, which can directly impact fee-for-service reimbursement for physicians and hospitals, have been cited for being overly complex and for disincentivizing innovative approaches to health IT use.

In addition, health care providers question the relevance of certain health IT measures and the overall impact of programs to actual quality improvement, especially relative to the investment of financial and human resources required. Authors of a 2016 study in *Health Affairs* analyzed data from a November 2014 Medical Group Management Association (MGMA) survey and found that practices reported spending 15.1 hours per physician per week—or 785.2 staff and physician hours per physician year—tracking measure specifications, developing and implementing data collection processes, entering information into the medical record, and collecting and transmitting data. Though this survey consisted mostly of self-reported data, it amounted to an “average cost of \$40,069 per physician per year, or a combined total of \$15.4 billion annually for general internists, family physicians, cardiologists, and orthopedists in the United States.”<sup>77</sup>

The transition of the Medicare EHR Incentive Program for eligible professionals from a stand-alone program to the Promoting Interoperability performance category, formerly known as the Advancing Care Information performance category within MIPS, gave CMS the opportunity to introduce greater flexibility in how health IT use was measured among clinicians. While that flexibility was welcomed, clinicians cited the complexity of the current MIPS scoring model as one of the barriers to successful use of health IT. Based in part on this reason, CMS finalized the overhaul of the MIPS Promoting Interoperability performance category in the CY 2019 Physician Fee Schedule final rule, and finalized a number of policies to simplify the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) in the FY 2019 IPPS/LTCH PPS final rule.<sup>78</sup>

In the CY 2019 Physician Fee Schedule final rule, CMS finalized proposals to simplify and revise the scoring methodology for this category by eliminating the base, performance, and bonus scores, and by establishing a new scoring methodology focused on clinician performance at the individual measure level. Changes also include a streamlined set of measures focusing on those that are most important to clinicians and patients, thus better aligning with those finalized for hospitals.

Hospitals and hospital organizations, prior to the FY 2019 rulemaking cycle, noted that the scoring methodology under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, formerly known as the Medicare EHR Incentive Program, was burdensome. The program used a pass-fail scoring methodology that did not provide partial credit or reward improvement for health IT usage. The majority of hospitals were able to meet the current health IT and quality measure requirements of the Medicare Promoting Interoperability Programs. However, CMS received feedback from hospitals and hospital associations that, while some measures have helped to drive improvement in quality of care, others are less meaningful and detract from the ability to provide optimal care to patients.

Stakeholders have further suggested, through inquiries and listening sessions, that the requirement to meet all of the health IT measures has been administratively burdensome, particularly those measures that require direct patient action. These stakeholders believe that there is a critical need for interoperability and





have expressed a desire to use certified health IT to further patient outcomes, but believe the current program structure constrains their ability to implement more interoperable environments and deliver quality care. In addition, a small but important minority of hospitals indicated they struggle with both the large number of measures that must be reported and a scoring model that requires participants to either meet all program requirements or be subject to the full penalty provided by statute. Often the hospitals that face the highest hurdles in participation are those that are most resource challenged, such as small and rural hospitals. A more incremental or progressive system would alleviate program participation burden for these hospitals.

A significant number of physicians and hospitals also identified the approach to measuring health IT use as not only limiting, but often without direct value in improving the quality of patient care or lowering health care costs. For example, in a 2017 letter to HHS, the American College of Surgeons stated that “MIPS measures lack meaning for surgeons and surgical patients.”<sup>79</sup> Unfortunately, the current standardized approach to health IT measurement, with all health care providers reporting on the same set of measures within EHR reporting programs, does not adequately incentivize or reward potentially more innovative uses of health IT that could significantly impact patient care and improve overall quality.

In effect, this “one size fits all” approach limits health IT innovation. In a 2015 comment letter, the American Medical Association urged CMS to develop new health IT measures that avoid process-based measurement for more goal-oriented measures that focus on patient outcomes.<sup>80</sup> CMS has finalized a number of programmatic changes to provide greater flexibility in reporting health IT measures, but there is likely an opportunity to consider new approaches to health IT measurement.

Finally, certain groups of clinicians can experience greater challenges in trying to participate in quality measurement and health IT reporting programs. Although smaller physician practices, for example, face financial hardships in implementing health IT and administrative challenges in program participation, they must meet the same program requirements as larger practices. While MIPS currently excludes participation by eligible clinicians below a certain volume threshold, there are still smaller, resource-challenged practices that continue to struggle to meet program requirements.

CMS has been actively working to address the challenges outlined above. Ongoing collaborative efforts with stakeholders and federal partners reflect our commitment to reducing provider burden, improving quality of care, and furthering interoperability. CMS finalized changes to the Promoting Interoperability performance category of MIPS for the Quality Payment Program and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. These changes include working to overhaul the scoring methodology to reduce the complexity of reporting for both programs. In addition, CMS has been working with stakeholders to develop flexibility in the program to allow providers to focus on measures that are meaningful to the care they provide to patients, while identifying areas for improvement.





## PUBLIC HEALTH REPORTING

The sources of EHR-related burden investigated in this area fall under four subcategories: (1) health IT integration and workflow-challenges-related retrieval of medication history from PDMPs; (2) adoption of capabilities around EPCS; (3) a general lack of automated, standards-based public health and health care reporting requirements across federally funded programs; and (4) burden related to difficulties implementing federal policies for SUD patient records, and how to integrate those requirements with the privacy required by the HIPAA Rules and 42 CFR Part 2.

The opioid epidemic highlights the need for the bi-directional exchange of health information to support both public health agencies implementing broad scale initiatives and health care providers seeking to prevent and treat opioid use disorder among patients. For the latter use case, EPCS and PDMPs offer prescribing clinicians tools as part of an automated approach for the prescribing and medication history retrieval process of controlled substances. However, challenges with workflow integration and interoperability between EHRs and PDMPs have limited their effective use in clinical practice. In addition, PDMPs themselves have varied requirements across jurisdictions relating to what data is available, who can access data, how data can be stored, and whether data can be shared across jurisdictions. These challenges with PDMPs are also reflective of the overarching issues identified by health care providers relating to public health reporting as a whole.

Health care providers have identified reporting burden associated with requirements to submit data for numerous state and federal programs, often through systems and processes that are not electronically standardized or harmonized. The majority of public health authorities are at the state or local level, and therefore the vast majority of public health reporting (i.e., sending data from a clinical setting to public health as required by law) happens at the state and local level. Public health reporting programs vary widely across states, both in the categories of health data that are reported and in the requirements established for reporting on a single category of data.

The federal government funds public health programs at the state and local level with the understanding that those programs meet specified reporting criteria, and these requirements may vary across federal programs even where such programs require the reporting of the same or similar types of data. In most cases the federal government receives a subset of the information reported. For instance, HIV public health programs receive funding from several federal agencies, including the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA), each of which imposes different funding reporting requirements on their grantees.<sup>81</sup> States are allowed to determine transport methods and further constrain the standards required by program participation. State and local authorities may also add requirements beyond what is federally required. This may include reporting of infectious diseases only found in specific regions in the country, or reporting of specific diseases based on state or local policy.

### EHRs and PDMPs

PDMP information can be used to avoid inappropriate prescribing, identify drug-seeking behavior, and allow health care providers to intervene when there are signs of prescription drug misuse. When integrated into EHRs, health care providers can quickly access a patient's PDMP report prior to prescribing or dispensing powerful prescription pain medications.<sup>82</sup>





From 2012 to 2016, SAMHSA funded PDMP-EHR integration demonstration projects in nine states.

Evaluating the initiative in 2017, the CDC reported that eight states succeeded in some level of integration and most reported large increases in queries to the system.<sup>83</sup> However, the lack of PDMP integration in EHRs to date has resulted in interruptions to health care provider workflows, as providers must separately check a PDMP prior to issuing a prescription for opiates. The increased number of clicks and account validations required throughout this process imposes several inefficiencies on practice workflows and is particularly challenging for health care providers in emergency and urgent care settings. Technical standards have been developed and balloted to enable better EHR-PDMP integration, but have not been consistently implemented across state PDMPs.

Historically, federal agencies supporting PDMPs had not consistently recommended or required the same standards for EHR-PDMP integration. The Department of Justice has funded state public safety departments to establish PDMPs which historically have used the National Information Exchange Model (NEIM) standard. HHS agencies and state health departments commonly recognize standards developed by NCPDP that also support e-prescribing transactions. There may additionally be separate standards in use for the data transported from pharmacy to a PDMP, which requires translation to then be stored in a PDMP, often in a proprietary standard. Proprietary standards are often commonly used in interstate PDMP transactions.

States also have different rules governing access roles for PDMPs, as well as for the use of PDMP data, which translates to variation in technical architecture and the electronic interfaces that enable integration of the PDMP into EHR systems. This means that EHR vendors need to accommodate more than 50 different PDMPs in onboarding users across states, which is further complicated by the need to implement variations in access controls for different access roles depending on the state. For example, some states may define only a few access roles while others define more than 20. In nearly all cases, PDMP integration allows the health care provider to view PDMP information on a patient but not to integrate that data into the patient's local EHR record. Finally, there are significant challenges with patient matching for PDMPs that are beyond those generally confronted by providers because there may be instances of deliberate misdirection.

HHS appreciates the need to encourage providers to consult PDMPs and to improve the efficacy of PDMPs as one tool in the efforts to address OUD prevention and treatment in the US. Due to continuing federal investments and the passage of the SUPPORT Act in the fall of 2018, new and evolving initiatives to enhance the use and effectiveness of PDMPs and to improve PDMP data integration into health systems and provider workflows are underway.

In an effort to better understand the current state of health IT and PDMP interoperability and integration, as well as identify opportunities for health IT to support improvement, ONC conducted a landscape assessment<sup>84</sup> focused on state-level technical and policy ecosystems from June 2018 to June 2019. This project included analysis of specific states' different policies, technical requirements, and systems implementation for PDMPs. Collectively, these state experiences gave rise to various findings and potential best practices to improve interoperability. These findings focused on topics such as: access to PDMP data by health care professionals; placement of PDMP data within health IT systems; enabling interstate data sharing; inclusion of non-prescription or non-controlled substance information in PDMPs; state-generated PDMP notices to health care professionals concerning patterns of patient behavior; and







reports for improvement of prescribing practices. Collectively, these state-based findings can help inform opportunities for advancing integration and interoperability of PDMP data that in turn can improve provider workflows, as well as reduce the real and perceived burden associated with use of PDMPs at the point of care.

### **Integration Challenges with Electronic Prescribing of Controlled Substances (EPCS)**

EPCS requires two-factor authentication, which can be burdensome for prescribing clinicians to integrate into their workflow. This has slowed adoption of EPCS nationally; today, only 24 percent of prescribing clinicians have EPCS capabilities.<sup>85</sup> While some health IT vendors and health care providers have seamlessly implemented authentication technology into clinician workflows, the incorporation of newer approaches to authentication into workflows still presents challenges.

To inform appropriate prescribing of controlled substances, most states require prescribers to query medication history from PDMPs. In addition, the number of states requiring a query of a PDMP continues to increase from 36 in 2017<sup>86</sup> to 45 states and 1 territory as of August 2019.<sup>87</sup>

State adoption of EPCS is expected to be impacted by the 2018 SUPPORT for Patients and Communities Act (SUPPORT Act), which requires the electronic prescribing of controlled substances for drugs covered by Medicare Part D, effective January 2021.<sup>88</sup>

### **Inconsistent Public Health and Grant Funding Requirements across Federal Agencies**

Clinician participation in legally mandated public health reporting has long been established as necessary to improve and protect the public's health. However, federal mandates to states to implement public health programs have inconsistent data requirements for a number of reasons: 1) the vast majority of these programs pre-date current health IT initiatives and are primarily paper-based reporting on pre-printed forms; 2) federal programs established at different points in time do not use consistent, nationally adopted standards aligned across federal requirements; and 3) these programs were implemented at state and local levels at different points in time with differing authorities and limited resources, resulting in persistent systems siloes at the state and local level, as well as varying requirements across states.

Health IT is an important tool for reducing the burden associated with reporting for these programs, and a number of initiatives have effectively reduced provider reporting burden over time. For example, electronic laboratory reporting (ELR), syndromic surveillance, and immunization registry reporting are submitted to public health through EHRs without provider interaction. This results in timelier and better quality public health reporting. It also includes reporting cases that would be missed using a manual system. However, providers continue to identify areas where further progress is needed in moving from inconsistent paper-based systems to reporting from an EHR using common data elements.

Health care providers note that the widespread variation in public health reporting across federal programs negatively impacts the ability to eliminate paper reports, faxing, and copying data from one system into another. For example, CDC, SAMHSA, FDA, HRSA, and USDA fund state and local public health jurisdictions to collect clinical data from health care providers for funding purposes in addition to numerous separate public health reporting requirements. Most of these systems are registries that collect information about reportable disease/outbreak investigation (e.g., salmonella) or those that are utilized for chronic disease surveillance (e.g., cancer). Many of these reporting requirements overlap with each other and with requirements from the CDC, and much of the data already exists electronically within the EHR. Despite





these overlaps, health care providers are often required to regularly report to a wide range of separate public health registries and systems developed to support these separate federal program or grant requirements.

Many state, local, territorial, or tribal public health agencies lack funding resources for a truly interoperable public health reporting infrastructure to consolidate these systems, despite much of the data being available in an electronic format. Health care providers also state that variation in the transport of electronic information to public health agencies is a source of burden, noting that different transport requirements may be required for different public health options or use cases, even within one public health jurisdiction. This is often the result of siloed funding that cannot be used for shared IT infrastructure such as common interface points. In addition, a lack of funding and low return on investment in some public health agencies has resulted in the ongoing use of transport methods that may be considered outdated.

Meanwhile, health IT vendors and large health care provider organizations report that variation makes it difficult and expensive to implement in different jurisdictions. This is further compounded by variations in requirements established at the state or local level based on unique state or local requirements or varied interpretations of federal requirements as established by each jurisdiction. Greater consistency is needed in how EHR systems approach disparate federal and state reporting requirements. For instance, implementation guides often contain requirements that can be interpreted in multiple ways, such as the PHIN Messaging Guide for Syndromic Surveillance,<sup>89</sup> which contains language about data transmission that is ambiguous and confusing. In addition, consensus around standards across the industry, as well as innovations that mitigate the burden on states to operationalize aligned requirements, are necessary to resolve the reporting burden on providers.

### **Confidentiality of Substance Use Disorder Patient Records**

In addition to the broadly applicable privacy and security protections of the HIPAA Rules, state and federal regulators have established narrower rules pertaining to sensitive categories of health information. Health care providers, especially those that provide coordinated care for their patients, frequently report difficulty navigating certain federal and state health information privacy laws and regulations.

In particular, they report difficulty in determining applicable patient consent requirements for sensitive categories of health information such as substance use disorders (SUDs) records, which are governed by Title 42 of the Code of Federal Regulation (CFR) Part 2: Federal Confidentiality of Substance Use Disorder Patient Records, known as 42 CFR Part 2 or Part 2. The disclosure of SUD patient records has the potential to lead to a host of negative consequences, including: loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration.

Pursuant to 42 USC 290dd-2, Part 2 is intended to protect the confidentiality of SUD patient records and ensure that a patient receiving treatment for a SUD in a Part 2 Program is not made more vulnerable by reason of the availability of their patient record than an individual with a SUD who does not seek treatment. Part 2 protects the confidentiality of SUD patient records by requiring written consent for most disclosures and restricting the circumstances under which Part 2 Programs or other lawful holders may otherwise use or disclose such records absent patient consent or limited exceptions.

Some clinicians have expressed concerns that Part 2 consent requirements are too restrictive, confusing, and challenging to technically implement, and that health care providers and organizations often struggle





to understand which legal requirements apply under which conditions.<sup>90</sup> (It is important to note that other laws and regulations such as the HIPAA Rules and state privacy laws also may apply to SUD patient records). As a result, clinicians may err on the side of caution and not share a patient's SUD information with another provider. In turn, this may limit the integration of a patient's SUD information into EHRs. This may also limit the sharing of important patient information among health care providers and plans, resulting in poor coordination and fragmented care.

Some stakeholders have called for closer alignment of Part 2 with the HIPAA Rules.<sup>91</sup> The HIPAA Rules protect most patient health information and do not apply special requirements to a patient's health information related to SUDs, thus permitting health care providers and health plans to appropriately access and securely share health information for treatment, payment and health care operations purposes without the patient's written consent. Others suggest that some alignment may be appropriate as long as patients retain the power to determine when and to whom their SUD patient record is disclosed. Generally, stakeholders agree that significant burden would be reduced by improving health care providers' understanding of Part 2 and developing tools to facilitate consent and disclosure processes. SAMHSA has proposed<sup>92</sup> broad changes to the Part 2 regulations to remove barriers to coordinated care and permit additional sharing of information among providers and part 2 programs assisting patients with SUDs.

HHS has recognized these implementation challenges and encourages the use of health IT to help clinicians appropriately share sensitive information while complying with legal requirements and respecting patient privacy preferences. For example, technical standards exist for electronically tagging health information to indicate privacy considerations, including legal requirements, within a patient record or summary of care document within the EHR, and SAMHSA supports ONC's Data Segmentation for Privacy initiative<sup>93</sup> to support clinicians' sharing of health information in accordance with patient choices. These tags on data elements, segments, or whole documents can then be used by automated access control solutions to prevent unauthorized access to patient data. In addition, SAMHSA, in collaboration with ONC, has released resources to help clinicians and health information exchange organizations understand how to manage patient consent.<sup>94</sup>

In its 21st Century Cures Act proposed rule, ONC proposed to remove the current 2015 Edition data segmentation for privacy (DS4P) send and receive certification criteria and replace them with three new DS4P criteria (two for C-CDA and one for FHIR®). The Health IT Care Continuum Task Force acknowledged that DS4P would support opioid management and provide greater confidence in sharing OUD information. The task force also recognized that the "consent management for APIs" proposal would aid in furthering the exchange of information. The task force noted that, with appropriate protections in place, health IT can help providers share patient health information while both complying with legal requirements and respecting patient privacy preferences through consent requirements.<sup>95</sup>





# Strategies and Recommendations

## CLINICAL DOCUMENTATION

### [Clin Doc] Strategy 1: Reduce regulatory burden around documentation requirements for patient visits.

[Clin Doc Strat 1] Recommendation 1: Continue to reduce overall regulatory burden around documentation of patient encounters.

Stakeholders frequently identify the documentation guidelines for patient visits as a source of EHR-related burden. Using the EHR to satisfy documentation requirements for E/M visit codes should generate greater efficiencies. Yet, in practice clinicians frequently use documentation templates to create clinical notes in the EHR that record unnecessary information for a patient encounter in order to meet billing requirements at the expense of a coherent record, resulting in what has come to be referred to as “note bloat.” While EHR design and usage practices must continue to address these issues, overall reduction in documentation requirements can simultaneously reduce EHR-related burden. As discussed in the Medicare CY 2019 and CY 2020 Physician Fee Schedule (PFS) final rules, CMS has taken a number of steps to reduce burden associated with physician payments under the PFS including continued work with the AMA/CPT to eliminate clinically outdated aspects of E/M visit documentation. These changes could ultimately result in a significant reduction in EHR-related burden, and HHS recommends coordination with other payers to adopt a similar or coordinated approach.

[Clin Doc Strat 1] Recommendation 2: Leverage data already present in the EHR to reduce re-documentation in the clinical note.

Many EHRs simply translate a paper-based documentation workflow, meeting the 1995 and 1997 E/M documentation guidelines, into an electronic one, while retaining a paper chart design paradigm and clinically outdated aspects of documentation especially regarding history and exam. This limits the ability of the technology to leverage information that may exist elsewhere in the health IT system. As a result, many pieces of information that clinicians enter into their clinical notes already exist in other places in the EHR. As discussed in the CY 2019 Physician Fee Schedule (PFS) final rule, CMS has expanded and clarified current policy for history and exam of office/outpatient E/M visits, such that certain information already present in the medical record need not be re-documented. Rather, it can be reviewed, updated, and signed off on by the billing practitioner.

To fully realize the burden reduction potential of these guidance changes, HHS should work with stakeholders, including providers, payers, and health IT developers, to explore ways that digital information from a wide variety of sources available to the practitioner can be seamlessly accessed and leveraged for documentation purposes—for example, information made available from another provider through the use of a secure standards-based API. In addition, stakeholders should work to ensure that relevant information already captured by other care team members is easily accessible to the clinician in the electronic record





to support documentation needs. As technology tools advance, modern computing resources and design space could allow developers to innovate in new ways to determine visit complexity beyond what is currently present in the clinical note. Advances could also facilitate seamless review and verification processes for existing information while allowing for audit functionality which could reassure payers of review and verification if systems are sufficiently interoperable.

**[Clin Doc Strat 1] Recommendation 3: Obtain ongoing stakeholder input on how to effectively implement documentation policy changes using health IT.**

As part of the effort to reduce documentation burden, HHS, either directly or as part of other stakeholder convening activities, should encourage broad input from key participants (e.g., government, industry, clinicians, payers, EHR developers, standards developers) on critical topics for ensuring that changes in documentation guidance policies are successful. For instance, HHS could work with clinicians and health IT developers to inform how technology solutions take advantage of the burden-reduction potential of these policy changes, as well as how to develop effective measurement strategies to assess whether EHR-related burden is reduced for clinicians over time. Clinical specialty societies could continue to provide input to define proper clinical standards for documentation and establish what is required for high quality patient care. HHS could participate in convening activities along with clinicians and other commercial payers to ensure updated guidance is being consistently implemented across different payer systems that receive encounter documentation. Finally, a broad set of stakeholders should continue to collaborate around factors driving over documentation within the EHR that have not yet been addressed.

**[Clin Doc Strat 1] Recommendation 4: Waive documentation requirements as may be necessary for purposes of testing or administering APMs.**

APMs can provide powerful motivation to deliver care in the most efficient manner possible, while simultaneously imposing additional reporting requirements on health care providers due to the need for data for model evaluation. With these considerations in mind, CMS recently piloted a program to reduce medical review burden for certain APM participants.<sup>96</sup>

CMS should, where feasible, explore further use of this concept by waiving certain documentation requirements in APMs. For instance, the Center for Medicare and Medicaid Innovation (CMMI) recently announced new model approaches focused on primary care.<sup>97</sup> These models test alternative modes of primary care payment that allow closer linkages between payment, outcomes, and the overall cost of an attributed patient population. Clinicians participating in these models, which aim to reduce primary care's focus on visit-based revenue, are especially well-positioned to benefit from reducing the documentation burden related to encounters.

**[Clin Doc] Strategy 2: Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements.**

**[Clin Doc Strat 2] Recommendation 1: Partner with clinical stakeholders to promote clinical documentation best practices.**

Best practices for clinical documentation in EHRs aimed at reducing issues such as “note bloat” are being developed in many settings. Dissemination of best practices and lessons learned, in tandem with new policies to reduce documentation burden associated with E/M guidelines, will help to reduce duplicative



documentation among physicians as well as broader clinical and administrative staff contributing to documentation processes. HHS, in partnership with clinical professional societies, will continue to work to promote an understanding of documentation best practices among members, recognize and potentially endorse best practice industry initiatives,<sup>98</sup> and increase awareness of tools and resources that can support implementation of best practices.

[\[Clin Doc Strat 2\] Recommendation 2: Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models.](#)

CMS should incorporate best practices for reducing documentation burden into technical assistance provided as part of CMS practice transformation initiatives such as the MACRA Technical Assistance (QPP-SURS), Innovation Center model learning and diffusion activities, and Quality Improvement Organizations (QIOs). Learning materials developed for these initiatives should be made public so that states and private sector partners can incorporate them into their own initiatives as well.

### **[Clin Doc] Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.**

[\[Clin Doc Strat 3\] Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.](#)

The prior authorization ecosystem is currently challenging for clinicians, frustrating for patients, and increasingly burdensome. While standardizing electronic transactions is an important avenue for reducing burden, other factors related to how prior authorization is implemented and conducted using technology tools may also contribute to burden. Within the framework established by the HIPAA Rules, HHS could consider ways to engage with stakeholders to further address these challenges, including but not limited to discussion of: (1) developing and disseminating best practices for optimizing electronic workflows around prior authorization; (2) health IT-enabled processes that leverage existing data to reduce the total volume of prior authorization requests that clinicians must submit; and (3) other rules and regulations that might impede implementation of optimal workflows. These efforts should also consider how the use of prior authorization within the EHR workflow is required for medications and medical services and items, as well as the clinical and coverage guidelines used by payers during the review of a prior authorization request, and how improved integration can help to reduce provider burden.

[\[Clin Doc Strat 3\] Recommendation 2: Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, and payers.](#)

Completing the clinical documentation required for justifying medical necessity when ordering certain items and services and/or obtaining prior authorization for items and services imposes significant burdens on clinicians and other staff. While health IT solutions can help to automate these processes, they remain underutilized, in part due to lack of an adopted health care standard for claims attachments. HHS should continue to partner with the clinicians, payers, medical product manufacturers, and health IT developers to expand existing work on ordering services and prior authorization processes. Development of tools such as standardized templates should be created with user-centered design principles that ensure templates can be easily integrated into clinician workflow. Such tools should be developed simultaneously with



exploration of more advanced solutions, such as the API-based transactions being explored by HL7's Da Vinci project.

[Clin Doc Strat 3] Recommendation 3: Incentivize adoption and/or use of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.

HHS should consider providing incentives or access to streamlined auditing and transmission processes in cases where provider use of specified health IT solutions could relieve health care provider burden and provide standardized documentation.

[Clin Doc Strat 3] Recommendation 4: Work with clinicians, suppliers, payers, and other intermediary entities to support pilots for standardized electronic ordering of services/items.

Maturing templates and sets of common clinical data elements for prior authorization and driving wider adoption across clinicians, suppliers, health IT developers, the medical product industry, regulatory agencies, and payers will require a robust piloting effort across different stakeholders. HHS should actively engage with efforts to pilot these functionalities with other payers, health IT developers, and third-party exchange organizations to accelerate adoption. For instance, HHS could facilitate participation in pilots by participants in CMS APMs focused on increasing efficiency.

[Clin Doc Strat 3] Recommendation 5: Coordinate efforts to advance new standard approaches supporting prior authorization.

HHS should continue to pursue standards that aim to improve the prior-authorization ecosystem through multi-stakeholder groups (e.g., clinicians, suppliers, health care information technology vendors, and payers), such as but not limited to the Da Vinci project and FAST Task Force. HHS can help build awareness for these efforts and promote complementary activities. Once new standards are mature, HHS should pursue consensus through the National Committee on Vital and Health Statistics (NCVHS) in order to adopt standards that support multi-payer, real-time, prior authorization and reduce provider burden.





## HEALTH IT USABILITY AND THE USER EXPERIENCE

### [HIT Usability] Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation.

#### [HIT Usability Strat 1] Recommendation 1: Better align EHR system design with real-world clinical workflow.

A disconnect exists between real-world clinical workflows and the design of health IT systems.<sup>99</sup> Clinicians and other health care providers must modify their preferred clinical workflow often to satisfy the electronic workflow of the health IT system. Health IT developers can take the lead by working with practicing clinicians, nurses, laboratorians, administrators, and professional organizations, who can advise developers as they make decisions and prioritize interactive display features during the development stage that will help streamline workflow. Experts in user-centered design (sometimes referred to as human factor engineering, or HFE) and in human-computer interaction should also be consulted during development, since they understand the processes and challenges of creating usable products, can help developers better support the clinical workflow, and reduce load on the end user—such as, for example, reduction of required clicks to complete necessary actions. Part of alignment with the clinical workflow is flexibility for an end user to personalize their individual electronic workflow. Achieving a balance between standardization and personalization is important,<sup>100</sup> and developers can use information about their customers' usage patterns to develop workflows that support such flexibility while maintaining design principles rooted in usability and best practices for patient safety. Clinical organizations can help to improve workflow alignment by interfacing regularly with health IT developers to ensure real-world workflow requirements are present in products that will be acquired. Individual clinicians can also contribute by providing feedback to their institution's IT staff and/or the developer when clinical workflow needs are not being met by the EHR system. Integration of patient-based data collection into the clinical workflow could help reduce burden by reducing the amount of information required by the physician or supporting staff.

#### [HIT Usability Strat 1] Recommendation 2: Improve clinical decision support usability.

The sheer volume and complexity of scientific knowledge is greater than ever before, and constantly expanding.<sup>101</sup> Tools are essential to help the health care team navigate this knowledge. The appropriate application of data standards and applications that associate critical clinical information data elements is essential to providing high-quality health care. CDS primarily takes the form of alert windows notifying clinicians of drug-drug interactions, drug-allergy interactions, dosing ranges, and other warnings. Pop-up alert functionality should be improved to prioritize critical information and minimize alert fatigue. There is a tremendous opportunity for CDS to be improved and augmented beyond alerts to include automation and predictive care suggestions to help make decisions at the point of care. This opportunity includes CDS for both clinicians and patients. To reach these goals, a robust CDS framework must be implemented and more research is needed in the use of advanced capabilities including machine learning. The National Academy of Medicine has published *Optimizing Strategies for Clinical Decision Support*,<sup>102</sup> describing what this framework should include: the development and adoption of technical standards; tools to measure efficacy of CDS; collaboration surrounding a common repository for CDS tools; a legal framework for CDS; and research into the safety, quality, productivity, and outcomes of successful CDS implementation that will help drive the business case for future CDS adoption. In addition, the AHRQ CDS Connect project aims to inform the development and promulgation of best practices for technical CDS development so that







evidence-based care can be more rapidly incorporated into clinical practice through interoperable decision support. Specifically, CDS Connect recommends project evaluation inform the translation of clinical guidelines into computable content for interoperable CDS that are shareable, standards-based, and patient-centered.<sup>103</sup>

#### [HIT Usability Strat 1] Recommendation 3: Improve clinical documentation functionality.

Current documentation tools in EHRs primarily take the form of free text entry, template completion, and “smart document” creation through the use of buttons and structured data fields. Less burdensome methods are needed to capture the structured and unstructured data inherent in a patient’s medical story. Speech recognition in clinical care documentation holds promise, but has not yet achieved widespread adoption.<sup>104</sup> Health IT developers (and speech recognition developers) can consider collaborative partnerships with large health care institutions to improve their speech recognition capabilities through machine learning as well as implementing other advanced technologies. Guidelines regarding copy-and-paste functionality should be put in place at an institutional level for the management of copied text that balances efficiency with safety. The private sector has led the way with best practices for copy and paste functionality.<sup>105</sup> Lastly, the use of EHR logging functionality can help identify the time clinicians are spending interacting with the EHR.<sup>106</sup> These tools can shed light on EHR workflows that can be further optimized to reduce documentation time, reuse existing documentation, and decrease burden.

#### [HIT Usability Strat 1] Recommendation 4: Improve presentation of clinical data within EHRs.

EHRs contain vast quantities of clinical data and are capable of sending and receiving incredible amounts of patient information with a keystroke. This can present a challenge for the end user trying to locate one critical piece of information; a needle in the proverbial haystack.<sup>107</sup> Various modes of information storage also complicate finding desired data—some information is stored as structured data, while other data are contained in scanned images files. Health IT developers can help to reduce cognitive load on the end user by working to optimize and improve information display and by developing open-source health care-specific front-end frameworks and user interface libraries that can be leveraged by all EHRs. Then the end user is presented with a manageable amount of data and successfully guided to needed information in a consistent, context-driven, and context-dependent manner. This will support effective interaction with the EHR interface to find necessary data in the busy clinical environment where interruptions are common.

Data contained in documents such as scanned reports should be automatically extracted and indexed by EHRs for better retrieval. Health IT developers can further help clinicians’ use of EHR by making it easy to use external applications, or “apps,” that have been optimized for targeted capability and may be best suited for the workflow. Lastly, health IT developers may want to explore ways to facilitate presenting a patient’s data in a longitudinal manner.<sup>108</sup> From both a patient-level and a population-health-level perspective, as time advances and more of the clinical data from a patient’s life is captured in an EHR, it will be important to be able to visualize that patient’s health status across his or her lifespan in a longitudinal manner.





## **[HIT Usability] Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.**

### **[HIT Usability Strat 2] Recommendation 1: Harmonize user actions for basic clinical operations across EHRs.**

Clinicians often serve at different clinical locations and need to become proficient in the use of multiple EHRs. EHRs currently have widely divergent GUIs and workflow steps required to complete clinical tasks. Consistent with antitrust requirements, while ensuring overall market competitiveness, health IT developers should have the opportunity to discuss and jointly arrive at a shared understanding of interface and design elements for common clinical tasks, beginning with those workflows that directly impact patient safety.<sup>109</sup> Identifying ways to harmonize design elements for these common workflows could significantly reduce the cognitive load on the end user by reducing the need to remember a series of divergent workflows for the same basic task. Examples of functionalities that health IT developers could standardize might include, but are not limited to medication reconciliation; medication, laboratory and imaging ordering; results review; problem list interaction; medical history interaction; and clinical documentation authoring and review. Similarly, harmonizing laboratory test codes could support better mapping across systems, better presentation of laboratory information, and better laboratory order entry as part of the clinical workflow. The Electronic Health Records Association's (EHRA) *Design Patterns for Patient Safety*<sup>110</sup> is a good example of this type of developer collaboration. Clinicians and clinical professional societies have the opportunity to collaborate with health IT developers to best inform how to potentially harmonize these across health IT systems.

### **[HIT Usability Strat 2] Recommendation 2: Promote and improve user interface design frameworks specific to health care delivery.**

There is currently variable adherence to usability best practices among EHR products.<sup>111</sup> This creates greater difficulty for end users to perform common workflow tasks and may increase clinician frustration. Resources exist, such as the NIST health IT usability resources. Developers can review and utilize these resources, and in the future can take the lead by formulating health IT specific user interface (UI) best practices and contributing to the development of open-source front-end frameworks and UI software libraries that provide UI consistency while still enabling EHRs to compete with each other. Steps in this new direction should include a focus on UIs to support the clinician's cognitive thought process in terms of complex pattern recognition, as well as the creation of health care-specific UI components designed to support the clinical workflows found in health care. EHR developers can then work together to identify and select from these resources to create a shared repository of EHR usability practices and UI components. In addition to incorporating these best practices, EHR developers can augment their internal usability design and testing programs with larger teams, additional human factors experts, and expanded open-ended testing that focuses on clinical usability. The results of these developer efforts should be highlighted on the ONC Certified Health IT Product List,<sup>112</sup> where prospective EHR customers can view an EHR product's Safety Enhanced Design report. This report includes a description of the user-centered-design process, health care specific front-end frameworks used in products and best practices used in testing; a description of the participants in the testing process including their education, roles, and experience; and the testing results. Potential EHR customers can see the efforts that went into the products they are considering acquiring. Finally, developers have the opportunity to improve the usability of interfaces used for capturing data for reporting requirements.





A shift from check-box interface elements to intelligent features that extract needed data from routine clinical workflows would provide a substantial reduction in usability-related clinician burden.<sup>113</sup>

#### [HIT Usability Strat 2] Recommendation 3: Improve internal consistency within health IT products.

Software can often contain modules written by different software engineering teams or can be the result of acquisitions in which the functionality of one piece of software is incorporated into a larger product. In some cases, this yields a degree of UI design inconsistency within a single product. This can create yet another cognitive load on the end user, who must learn slightly different navigation steps while working in different portions of the software. Software developers can review their suite of software solutions to ensure that all aspects of the system share a common user interface or are developed using common front-end frameworks and UI style guides. Health care institutions also have a responsibility during the implementation phase of an EHR to thoughtfully make decisions that will not drastically alter the internal interface consistency of a health IT product.

#### [HIT Usability Strat 2] Recommendation 4: Promote proper integration of the physical environment with EHR use.

The integration of EHRs with the physical environment affects both efficient clinical team interaction<sup>114</sup> and clinician-patient interaction.<sup>115</sup> Health care institutions contemplating renovation or new construction have the opportunity to keep in mind EHR usage and clinical team interaction when designing environments such as emergency departments, surgical units, and intensive care units, while also considering patient privacy concerns. In high acuity environments, EHR workstations must be placed to enable effective verbal communication between ordering clinicians and the clinical team. In the ambulatory environment, EHR display monitors can be placed in a manner that allows both the clinician and patient to view the display while simultaneously allowing the clinician to face and make eye contact with the patient. EHR developers can support this priority with implementation guidance and software support for multiple displays.

### [HIT Usability] Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.

#### [HIT Usability Strat 3] Recommendation 1: Standardize medication information within health IT.

Prescription drug information in EHRs should be displayed in a standardized format to avoid confusion, increase patient safety, and reduce burden.<sup>116</sup> This standardization is necessary during both the ordering of medications and the display of existing medication information. EHR developers have the opportunity to ensure their products follow best practices including the use of generic drug names, “tall man lettering”, and appropriate representation of drug signetur (Sig) information guidance from organizations such as the NCPDP,<sup>117</sup> the Institute for Safe Medication Practices (ISMP), and the FDA. Health care institutions should refer to ONC’s *SAFER Guide: Computer Provider Order Entry with Decision Support and Report on the Safe Use of Pick Lists in Ambulatory Care Settings* for guidance on implementation decisions that can help optimize medication information display to reduce cognitive load and clinician burden.<sup>118</sup>

#### [HIT Usability Strat 3] Recommendation 2: Standardize order entry content within health IT.

Order entry for laboratory orders, imaging orders, and procedure orders can be burdensome for end users due to the number of test options available. Frequently, differences in selectable orders are represented by





variances of only several characters.<sup>119</sup> EHR developers have the opportunity to collaborate with each other and relevant stakeholders to refine descriptions for unique imaging tests that are clear, concise, and reduce confusion. Similarly, laboratory orders also contain potentially confusing options. Organizations such as the American College of Pathology, the Regenstrief Institute (which administers the Logical Observation Identifiers Names and Codes (LOINC) code set), and commercial laboratory corporations can refine test codes and names that are clear, concise, and reduce burden. To increase the clarity of test options, developers and their collaborators can further improve this functionality by improving default listings of common tests and “favorites” capabilities so that the end result also shortens the available list to reduce end user cognitive load.<sup>120</sup> Health care institutions can refer to *ONC’s SAFER Guide: Computer Provider Order Entry with Decision Support* to help further optimize systems in this area and reduce clinician burden.

**[HIT Usability Strat 3] Recommendation 3: Promote best practice and user interface design frameworks for results display within health IT.**

Currently, there is wide variation within health IT in how clinical results are displayed to the clinician. Clinicians may miss important results due to the design of the results screen.<sup>121</sup> EHR developers can collaboratively work to develop best practices, health care specific front-end frameworks and UI software libraries for displaying results. For example, optimizing and standardizing the display of laboratory test results would allow critical information to be reported first and reduce the overall number of clicks required by physicians. Developers can arrive at a guide for chronological display (older results on left vs. right), abnormal display (flag symbols vs. different colors), and reference range inclusion. Health care institutions can check to see that they have followed *ONC’s SAFER Guide: Test Results Reporting and Follow-Up*<sup>122</sup> to both improve patient safety and reduce clinician burden in this area.

**[HIT Usability] Strategy 4: Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.**

**[HIT Usability Strat 4] Recommendation 1: Increase end user engagement and training.**

EHR end user involvement is critical to the success of an EHR implementation in terms of both safety and usability.<sup>123</sup> Clinical users should be involved from the very beginning of the acquisition process to ensure that the product purchased by an organization will meet the needs of its end users and their desired workflows. During implementation, clinical users should be involved in all phases of the institutional configuration to ensure decisions made during this process are clinically appropriate. After implementation of an EHR system, it is essential that clinical end users are actively involved with ongoing optimization of the EHR system, including workflow refinements, CDS tool review, and documentation and template optimization.<sup>124</sup> Smaller practices can refer to the *ONC Change Package for Improving EHR Usability* for information on how to start optimizing their EHR implementations.<sup>125</sup> To promote competency, it is absolutely critical that health care institutions ensure that all end users receive initial and ongoing EHR training,<sup>126</sup> with easily accessible and ongoing technical support, along with systems. EHR developers can provide tools to institutions to leverage EHR metadata such as audit logs to help develop insight into workflow and usage patterns.<sup>127</sup> These insights can help identify areas of difficulty and end users that might benefit from additional training and support. Institutions can also ensure that adequate clinical staff are assigned to EHR-related tasks such as upgrade planning or change requests.





**[HIT Usability Strat 4] Recommendation 2: Promote understanding of budget requirements for success.**

Health care institutions can transition from a model that revolves around a fixed implementation budget to a budget model that accounts for ongoing costs such as ongoing technical support for end users, ongoing training of clinical staff, and required technical resources to support timely upgrades, system maintenance, troubleshooting, system backup, and disaster recovery functionality. EHR developers can help institutions plan for this by being transparent with projected costs (and associated benefits) over the anticipated lifespan of EHR implementation.<sup>128</sup> Health care institutions can refer to *ONC's EHR Contracts Untangled* to be aware of important contracting issues and for ideas on how to approach contract negotiations.<sup>129</sup> By implementing a budget that provides for the above ongoing resources, clinician burden due to lack of training or support can be minimized.

**[HIT Usability Strat 4] Recommendation 3: Optimize system log-on for end users to reduce burden.**

The implementation and configuration decisions made by health care institutions can have significant impacts on clinician and end user efficiency and burden reduction.<sup>130</sup> EHR developers can offer various modes of authentication and system sign on with their products, including traditional user name and password log-on and other modes, such as token based authentication (e.g. swipe cards) or biometric authentication. As biometric authentication for health care applications becomes more readily available, health care institutions could incorporate these alternate modes to reduce the burden of frequent end user sign in/sign out while still reducing security and privacy risks due to unauthorized access to the EHR.

**[HIT Usability Strat 4] Recommendation 4: Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.**

True interoperability, as defined by the 21<sup>st</sup> Century Cures Act, “enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user.”<sup>131</sup> In practice, this means that all clinical information, including clinical notes, imaging orders, laboratory orders, and other clinical information, should be easily—and securely—available for review within EHR without requiring the clinician to use another system. Health care developers can continue efforts to conform to relevant standards pursuant to ONC and CMS policies. Since the passage of the 21<sup>st</sup> Century Cures Act, HHS and other federal partners have worked to implement provisions around interoperability, such as proposing a framework for trusted exchange among health information networks<sup>132</sup> and improving the effectiveness of ONC’s Health IT Certification Program.





## EHR REPORTING

### **[EHR] Strategy 1: Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.**

#### **[EHR Strat 1] Recommendation 1: Simplify the scoring model for the Promoting Interoperability performance category and Medicare Promoting Interoperability Program.**

In the 2019 rulemaking cycle, CMS finalized the restructure of program requirements for both the Promoting Interoperability performance category in MIPS and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. The restructure of the program requirements focused on aligning the programs to reduce both health care provider and EHR developer burden, as well as to increase focus on interoperability and patient-focused care.

To accomplish this goal, CMS finalized a significant overhaul of the scoring methodology for both programs and introduced new measures. In addition to enabling more interoperable practices and patient-focused measurement, the modifications were responsive to hospital and clinician feedback to align the programs, simplify program requirements, and increase flexibility and health care provider choice.

CMS is committed to working with stakeholders, such as clinicians and hospitals, to develop program requirements that reduce burden while improving quality of care. In the CY 2020 Physician Fee Schedule final rule, CMS established a new future direction for the Quality Payment Program through a MIPS Value Pathways (MVPs), a conceptual participation framework that will be implemented beginning with the 2021 performance year following additional rulemaking. The goal is to move away from siloed activities and measures and move towards an aligned set of measure options more relevant to a clinician's scope of practice that is meaningful to patient care. The MVP framework aims to align and connect measures and activities across the Quality, Cost, Promoting Interoperability, and Improvement Activities performance categories of MIPS for different specialties or conditions.

CMS is working closely with federal partners, such as ONC, and with stakeholders to improve the Quality Payment Program and the Promoting Interoperability Program to reduce burden and increase value by (1) continuing efforts to be evidence-based and relevant to clinical care; (2) promoting higher-value functionality, such as widespread interoperability and clinical support tools; (3) aligning measurement with clinical workflow so that data collection for each measure does not contribute to extra or unnecessary steps in the use of health IT in patient care; and (4) increasing patient and/or authorized caregivers' access to health information to make fully informed health care decisions.

#### **[EHR Strat 1] Recommendation 2: Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.**

To spur clinicians and health care organizations to use health IT in impactful ways, HHS should continue to explore opportunities within existing reporting programs such as the Quality Payment Program, the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, and the Hospital IQR Program to reward both innovative uses of health IT and advancements in interoperability that improve care for patients. The nature of these incentives could range from simple bonus scoring for the use of health IT to specific use cases that might serve as alternate pathways of program participation. For example, HHS





could consider establishing a specific category of health IT Improvement Activities within MIPS that would allow physicians to maximize their scores across the Quality, Promoting Interoperability, and Improvement Activities performance categories by participating in and reporting on a smaller, less burdensome set of activities that use health IT in innovative or advanced ways. Similarly, HHS should look for opportunities within existing reporting programs to incentivize clinicians that participate in activities that demonstrate advanced interoperability. This could include taking part in the Trusted Exchange Framework and Common Agreement ONC is currently implementing. Finally, HHS should look at innovative uses of health IT that can reduce the reporting burden itself by making it easier for federal agencies to pull data directly from health IT to facilitate reporting.

**[EHR Strat 1] Recommendation 3: Reduce burden of health IT measurement by continuing to improve current health IT measures and developing new health IT measures that focus on interoperability, relevance of measure to clinical practice and patient improvement, and electronic data collection that aligns with clinical workflow.**

Physicians and hospitals commonly identified the current set of health IT measures to be excessively burdensome relative to the value they provide. Working with ONC, CMS should revise the current set of Promoting Interoperability measures within MIPS and the Hospital Promoting Interoperability Program, formerly known as the Hospital EHR Incentive Programs, and develop new health IT measures that reduce burden and provide value by: (1) being evidence-based and relevant to clinical care and a health care provider's individual specialty; (2) promoting higher-value functionality, such as wide-spread interoperability or clinical support tools; and (3) aligning measurement with clinical workflow, so that data collection for each measure does not contribute extra or unnecessary steps to the use of health IT in patient care.

CMS is actively working to engage stakeholders, clinicians, and patients in burden reduction efforts. One example of this is the EHR Call for Measures activities, in which CMS highlighted a need for measures geared toward promoting interoperability and focused on health information exchange. Measures resulting from this process will be considered in future years to continue the shift from health IT process measurement to measurement of health IT interoperability and the use of health IT in patient-focused care. This approach has been strongly supported by the hospital and clinician communities, both of whom have been heavily involved in suggesting new measure concepts for these programs. We believe the approach above will not only reduce unnecessary clicks and steps within health IT that are attributable to program measurement, but will also result in measures of health IT usage that contribute to health care provider efficiency and patient care.

**[EHR Strat 1] Recommendation 4: To the extent permitted by law, continue to provide states with federal Medicaid funding for health IT systems and to promote interoperability among Medicaid health care providers.**

CMS is exploring how other sources of enhanced Medicaid federal financial participation (such as enhanced federal financial participation for the design, development, installation, maintenance, or operation of a Medicaid Management Information System) might support state health IT projects after the end of the Medicaid Promoting Interoperability Program. To the extent permitted by law, CMS expects to continue to support state initiatives that promote interoperability within and beyond the Medicaid enterprise. CMS intends to work with states to integrate health IT into larger Medicaid Enterprise systems. To the practicable and appropriate extent, state Medicaid Enterprise systems should leverage or build upon existing federal





investments including projects supported by Medicaid Promoting Interoperability Program funding, such as state efforts to establish secure and trusted health information exchange.

**[EHR Strat 1] Recommendation 5: Revise program feedback reports to better support clinician needs and improve care.**

Although certain quality reporting programs, such as the legacy programs that preceded the Quality Payment Program, provided annual feedback reports to clinicians regarding program performance, many clinicians have indicated that these feedback reports do not provide meaningful insight into program performance or how to improve. In implementing MIPS, CMS engaged with clinicians and other stakeholders regarding what information would be most useful to have included in the feedback reports and revamped the performance feedback from what they provided under the legacy programs. Even after the release of the MIPS Year 1 performance feedback in July 2018, CMS continued to do extensive user research. The responses were very positive about the current design that facilitates early feedback during submission, as well as a continued experience between the close of submission in the spring and the final feedback delivered in July. Users found the format easy to use and understand. Suggested improvements include providing more beneficiary level data, limiting updates that occur between the close of submission and the release of the final feedback in July to minimize confusion, clearly communicating what has been updated, and expanding information around costs and utilization inside and outside of a practice for attributed beneficiaries.

CMS should continue to enhance the MIPS performance feedback based on their user research findings. HHS should also explore a secure standards-based API approach to integrate these feedback reports and supporting data with health IT. If health IT can support a consistent, integrated feedback loop, it could reduce burdens related to program participation and improve overall quality and patient care.

**[EHR] Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.**

**[EHR Strat 2] Recommendation 1: Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting.**

Physicians and hospitals have consistently noted data and reporting accuracy issues related to the methods by which data is mapped within health IT, and how measure calculations are incorporated into certified health IT products. Mistakes in data mapping, and poor data integrity overall, not only necessitate added costs for health care providers but may result in adverse payment adjustments through a variety of reporting programs. ONC should coordinate stakeholders focused on best practices for data mapping and data integrity and include industry-approved mappings as part of the Interoperability Standards Advisory, that all stakeholders, including certified health IT developers, could then use.

**[EHR Strat 2] Recommendation 2: Adopt additional data standards to makes access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals.**

Physicians and hospitals routinely cite access to data, both within their own health IT systems and across health IT and other electronic platforms, as a significant challenge not only for participating in and reporting







to quality programs, but also in repurposing the data for multiple uses. Difficulty in accessing data hampers numerous industry-wide efforts related to quality improvement, patient access to personal health information, and reduction in health care costs. While the introduction of API technology certification criteria as part of ONC's *2015 Edition Health IT Certification Criteria* aimed to make it easier for physicians and hospitals to access and integrate certain data, the continued standardization of electronic data and health IT functionality is also needed. For example, the use of the Health Level Seven (HL7®) *Fast Health care Interoperability Resources (FHIR®)* standard could allow for the development of electronic resources to facilitate requests for data without requiring a clinician or health care provider to individually address potential variations in each individual request. FHIR® could also potentially support data segmentation for privacy in health information exchange and recently released mobile solutions, which can integrate clinical data with a patient's personal health tracking applications on their mobile device. Further, HL7® is currently working on an update to the FHIR® standard to support API access to request data on populations of patients, which could potentially address additional use cases, including supporting payer needs, public health and quality improvement efforts, and health research organizations. The adoption of FHIR-based APIs, especially for population-level data exchange, has the potential to reduce clinician burden and overall cost to clinicians. Similarly, ONC recently proposed the Draft US Core Data for Interoperability (USCDI), which aims to specify a common set of data classes required for interoperable exchange and identify a predictable, transparent, and collaborative process for expanding the USCDI's scope. The data referenced in the USCDI is currently proposed for use within the Trusted Exchange Framework and Common Agreement (TEFCA); however, ONC should explore the potential for use of the USCDI beyond the TEFCA in order to expand the availability of predictable, transparent, and collaborative processes that promote interoperable data exchange while also relieving physician and hospital burden related to health IT use.

**[EHR Strat 2] Recommendation 3: Implement a secure standards-based API approach to HHS electronic administrative systems to promote integration with existing health IT products.**

A chief complaint from clinicians and health care organizations is that most electronic administrative systems do not integrate with current health IT. This wastes time as clinicians and other staff must continually switch interfaces in order to access or update information. To reduce wasted time and effort on the clinician side, and to improve overall data accuracy, HHS should implement secure standards-based API interfaces for its own electronic systems such as the Provider Enrollment, Chain, and Ownership System (PECOS) that use and maintain administrative information. Ideally, HHS should implement an API approach that supports bidirectional data integration, which would allow health IT to seamlessly integrate with these systems and regularly update information related to physicians.

**[EHR] Strategy 3: Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden**

**[EHR Strat 3] Recommendation 1: Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures.**

Many physicians and hospitals note that the measurement and reporting of completely new eQMs poses significant burdens for clinicians and organizations. Often the timelines on which clinicians are expected to update health IT systems and adopt new eQMs pose data mapping, financial, and workflow training challenges that result in poor performance and increased costs. HHS should reevaluate its approach to the adoption of new eQMs to reduce these burdens. For example, HHS could introduce a "test year" into





programs for new eCQMs wherein reporting on these eCQMs is optional, with program incentives made available to encourage physicians and hospitals. This would encourage provider participation in eCQM testing. HHS could use this measure data to refine new eCQMs as needed, but not as part of public reporting or performance evaluation.

**[EHR Strat 3] Recommendation 2: Continue to evaluate the current landscape and future directions of electronic quality measurement and provide a roadmap toward increased electronic reporting through the eCQM Strategy Project.**

Ideally, the electronic measurement and reporting of quality performance data should result in less time and money invested by clinicians than the use and reporting of traditional chart-abstracted measures. However, there are a number of challenges to making a full transition to health IT use for quality measurement. Similar to its approach with the Promoting Interoperability performance category of MIPS and the Promoting Interoperability Program for hospitals, formerly known as the Hospital EHR Incentive Program, HHS should, after consultation with stakeholders, both revise existing eCQMs and develop new eCQMs that will allow physicians and hospitals to increasingly transition to electronic measurement and reporting.

The beginning of this effort is underway through CMS's eCQM Strategy Project. After evaluating current state processes of eCQM development and soliciting public feedback to make future state recommendations, CMS is currently implementing project recommendations to reduce eCQM development and implementation burdens through adding workflow considerations in the development process while reducing development time, obtaining more stakeholder feedback for the new eCQMs under development, and adding increased stakeholder transparency to these processes, with an emphasis on ensuring that electronic data collection for quality measures does not contribute extra or unnecessary steps to the use of health IT in patient care. In addition, HHS announced in July 2019 the formation of the [Quality Summit \(QS\)](#), which will bring together key industry stakeholders and government leaders to discuss how current quality programs administered by HHS can be further evaluated, adapted, and ultimately streamlined to deliver a value-based care model focused on improving outcomes for American patients. CMS and ONC should also work together to refine and develop eCQMs so that quality measurement aligns with clinical workflow, with an emphasis on ensuring that electronic data collection for quality measures does not contribute extra or unnecessary steps to the use of health IT in patient care.

Finally, a number of stakeholders pointed specifically to multiple health IT and digital efforts underway across HHS and the need to align such efforts in order to reduce provider burden and promote value in the delivery of care. To that end, HHS should commit to an overall digital strategy that will publicly communicate goals and milestones to clinicians, IT developers, and other invested stakeholders.

**[EHR Strat 3] Recommendation 3: Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.**

Developing eCQMs that align with clinical workflow and do not contribute extra or unnecessary steps to the use of health IT in patient care can make a major impact on the burden associated with electronic quality measurement. However, there may be other approaches to electronic quality measurement that are even more efficient and less burdensome than our current approach to quality measurement. One example is data element reporting in which health care providers would submit specified indicators instead of pre-



defined eQMs. CMS is conducting pilot activities to explore the feasibility and reliability of collecting FHIR-based data elements, in an effort to reduce burden associated with reporting this data. Alternatively, mining health IT databases for clinician performance trends could yield more robust and detailed quality measurement and improvement strategies while simultaneously eliminating much of the physician burden associated with current quality measurement and reporting programs. Similarly, artificial intelligence and machine learning present opportunities to assess quality performance and improvement in wholly new ways that can yield more detailed feedback. HHS should explore the feasibility of programs that can help develop and evaluate future approaches to quality measurement that will be less burdensome, more accurate, and more impactful in assessing the quality of care provided to patients.



## PUBLIC HEALTH REPORTING

**[PHR] Strategy 1: Increase provider PDMP query for the retrieval of medication history from a state PDMP. Improve health care provider workflow for conducting the query by integrating the PDMP with health IT.**

[PHR Strat 1] Recommendation 1: Federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Rules, to improve timely access to medication histories in PDMPs. States should also leverage funding sources, including but not limited to the 100 percent federal Medicaid matching funds available pursuant to section 5042 of the SUPPORT for Patients and Communities Act, to facilitate EHR integration with PDMPs using existing standards.

Federal investments should continue to support PDMPs and activities to enhance PDMPs including their integration with EHRs. This includes CDC funding to states as part of their Preventions for states Program, as well as the Department of Justice, Bureau of Justice Assistance (BJA) PDMP funding. Section 5042 of the SUPPORT Act, which added section 1944 to the Social Security Act, provides 100 percent federal Medicaid matching funds for FY 2019 and FY 2020 for certain state expenditures related to qualified PDMPs. CMS expects many states to integrate their qualified PDMPs with existing Medicaid mechanized claims processing and information retrieval systems. All of the above-listed efforts should include or expand incentives and requirements (where feasible) for the use of non-proprietary standards for PDMP data exchange.

ONC and CDC are also working in partnership to advance and scale PDMP integration with health IT systems, including pilot testing and refining standards-based approaches to enable effective integration into clinical workflows; identifying and advancing promising approaches that support scalability and sustainability of PDMP-health IT integration; exploring emerging technical solutions to enhance access and use of PDMP data; and compiling lessons learned and best practices that can be translated into technical resources for states and health systems.

In addition, ONC has included several updates to the Interoperability Standards Advisory (ISA) for standards related to opioid prescription data and transactions including adding a section to the ISA which compiles these standards for ease of reference.<sup>133</sup>

Federal agencies should build on these efforts to coordinate a shared strategy for all PDMPs to adopt common standards over time to support PDMP and health IT integration. In addition, federal agencies should support the convening of states and local jurisdictions to promote the adoption and use of national, non-proprietary standards for PDMP systems, as well as to develop consensus around PDMP policies related to access roles, data storage, data use and integration, and data sharing across jurisdictions.

**[PHR Strat 1] Recommendation 2: Promote standards-based API emerging technologies to support improved access to and use of opioid prescription histories for OUD prevention and treatment.**

ONC has proposed adoption of a new secure standards-based API for health IT certified to support multiple use cases of health information exchange, including provider-to-provider exchange and provider-to-patient





exchange. Standards-based APIs could also support the potential exchange of information with third parties for purposes such as public health and clinical quality measurement.

In 2018, ONC initiated a project to explore how a standards-based API might support a PDMP use case by mapping the opioid prescription data exchange use case to the FHIR® standard. The first phase of the project was to develop a PDMP implementation guide to enable EHRs to access PDMPs using the FHIR® standard and to ballot that implementation guide. The second phase of the project is conducting pilot testing of that IG in states and updating the IG based on pilot results.

HHS should continue to explore how the use of APIs might help to support OUD prevention and treatment through multiple approaches. First, focusing on continued efforts to convene states and other PDMP operators to achieve consensus on access roles, data use, and trusted data exchange so that standards development organizations and health IT developers can build and develop more consistent and cost effective implementation across jurisdictions. Second, HHS should leverage federal funding to support the adoption and use of standards-based API technologies for public health and PDMP use cases to maximize enterprise solutions for state systems and reduce health IT development cost and burdens.

**[PHR] Strategy 2: HHS should increase adoption of EPCS with consideration for provider-specific preferences, workflow, and use of available standards.**

[PHR Strat 2] Recommendation 1: HHS should increase adoption of electronic prescribing of controlled substances with consideration for provider-specific preferences, workflow, and use of available standards.

Through the implementation of the SUPPORT for Patients and Communities Act, CMS will require controlled substances covered under Medicare Part D to be electronically prescribed. Additionally, states may claim the 100 percent federal Medicaid matching funds available under section 1944 of the Social Security Act (added by section 5042 of the SUPPORT for Patients and Communities Act) only for certain expenditures related to qualified PDMPs. A qualified PDMP must facilitate the integration of medication history information into prescribers' workflow, which may include EPCS. CMS has explained that it would be appropriate for states to seek the 100 percent federal Medicaid matching funds for their expenditures to design, develop, or implement PDMP functionality that will enable connections between the qualified PDMP and providers' EPCS systems, or that will enable connections between the qualified PDMP and other provider electronic health records systems that might include prescription history information.<sup>134</sup> Two-factor authentication required by the Drug Enforcement Agency (DEA) can be implemented in physician practices in ways that reduce the overall burden of the prescribing processes for clinicians. EPCS, when properly integrated into the EHR, can allow all prescribing to remain in a single workflow, reduces the time clinicians spend on medication reconciliation, automates CDS such as drug-drug interactions, and facilitates the tracking of prescription fulfillment. The SUPPORT Act also requires DEA to update multifactor authentication requirements that will permit biometrics and modern approaches to authentication that can be more easily integrated into provider workflows.



**[PHR] Strategy 3: Develop a process to address the issue of inconsistent data collection by federal, state, and local programs. This would include programs whose data sources may be found in EHRs and where consistent reporting requirements could be met with data collected during clinical processes and reused for reporting purposes.**

[PHR Strat 3] Recommendation 1: HHS should convene key stakeholders, including state and local public health departments and community health centers, to inventory reporting requirements from federally funded public health programs. This inventory would be used by federal agencies to identify common data reported to relevant state health departments and federal program-specific reporting platforms.

As described previously, many federal, state, local, territorial, and tribal agencies have funding requirements to report EHR-derived data related to the provision of care, eligibility, and public health activities in these programs. These funding requirements differ widely by program in content, format, and reporting methodology, and often require data collection outside the normal clinical workflow. Specific actions that could help reduce data collection and reporting burden include but are not limited to: identifying common and disparate data reporting requirements across all programs, aligning similar reporting requirements with data collected in normal workflows, investing in state and local public health reporting infrastructure, and harmonizing reporting requirements across programs.

[PHR Strat 3] Recommendation 2: HHS should continue to work to harmonize reporting requirements across federally funded programs.

HHS should analyze and harmonize common data elements and recommend transport standards across reporting requirements. This analysis will drive the prioritized implementation of standards that are based on use cases determined to be of high value and high total return on investment. This focused approach to standards and prioritized implementation planning will help ensure the proper use of limited resources and identify areas where implementation resources are underfunded. Agencies should then adopt a common standards-based approach to reporting EHR-captured data as a part of their modernization of reporting systems across relevant government programs.

**[PHR] Strategy 4: HHS should expand upon existing guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorders (SUDs) health information in order to better facilitate electronic exchange of health information for patient care.**

[PHR Strat 4] Recommendation 1: HHS should expand upon existing guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorders (SUDs) health information in order to better facilitate electronic exchange of health information for patient care.

HHS should provide additional guidance about the federal confidentiality of alcohol and drug abuse patient records regulation (42 CFR Part 2),<sup>135</sup> which requires the protection of the confidentiality of certain SUD-related information, and the privacy and security requirements of the HIPAA Rules,<sup>136</sup> which govern privacy and security of patient health information maintained by or for most providers. Such guidance can facilitate HHS's goal of promoting electronic exchange of health information for better care coordination.

HHS should continue to monitor, test, and support the development of technical standards for applying security labels and meta-data (commonly referred to as “data segmentation”) to health information in a consistent manner to reflect confidentiality requirements, and enable health care providers to comply with existing requirements.

HHS should coordinate across federal agencies to educate health care providers and health IT vendors about 42 CFR Part 2 requirements and provide more clarity on when health care providers and their health IT vendors need to comply with 42 CFR Part 2 patient consent and health information re-disclosure requirements. This education and outreach should include the availability of technical standards<sup>137</sup> and technologies to enable confidentiality and data segmentation of health information, as well as technical assistance to help health care providers and organizations adopt and use existing health IT solutions for protecting patient confidentiality and managing patient consent.



# Notes

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<sup>1</sup> The House of Medicine. C. A. Hoffman, MD. JAMA. 1972;221(5):483-485.

<sup>2</sup> 21st Century Cures Act, Pub. L. No. 114–255, 13 December 2016 at:  
<https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW114publ255.pdf>

<sup>3</sup> Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5) at:  
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- <sup>135</sup> See 42 CFR Part 2, “CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS,” at: <https://www.govinfo.gov/content/pkg/FR-2017-01-18/pdf/2017-00719.pdf>
- <sup>136</sup> The complete suite of HIPAA Administrative Simplification Rules can be found at <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/combined-regulationtext/index.html?language=es>; Health Insurance Portability and Accountability Act of 1996 at: <https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf>
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