Office of the National Coordinator for Health Information Technology

Accelerating Application Programming Interfaces for Scientific Discovery: Provider Perspectives

PREPARED BY

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Introduction

The increased use of multi-functional digital health tools allowing consumers and providers to access patient information has the potential to enhance patient care, improve health and wellness, and support reporting requirements. For example, the digital platforms of some consumer health applications (apps) support vaccination records management, telehealth, fitness tracking, remote health monitoring, patient navigation, communication between patients and providers, and dissemination of clinical trial information. Leveraging patient-facing and provider-facing apps can give consumers and providers greater access to data from health information technology (health IT) systems to support their goals of improving quality of care, enhancing clinical decision-making, and increasing patient engagement and satisfaction. Apps rely on application programming interfaces (APIs) to retrieve data from source systems, such as electronic health records (EHRs), to provide useful information to achieve these goals. The discussion below focuses on the growing adoption of both patient-facing and provider-facing apps and the challenges, barriers, and considerations to address within the health care provider community.

Under the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted in 2009, the goal of achieving meaningful use of EHRs drove provider organizations to adopt, implement, and upgrade their health IT systems to support the requirements of the HITECH Act and earn financial incentives under the Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs). Today, nearly all hospitals and a majority of ambulatory providers now use certified EHRs.[1] Providers continue to advance their use of EHRs to not only meet the requirements of the Promoting Interoperability Programs but also to leverage technologies that support clinical decision support and interoperability of electronic health information (EHI). EHI is defined as electronic protected health information (ePHI) to the extent that it would be included in a designated record set (DRS), regardless of whether the group of records is used or maintained by or for a covered entity.[2]

The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, includes provisions that encourage greater interoperability of EHI. A key driver in the implementation of these interoperability provisions is the Cures Act Final Rule (Final Rule), published in March 2020 by the Office of the National Coordinator for Health Information Technology (ONC).[3,4] The Final Rule supports seamless and secure access, exchange, and use of EHI. The Final Rule also requires certain certified health IT developers to develop standardized APIs that enable secure data exchange between disparate systems using the Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard and make these APIs available for implementation by provider organizations. These standardized APIs must support services for a single patient as well as multiple patients. Provider organizations can use these standardized APIs to connect to patient-facing and provider-facing apps[5] for individuals, and FHIR Bulk Data Access APIs[6] (Bulk FHIR) for API-based exchange for groups of individuals.

The Cures Act and Final Rule further motivate providers to implement the newly required standardized APIs to achieve greater interoperability, expand functionality not found in EHRs alone, and provide seamless access to EHI. Gaining the perspectives of providers working to implement APIs and apps may be helpful to highlight how policy decisions and regulatory requirements affect organizations in practical ways and inform future technology and interoperability efforts to accelerate the adoption of standardized APIs and apps.

The ONC contracted with Clinovations Government + Health to conduct discussions with a diverse group of provider organizations in 2021, before many of the Final Rule compliance deadlines. Therefore, the perspectives gained for this report reflect the experiences, challenges, and opportunities for providers at the time of the analysis. As provider organizations and their health IT developers approach the compliance deadlines for the new standardized API functionality at the end of 2022, the state of their readiness, use, and adoption of APIs and apps is expected to progress.

METHODOLOGY

To gain a better understanding of provider perspectives on their adoption and use of APIs and apps, an initial list of possible discussants included successful Sync for Science[7] implementation sites, Healthcare Information and Management Systems Society (HIMSS) Davies Award[8] winners, HIMSS Electronic Medical Record Adoption Model (EMRAM)[9] Stage 6 and 7 participants, and organizations represented in the College of Healthcare Information Management Executives (CHIME).[10] Of the thirty (30) organizations initially identified and invited, nine (9) responded and elected to participate in these discussions.

The semi-structured discussion sessions occurred between October and November 2021. The team identified clinical and IT leadership within each organization with detailed knowledge and relevant insights and perspectives based on their expertise or role in implementing or utilizing APIs and apps in their organizations. Participating provider organizations represented a diverse sampling of perspectives from varied geographic locations, visit volumes, organization types (e.g., academic medical center, federally qualified health center, community hospital, post-acute care health system), and usage of EHR systems.

The organizations included in this report and their respective discussion participants are listed in Table 1.

Table 1. Provider Perspectives: Discussion Participants

Organization	Role	Discussion Participant
Cedars-Sinai	Medical Director, Technology and Architecture	Raymond Duncan, MD, FAAP
Duke Health	Clinical Integration Solutions Engineer	Tres Brown, III
	Senior Director, Enterprise Analytics	Ryan Craig, MMCi
	Associate Chief Health Information Officer	Karen Rourk
Encompass Health	Director of Business Intelligence and Data Warehousing	Darren Freeman
	Associate Director of Data Management	Henry Lovoy
	Chief Information Officer	Rusty Yeager, MBA
GBMC Healthcare	Data Courier Administrator and environment Release Manager	Barbara Bodyk
	Chief Medical Information Officer	Fred Chan, MD
	IT Applications Director	Cindy Ellis MSN, RN, ACNS-BC, CHCIO
	IT Clinical Applications Manager	Kay Everett
	Clinical Informatics Quality and Safety Specialist	Rachael Whiteside MSN, RN, CMSRN
MaineHealth	Chief Digital Officer and Chief Information Officer	Daniel Nigrin, MD
Mass General Brigham	Director, Solution and Experience, Digital Care Transformation	William Gordon, MD

Organization	Role	Discussion Participant
Unity Health	**Vice President of Information Systems**	**Angela Diop, ND, CHCIO**
	Information Systems Manager	**Cherie Jones**
University of Missouri Health Care	**Chief Information Officer**	**Bryan Bliven, MBA, FACHE**
Wellforce	**Chief Digital Officer and Chief Information Officer**	**Shafiq Rab, MD, MPH, FCHIME, CHCIO**

Background information regarding the project's scope and preliminary discussion topics were distributed to discussion participants before each of the sessions. During each session, a facilitator was joined by a notetaker who documented the discussion, organized the information that was collected, and assisted in the identification and analysis of responses using grounded theory techniques.[11] Sessions focused on each organization's current capabilities and needs when implementing standardized APIs, custom or proprietary APIs, and apps to access data from EHRs and other health IT systems. Specific topics addressed during the discussion sessions included:

- Knowledge of related regulations and certification requirements of APIs and apps;
- Experience with evaluation, implementation, and adoption of APIs and apps;
- Experience working with health IT developers, data integrators, and app developers;
- Emerging and relevant use cases for consumers and providers using patient-facing and provider-facing apps;
- Considerations and risks for privacy and security related to the implementation of apps; and
- Process improvement opportunities for app selection, governance, and implementation.

Findings

The Final Rule provisions require certain certified health IT developers to develop and make available to provider organizations standardized APIs (i.e., FHIR®-based) to support a patient's or other authorized user's ability to use an app/service to access EHI and to support a provider's ability to leverage apps of their choosing to make use of the EHI within their certified health IT. Although some organizations develop, test, and manage their APIs and apps, most depend on certified health IT developers for access to vetted apps typically published in developer app directories, also referred to as "app galleries". In some cases, organizations use intermediaries, such as data integrators, to facilitate API management and integration between disparate systems.[12]

When asked to describe motivators and experiences with identifying, implementing, and managing APIs and apps, discussion participants expressed the following key themes:

- Organizations generally support the use of APIs and apps that enhance current health IT systems by providing additional functionality that existing EHRs do not provide.
- Clinical, administrative, and research use cases may benefit from the adoption of APIs and apps that provide additional data, clinical decision support, or analytics capabilities that may be needed to best meet patient or provider needs.
- Governance processes require a formal strategy that aligns app implementation and usage to strategic goals, prioritizes initiatives, assesses the impact of evolving standards and health IT developer timelines, and dedicates experienced and knowledgeable resources.
- Privacy and security concerns remain a barrier to the adoption of new apps, as most organizations cite having a low-risk tolerance and resistance to expanding the number of systems they manage.
- Providers cited a lack of knowledgeable, internal resources to systematically evaluate apps, support consumer education, and provide ongoing maintenance.
- Regulatory requirements and compliance initiatives are often challenged by liability concerns regarding the implementation and use of apps.

ORGANIZATIONAL DRIVERS FOR APIs AND APP USE

As of 2016, the year the Cures Act was signed into law, only 38 percent of non-federal acute care organizations enabled patients to access their health information via an API-based health app.[13,14] By 2019, 70 percent of non-federal acute care organizations enabled inpatients to access their health information via an API-based health app, and 97 percent of organizations enabled patients to view their EHI through a patient portal. This growth in API and app usage suggests that the Cures Act may be a key driver of implementation efforts promoting interoperability and access to EHI for all consumers.

In addition to organizations' motivation to meet the interoperability goals of the Cures Act and, more recently, the Final Rule, participants described other drivers for using APIs and apps as part of their overall digital health strategy. Consistent feedback based on participants' experiences implementing APIs and apps is reflected in the following themes, which will be discussed in further detail in the sections below:

- Patient portals are considered the central repository of patient data, and organizations promote it as the primary method for consumers to gain access to their EHI. Platform-based apps like Apple Health (iOS) and Common Health (Android) are increasingly being used.
- Provider use of standardized APIs with EHRs is limited but gaining traction for uses such as social determinants of health (SDOH) data integration, care coordination, condition-specific risk scoring, and digital health ordering.
- Coronavirus SARS-CoV2 (COVID-19) is a major catalyst for organization interest, development, and investment in digital health solutions that support care and administrative tasks outside traditional settings.
- Innovation can be fostered in a learning environment through accelerator programs aimed at developing solutions using standardized and non-standardized (i.e., proprietary or custom) APIs.
- Although organizations expressed excitement by the promise of using apps through the implementation of APIs, they are not yet widely implemented in most provider environments.

> **"Well-developed and widely implemented APIs are the key to fulfilling so much of the promise of EHRs to provide more efficient, safer, and more connected care."**

Discussion participants strongly believe APIs will allow their organizations to implement health IT solutions, including apps, that supplement or replace features in their core EHR or create new functionality for providers and patients to fill unmet specific needs. One discussion participant remarked that best-in-class apps could not be accessed by their organization because the apps were outside their health IT developer's app ecosystem. However, the same discussion participant suggested that standardized APIs have the potential to solve this challenge because they may allow organizations to "plug and play" with best-of-class apps, enabling their care teams to provide patients better access to their health information and care. However, health IT developers still need to make APIs available and provide support to test and implement them, before organizations can implement apps. One discussion participant

also said the ability of organizations to use apps to meet specific clinical needs without depending solely on the health IT developer's app ecosystem will support safer, more efficient, and more connected care.

Patient Portal and App Use as the Main Method to Access Health Information

Without exception, discussion participants pointed to their EHR's patient portal, and health IT developer's apps, as the primary method for providing consumers access to their EHI. Discussion participants reported that patient-facing apps such as Apple Health and Common Health are also commonly implemented to provide consumers access to their EHI. One discussion participant said that - except for data included in employee health records, workman's compensation claims, and certain sensitive data - their organization uploads most of a patient's EHR-based EHI to the patient portal. If an organization provides behavioral health services, discussion participants noted that psychotherapy notes (which receive extra protections under HIPAA) would be excluded from the patient portal. Overall, discussion participants expressed the belief that a consumer's health information should be shareable, with very few exceptions, in electronic format. Providers reported that patient engagement and portal strategies at their organizations reflect a commitment to that belief.

Although some organizations use the patient portal exclusively as a method for consumers to view, download, or transmit their health information, others have implemented portal features that support consumers' ability to perform other tasks, including:

- Scheduling appointments with providers;
- Communicating with providers and administrative staff;
- Requesting prescription refills;
- Paying bills and checking reimbursement rates from insurance companies;
- Requesting and conducting virtual encounters (e.g., "e-visits", electronic messages between patients and providers, video visits);
- Assigning health care proxies or role-based access to health apps to track patient progress toward treatment goals; and
- Uploading vital signs and other patient-generated health data (PGHD) (e.g., surveys, documents)

One discussion participant discussed three (3) unique features their organization enabled in their patient portal. The first feature allows providers to establish notification criteria for PGHD provided via the patient portal. This enables the care team to send secure messages advising the patient to submit additional vital signs, call the provider's office, or, if necessary, go to the emergency room. The second feature assigns a care manager as an intermediary to the clinical team to assist with the coordination of care and communication. The third feature allows patients to send problem lists, medications, allergies, and immunizations directly and in real-time to non-affiliated organizations through their patient portals.[15]

One discussion participant described relying on their patient portal because of its inherently robust authentication and authorization processes for patient-directed data exchange. However, the participant also stressed that, according to the HIPAA regulations, at the point EHI leaves the patient portal, the consumer is responsible for the data and its security.

In Table 2, provider organizations reported their current app usage (by FHIR® version), as well as the percentage of active patients using their patient portal. It is interesting to note that Vendor A's product was not capable of producing the report required to provide statistics to the provider. In addition, Vendor B provided complete values for the data points requested and had the most FHIR-based apps available with its product, using multiple versions of FHIR®. Vendor C could report statistics to the provider, but that organization only had one FHIR-based app implemented.

Table 2. Current Portal and App Use by Provider Organization

	Provider 1	Provider 2	Provider 3	Provider 4
	Vendor A	Vendor B		Vendor C
# apps using FHIR DSTU2	No Capability to View	24	1-3	0
# apps using FHIR STU3	No Capability to View	5	1-3	0
# apps using FHIR R4	No Capability to View	3	1-3	1
# apps using FHIR Bulk Data Access API	No Capability to View	0	0	0
# apps with write-back capability	No Capability to View	27	1	0
% active patients using a patient portal	No Capability to View	67%	62%	0

Provider Use of SMART on FHIR® APIs

Before the Final Rule, which included health IT certification requirements for standardized APIs, provider organizations that were early adopters of APIs created their FHIR server infrastructure that was integrated into their certified EHRs. Early adopters tended to be large academic medical centers with extensive medical informatics programs or resources.

With standardized API capabilities available within certified EHRs, while patient-facing app integration is advancing as described in the previous section, discussion participants indicated that provider-facing app integration is still most common among academic institutions. However, community-based health systems and federally qualified health center discussion participants indicated high enthusiasm and interest in expanding the use of Substitutable Medical Applications, Reusable Technologies (SMART®) on FHIR technology. They also expressed a lack of knowledge and awareness of available apps that integrate with their EHRs. Discussion participants reported they seek apps that are implemented widely, proven, and can be integrated with their EHRs.

The SMART on FHIR App Gallery lists 100 SMART apps, with 51 of these designed only for clinician use and 36 designed for patient and clinician use. Individual health IT developers' app galleries require additional fees to be paid by the app developer and most do not yet offer a method (beyond keyword search) to identify FHIR-based apps. However, some EHR developers do offer mechanisms to filter based upon

end-user type (e.g., clinician, patient, IT). A listing of available provider-facing apps was reviewed and confirmed with discussion participants. Their feedback indicated that provider-facing apps are emerging in the following areas:

- condition-specific risk-scoring and clinical decision support;
- specialty-specific documentation efficiency and clinical decision support;
- social determinants of health data integration; and
- prescribing of digital health solutions.

Discussion participants indicated frustration with sales and marketing efforts from app developers, citing a lack of bandwidth to vet a growing number of applications and preferring solutions at this time that are native integrations with their EHR solution, evaluated through their internal innovation centers or researchers, or are implemented by their peer organizations.

COVID-19 as a Catalyst for Technology Adoption

One unexpected outcome of the COVID-19 pandemic is the positive impact it had on the development and use of apps for patient communications, telehealth, and virtual care, which were marginally used pre-pandemic. Discussion participants described using apps that can assist with assessing mental health and suicide risk prevention and reporting COVID-19 symptoms. Discussion participants from four organizations noted that COVID-19 was a major catalyst for the increased development, interest, and investment in telehealth and apps, including advances in their patient portals. Three discussion participants noted increased uptake and continued growth of their patient portals during the COVID-19 pandemic and, at two organizations, patient portal use by active patients increased to 63 percent and 65 percent, respectively, since the beginning of the pandemic. The third discussion participant noted that "at the height of the pandemic," up to 1,000 telehealth visits occurred daily.

> **"COVID-19 showed us that we have to have an out-of-hospital ability to communicate [with patient families], because we were killing ourselves trying to set up FaceTime for all of our patients."**

Discussion participants reported that, during the pandemic and despite a lack of clarity on reimbursement or long-term guidance for telehealth, their organizations implemented a variety of technology solutions, including upgrades to patient portals, telehealth, and other health apps. One discussion participant observed that their organization adapted clinical and operational workflows to onboard new technologies. As part of the pandemic efforts to minimize contact between individuals, some organizations promoted contact-less check-in and scheduling features through the use of patient portals and apps. Some organizations changed their pre-existing workflows and processes because a patient check-in no longer guaranteed that the patient was in the waiting room. Some patients waited in their cars, while others checked in from home.

Providers and care teams had to be trained to accommodate the new, necessary features and functionality available to consumers. To build on the concept of adjusting clinical and operational workflows to accommodate telehealth and new health apps, one discussion participant described the concept of virtual care. Using a patient with newly diagnosed hypertension as an example, the discussion participant described that the patient could receive care from the provider without an in-person visit. In this model, the

provider sends the patient a device that monitors their condition. The monitoring device sends back information via an API to the provider and, based on the data that is received, the provider can call, text, or email clinical instructions to the patient. The discussion participant added that their organization offers similar virtual care programs for other conditions and that these programs have been extremely popular throughout the COVID-19 pandemic.

The pandemic also prompted significant technology uptake, because patients were required to use their phones for apps and telehealth visits. However, questions remain about whether this uptake and growth of apps are sustainable as the pandemic wanes.[16] When asked, one discussion participant described an internal study conducted by their organization. Based on the study's quantitative (via surveys) and qualitative (via interviews) feedback from providers, IT staff, and patients over the age of 65, the discussion participant believes that app use is here for the long term and that even the most vulnerable consumers are embracing apps, albeit slowly.

> **"Last year, as you are well aware with COVID-19, we had this astronomical uptake of [patient portal] utilization, especially around video visits. And fortunately, we were well prepared at that time and had laid a foundation that allowed us to pilot video visits even at that time prior to any sort of clarification or any clarity around"**

Fostering Innovation

With the rapidly changing digital health sector, provider organizations are generally not structured to participate in fast-tracked pilot projects. Information Technology (IT) departments are at capacity managing the multitude of health IT systems that are evaluated, selected, and implemented using extensive criteria and processes. A common trend among provider organizations is the creation of innovation centers with separate staff and budgets that are encouraged to engage with industry and startups to test new products and sometimes co-develop technology solutions. Innovation centers are designed to be nimble in their operations and governance processes and provide a testbed for new solutions without having to go through the vetting and risk assessment processes required for health system-wide deployment. In 2018, Becker's Hospital Review recognized 66 hospitals and health systems with innovation programs[17] and reported that 24 new centers were launched or planned in 2021.[18]

One discussion participant described the health IT accelerator program created by their organization to help small startup companies in a wide variety of areas test and implement their apps using FHIR® APIs. Some of these apps have been published in their health IT developer's app gallery. The provider organization selects between 8 and 10 startup companies from among more than 400 applicants for the program's two annual accelerators. During a 90-day cycle, the organization provides mentorship and app development support in exchange for a small interest in the company. The accelerator team provides first-time accelerator participants with a sandbox environment to use that contains test patient data. After completing this pilot phase, the organization provides the company with a proxy ID until it receives a client ID from the health IT developer. Once the company has a client ID and a signed Business Associate Agreement with the organization, they can access real patient data for implementing the app in the provider organization's production environment.

While many apps developed through the organization's accelerator program have been unsuccessful, those that have emerged successfully from the program have resulted in many benefits. Startup accelerator

programs benefit the industry by bringing innovative ideas to market quickly and positively impacting the regional entrepreneurial ecosystem.[19] By mentoring startups that use FHIR standards, the organization gains practical experience with FHIR and increases the health IT community's overall FHIR knowledge base.

Data Analytics with FHIR® Bulk Data Access

Bulk FHIR® APIs are designed to exchange large analytical data sets by regularly querying to extract data (via streaming) into a platform that will be used for analytics. Bulk FHIR APIs enable data requestors to access data from multiple EHRs in a standardized and secure method without manual processes or having to customize routines for every developer or site.[20] As population-level analytics and research studies require greater access to standard data sets, provider organizations seek ways to leverage automated methods, such as using Bulk FHIR APIs, to extract data.[21] Health informatics researchers are also testing and demonstrating the use of Bulk FHIR APIs for research and learning through efforts such as ONC's Leading Edge Acceleration Projects (LEAP) in Health IT.[22]

All discussion participants were enthusiastic about the future promise of Bulk FHIR APIs, however, very few organizations had implemented any. Four discussion participants noted that their organizations were generally aware of Bulk FHIR APIs, but they had not yet successfully implemented them. Two organizations are implementing Bulk FHIR APIs as part of their EHR's upgrade to FHIR R4. Discussion participants reported that each health IT developer has a unique timeline for the rollout of Bulk FHIR APIs and when that functionality is available, their organization will work with their health IT developer to implement them. Specific use cases for Bulk FHIR APIs are described in the "Use Cases that Benefit from Integration of Apps" section below.

USE CASES THAT BENEFIT FROM INTEGRATION OF APPS

Many organizations are beginning to leverage APIs as part of their strategic plans to engage consumers and promote interoperability using apps. Successful implementations commonly identify specific use cases that might benefit from the integration and support provided by various apps. During discussions, participants indicated their shift towards more consumer engagement and described several use cases for apps that would assist in administrative processes such as patient scheduling, bill payment, patient flow and navigation, and collecting pre-registration forms before check-in. Additional use cases focused on patient-centered care and clinical workflows such as collecting and integrating PGHD into the patient's EHR, managing chronic conditions, tracking outcomes, and possibly developing or revising treatment plans.[23]

Discussion participants noted common themes across the following topics:

- Provider organizations most often implement apps to extend the core functionality of their EHR.
- Clinical care processes may improve by using apps that exchange structured data to calculate patient disease risk and support multiple clinical use cases.
- Bulk FHIR® APIs offer the potential to address emerging use cases in population health and research. However, they have not been widely implemented ahead of the regulatory deadlines.
- Write-back APIs may support advanced clinical decision support by integrating risk scores, SDOH data, PGHD, questionnaires, and other valuable data into the EHR.

Extending EHR's Core Functionality

Provider organizations reported they often implement apps to promote patient safety and organizational efficiency in clinical areas not adequately supported in the EHR (e.g., oncology, genomics, chronic disease management) or where apps facilitate a more seamless user interface that provides access to external data, information, or analytics. Current use cases include apps that enhance patient engagement and education, analytics and population health, clinical decision support, as well as care coordination and administrative processes such as patient scheduling and bill payment.

As described in the previous section, provider organizations are beginning to integrate apps to extend their EHR's core functionality, however, only two of the nine organizations reported the use of standardized APIs for provider-facing apps. Apps for risk scoring, clinical decision support, SDOH integration, and telehealth are currently used by early adopters with in-house FHIR and API expertise. In some cases, health IT developers who work with provider organizations to deploy new apps now incorporate similar functionality in their core EHR products.[24,25]

When asked about implementing standardized APIs for use in the provider setting, one discussion participant prioritized using APIs that facilitate the exchange of data between ancillary clinical systems, PGHD, and other sources to the EHR. This functionality has the potential to meet providers' specific clinical needs and eliminate requesting and waiting for the health IT developer to implement custom solutions to the EHR. Once implemented, this API-facilitated data exchange may result in improved patient safety and increased organizational efficiency. The discussion participant provided the example of exchanging structured clinical data elements (e.g., cholesterol values, smoking status) with a cardiovascular risk

calculator app integrated within the EHR to aid providers in clinical decision-making and offer an alternative to manually performing the calculation. Alternatively, another participant discussed simply adding hyperlinks in the EHR which launched a web-based risk calculator app, rather than implementing an app integrated within the EHR.

Data for Research and Population Health Using Bulk FHIR® APIs

A provision in the Final Rule requires health IT developers to support and make available to their customers the FHIR® Bulk Data Access API (i.e., Bulk FHIR) for group export by December 2022.[4] Non-standardized (i.e., proprietary) and standardized APIs such as Bulk FHIR are emerging as pathways for gathering critical patient data from disparate systems for research, clinical areas not currently supported by the EHR, and population health purposes. One participant said that apps outside the EHR are frequently implemented for oncology treatments and research purposes. For example, different therapies and treatment plans are often reported manually to oncology registries, however, apps using Bulk FHIR APIs may provide automated and more efficient processes to manage data required for registry reporting. However, mapping clinical data elements gathered using Bulk FHIR from EHRs to external data sets such as registries is more complex than integrating demographic and admission-discharge-transfer (ADT) information between health IT systems.

Discussion participants also reported few implementations of Bulk FHIR, particularly among smaller organizations with limited resources and expertise. Larger organizations may be ready to implement Bulk FHIR sooner as they may have more skilled resources, time, and budgets. Discussion participants spoke of organizational plans to implement Bulk FHIR but could not offer specific timelines. One participant also reported encountering limited marketplace availability of FHIR servers that support Bulk FHIR at this time.

A recent ONC and National Institutes of Health (NIH)-funded landscape analysis discussed how Bulk FHIR is implemented in a variety of use cases by pioneers in the health care industry for precision medicine research, chronic disease management, high-risk patient identification, population health analytics, fitness tracking, and medication adherence.[26] Discussion participants expressed great interest in using Bulk FHIR for similar use cases once their organizations implement Bulk FHIR.

In one example, a discussion participant described using the Center for Medicare and Medicaid Services (CMS) Data at the Point-of-Care Initiative (DPC). DPC provides Bulk FHIR data files to fee-for-service providers to treat active patients. With DPC, providers identify their rosters of patients to track, and no action is required from the beneficiary (i.e., the patient) to authorize sharing of data. Data are shared between covered entities for treatment purposes as defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[27]

Integration of External and Third-Party Data Using Write-Back APIs

Although read-only APIs that exchange patient-level EHR data with apps are most common in the market, particularly for patient-facing apps, discussion participants shared potential use cases for using write-back APIs with the ability to enter data directly into the EHR. Risk calculator scores, external data sources (e.g., SDOH data, PGHD), patient reported outcomes, remote patient monitoring (RPM) device data, and fitness trackers are gaining interest. Concurrently, health IT developers continue to expand the development, testing, and implementation of write-back APIs and include the necessary FHIR® resources in their published (i.e., publicly available) FHIR profiles to create or update more data types in the EHR.

As an example, one participant organization implemented an advance directive app that transfers patient-signed advance directives – forms often completed by patients to express their wishes to providers and families regarding medical treatment –back into the EHR. In this scenario, a physician writes a referral order in the EHR, it goes to the advance directive team's app using an API, the patient signs the form when prompted by the advance directive team, and the form is then filed in the EHR's document management system.

Discussion participants were also enthusiastic about the potential uses of write-back APIs for purposes of populating EHRs with PGHD. Discussion participants noted that some apps that collect PGHD may produce a summary view of multiple data points, or only highlight certain data points for the provider to review before any information may be entered into the EHR. Consequently, requiring manual intervention from a provider limits the ability to use an API to write-back data directly to the EHR. The ability to write back PGHD into a patient's EHR may offer critical information to the provider to support clinical decision support in a more automated fashion. In one example, the organization uses an app to compile the average blood pressure readings collected at a patient's home over a 6-to-10-day period. The information is sent to the EHR and routed to the provider, who then uses it for clinical decision support outside of the in-clinic patient encounter. Another discussion participant described a sepsis-related use case that collected data on sepsis risk factors and populated the EHR for review by the provider, thereby also improving clinical care.

Discussion participants described additional use cases implemented at their organizations that included using write-back APIs, such as one participant who discussed their development of an encounter notification system that watches for ADT events from other organizations and then pushes FHIR notifications back to the patient's EHR. The notifications are converted into an inbox message for the primary care provider and often contain clinical information that, otherwise, would not be available in the EHR, thereby improving clinical decision support and patient care.

Participants said that some health IT developers may support a limited number of discrete data elements that can leverage an API to write back to an EHR, such as populating a numeric field with a specific lab value. However, these fields are often limited and must be developed and customized by the organization to ensure that proper values are entered into the proper EHR fields.

Although discussion participants shared a variety of currently implemented and potential future use cases for write-back APIs to enter data directly in the EHR, they expressed caution about adding large amounts of data to the record. They cautioned that data needs to be useful to clinicians and not create clutter or extraneous information in the record. Discussion participants also noted that the needs of multiple clinical specialties may vary and require different data types. Therefore, it is crucial to evaluate each use case individually to determine its potential value to the organization and, ultimately, to patients.

IMPLEMENTATION CHALLENGES

While the adoption of APIs is growing among non-federal acute care hospitals, health care providers are still experiencing several challenges related to the implementation of these technologies.[28] For example, health IT developers are incorporating standardized APIs in their current EHR releases, but providers require time to upgrade, implement changes to workflows, and develop and deploy training and ongoing support for full adoption and use. In addition, each health IT developer has a different schedule for rolling out changes to individual customers. Developers are often backlogged due to upgrading customers off-hours and on weekends to limit production system impact, so provider organizations must accommodate these schedules as they plan for upgrades. At the same time, app developers who wish to leverage the new standardized APIs require access to provider organizations that are willing and able to test new functionality in their sandbox environments using FHIR® endpoints. These factors contribute to the current state where providers must often wait to implement API capabilities based on their health IT developer's schedule, which limits which app developers will be able to test their apps with any provider organization they choose.

While many provider-facing and patient-facing apps are emerging with early adopters with in-house informatics teams enthusiastic about app use, most provider organizations are challenged in navigating the current landscape. In addition, many provider organizations remain risk-averse, unaware of available apps, and look to their health IT developer to assist with implementation decisions. As a result, provider organizations have not yet implemented many apps, rather focusing on implementing core EHR functionality, internally developing apps using either proprietary or custom APIs, or only those standardized APIs that are required. Any additional use of APIs is considered most often when existing health IT systems cannot accomplish the desired function, or when the technology is warranted based on the strategic goals of the organization.

Across all discussions, participants provided various approaches to governance and implementation processes to address requests for new API or app functionality. Discussion participants reported that several of their organizations have a formalized, robust process to evaluate, strategize, prioritize, and implement new technologies; others reported that their organizations had no formal process. The organizations without formal governance procedures lacked the resources required for successful implementation and management of APIs and apps.

When asked to describe how their organizations manage the implementation of new API and app technologies, discussion participants provided insights on governance and implementation challenges based on their experiences working with health IT developers, internal staff, and third parties. These are represented in the following key themes:

- Health IT developers play a major role in the successful implementation, integration, and use of APIs and apps because the majority of organizations are not actively building and developing their own. Specific implementation challenges working with some health IT developers include:
  - Lack of available standardized API functionality;
  - Poor communication and project management; and
  - Lack of available or sufficient documentation, guidance, and support.

- Organizations have a shortage of experienced internal resources to implement, manage, and maintain APIs and apps, causing organizations to limit new API project initiatives.
- Governance models for APIs and apps vary between organizations - some have robust decision-making and approval processes, while others are more limited.
- Third-party data integrators or middleware solution providers may be contracted to perform the implementation, management, and maintenance of an organization's APIs and apps, which may reduce the overall cost and burden to the organization.
- Data quality and mapping challenges continue to delay successful implementations. Once the API-based system integration is complete, organizations must investigate the health IT developer's data mapping to ensure accuracy based upon organizational workflows and documentation practices.

Health IT Developer Support

Although organizations want to implement APIs and third-party apps (i.e., developed by other health care providers, pharmaceutical companies, researchers, and consumer product companies), all discussion participants agreed that the lack of available standardized APIs in some versions of their EHR software presents many difficulties when developing, implementing, or integrating an API or app. Discussion participants reported that certain APIs are not yet available in current versions within their organizations; this includes Bulk FHIR® APIs, write-back APIs, and APIs that can access specific data elements not in the United States Core Data for Interoperability (USCDI).[29] In many cases, organizations must wait for their health IT developer to complete the development and rollout of new software versions (in support of the Final Rule) to access standardized APIs. Due to implementation delays and compliance extensions related to the COVID-19 pandemic, participant discussions occurred before FHIR R4 was required to be implemented. Participants represented organizations using EHRs with FHIR DSTU2, STU3, and R4 standards. Therefore, some discussion participants used EHR versions that are not yet capable of connecting to R4-based apps.

> **"[The Health IT developer] says they have the capability and, on their website, you see a lot of the APIs and the apps and the connections…[but] I keep reaching out to get more information about these provider-centric apps that they have, and I'm not really getting anywhere…"**

Given that most organizations rely on their health IT developers to provide and manage APIs and apps, discussion participants agreed that it is essential for health IT developers to communicate effectively with them regarding API functionality, availability, timelines, and costs associated with the implementation of new features. While some health IT developers take a very active role in ensuring their customers have effectively upgraded and implemented API capabilities, others take a more passive and customer self-service approach where it is up to the customer to initiate the implementation process. Health IT developers who communicate well with their customers ensure that their systems are maintained and remain current when software changes or upgrades occur. For example, one discussion participant described receiving notes for FHIR APIs, PDF strategy guides, and handbooks to ease the transition from one version of FHIR to the next in their EHR. When asked about the project timeline to upgrade from DSTU2 to R4, the health

IT developer estimated it would take 4 to 8 weeks and 20 hours of resource time required from multiple provider organization team members.

In the self-service approach, once the software has been upgraded, it is up to the customer (provider organization) to enable the software and implement it and contact the health IT developer to troubleshoot if necessary. Discussion participants in this group described not receiving much support or information from their health IT developer. These participants reported they did not know when their health IT developer would be starting the standardized API implementation process and did not receive regular communications from their support contact.

Although the Final Rule requires that patient-access APIs be freely available from health IT developers, organizations must often pay health IT developers to test and support other APIs and apps. One discussion participant emphasized that, even when organizations can pay for the technology (i.e., APIs and apps) and support, implementation timelines vary because there is often a significant wait to schedule upgrades and support. Discussion participants observed that health IT developers may provide more attentive support to prestigious organizations, and smaller organizations can be negatively impacted.

Staffing and Resource Limitations

According to discussion participants and from what is known in the industry, many provider organizations' IT departments are understaffed, under-resourced, and lack the required expertise to implement and maintain both proprietary and standardized APIs. One discussion participant from a large organization described their organization as "lucky" because their IT department employs interface integration architects (including staff who participate in HL7 standards committees), engineers who focus on APIs, and individuals who serve on compliance committees. The interface integration architects understand the process of applying the different FHIR® standards. The dedicated engineers' primary task is to implement APIs, and are also responsible for continuous learning and knowledge-sharing when new standards emerge. The compliance committee ensures that regulations are being met. In contrast, one discussion participant described their organization's IT department staffing as "stretched thin" with staff members often playing multiple roles and spending most of their time providing general IT and end-user support to ensure smooth day-to-day operations. The participant did not have any in-house API integration expertise and did not have resources that could be partially dedicated or trained to support a new area of service. As a result, many smaller organizations do not have the resources to advance their digital health capabilities.

For organizations with the technical capabilities and internal teams to manage APIs, discussion participants felt that the cost-to-benefit ratio was often not high enough for the organization to investigate, develop, and implement many apps. One example provided was the use of risk calculator apps. The discussion participant explained that risk calculator apps requiring manual input of data were built and then either embedded into the EHR itself, white-listed as a link to a website, or saved into a library. The majority of risk scores or risk calculators at the organization are embedded into its EHR system, whether or not the risk calculator uses PGHD or pulls data directly from the EHR. Providers then access these risk calculators via their smartphone or computer. The discussion participant stated that although a risk calculator app may save a provider a few steps, it did not make sense for the organization to pursue its implementation based on the overall lack of risk calculator usage by the organization's providers and the increasing number of risk calculators built directly into the EHR. However, the discussion participant said that the organization would re-evaluate that decision when the use of risk calculators increased in provider workflows or is available natively or integrated within the EHR.

Governance and Evaluation Process

To better evaluate the potential benefits of implementing APIs and apps, discussion participants were asked about the need for guidance from an implementation perspective, specifically regarding governance processes used when considering patient or provider requests for a new app outside the existing EHR ecosystem. At the time of these discussions, provider organizations were still playing an active role in evaluating both patient-facing and provider-facing apps connected to their EHRs using DSTU2. Health IT developers are updating and upgrading health IT systems to implement the new FHIR R4 standardized API, required to be made available by December 31, 2022.

Provider organizations conducted a thorough evaluation and vetting process to determine the feasibility and security of implementing and integrating third-party apps. Throughout the discussions, participants reported the absence of a standardized way to investigate, evaluate, vet, and implement third-party apps. As a result, many organizations often encouraged users to use apps within the existing EHR ecosystem or those that had been vetted, approved and authorized by the organization.

> **"From our organization perspective--and we say this to the people that are requesting it--it's not just a no and we don't have time to deal with [adding third-party APIs and apps]. It is [the necessity of] evaluation and vetting."**

Although a patient or provider may ask to use a particular app for specific features and/or datasets, discussion participants emphasized that many desired features (e.g., telehealth, scheduling, bill pay, EHI management) are available via the patient portal or an app in the organization's app ecosystem. While there was a clear hesitancy to implement duplicative third-party apps, organizations will consider requests if the app or device in question offers additional benefits and/or functionalities beyond those offered by their health IT developer's app ecosystem.

Patient-Facing Apps

> **"Is this [third-party app] something that we can already do to leverage the platform that we have in place today? If this is outside of the platform, is the value worth the risk?"**

When asked if their organizations had a formal evaluation process for the implementation of patient-requested apps, the majority of discussion participants said they have not received any patient requests for specific apps. However, some organizations described the importance of conducting due diligence on third-party apps because they expressed their concerns and lack of industry standards for the investigation, evaluation, vetting, and implementation of apps. Their concern is that the onus is on the provider organization to ensure connectivity, safety, privacy, and security.

In April 2022, the Clinovations Government + Health team also reviewed current health IT developer capabilities to investigate R4 adoption and advancement in approaches for patient-facing app deployment. The team noted an increasing number of developers supported R4 and offered app developers the ability to publish apps to (provider) customers' endpoints, thus enabling the ability for patients to connect to available apps directly without contacting their provider organization. As a result, provider organizations may need to modify their governance and evaluation processes to keep pace with changing health IT developer capabilities and compliance with Final Rule requirements.

Provider-Facing Apps

> **"We'll go through the budgeting process with specific items that we know are upcoming for that year, but we also try to retain a pool that we can add some flexibility just because of the dynamic nature of technology and the changes that happen because of that."**

For provider-facing apps, one discussion participant described a process (seen in Figure 1 below) for vetting and evaluating requests for apps. Provider-facing apps are typically introduced to the organization by a clinician, researcher, or clinical department. Upon receipt of the request, the governance body (often called "Digital Transformation" or "Digital Innovation" teams at provider organizations) meets monthly and identifies whether the strategic plans and goals align with the provider-facing app requested. Once the strategic plans and goals and objectives are identified, the governance body decides whether the app fits into the organization's overall health IT strategic plan and budget. If the provider-facing app aligns with strategic objectives, the app must receive approval from executive and clinical leadership. To obtain approval, the app must provide measurable value, solve or address a defined problem, and have appropriate clinician and leadership engagement. Once the organization's governance body approves the app, the implementation process begins.

Figure 1. Sample Provider-Facing App Governance Process

API and App Management

Discussion participants noted that their organizations must consider the management and maintenance costs and resources necessary when implementing multiple APIs and apps. The number of resources needed, the required skill set, and costs associated with implementing and maintaining apps, may prompt some organizations to implement only apps currently available in their health IT developer's app gallery, rather than developing their apps or implementing third-party apps. Discussion participants from smaller organizations reported that the effort needed to maintain and manage the EHR is already burdensome, and they struggle to find qualified resources required for managing and maintaining third-party APIs and apps.

For larger organizations, discussion participants reflected on the time-consuming and resource-intensive implementation and maintenance resources required for the ongoing support of apps. There are rigorous processes required to collaborate with developers, track outages, and maintain strict security guidelines. Discussion participants also noted that since only some apps support the recent FHIR® R4 standard required by the Final Rule, they cannot take advantage of the full capabilities of that version.

> **"We want to do one thing and leverage one app to 100 percent. [If we] try to dilute that and bring in other information, we won't be able to do it well. As part of [the implementation process], organizations are now being asked to be a jack-of-all-trades. It's a challenge for an organization to really be able to do it well."**

Data Quality and Mapping

When an API is used to read from or write-back data to an EHR, most EHRs do not hard-code or default the data that is mapped to the API. Health IT developers offer configuration mechanisms for individual provider organizations to map data elements based on the organization's workflow and documentation practices. This mapping can be performed by either the health IT developer or the provider organization's health IT team. However, mapping across multiple provider organizations and sites - even within the same organization - can be a resource-intensive and iterative process. Although there is general variation among different EHRs, even within the same EHR system and organization, loosely standardized data along with local customizations can lead to data mapping challenges across provider types and sites.[30]

> **"Making APIs available is not the same thing as having them be useful."**

Most discussion participants agreed that the data shared by APIs with patients and providers must be useful and not just extracted for the sake of meeting a compliance requirement or testing new app functionality. As previously noted, discussion participants gave examples of using APIs to average blood pressures or share sepsis information as a useful way to provide relevant clinical information to patients and providers. Discussion participants shared their efforts to map the data, which included determining what FHIR resource to expose and documenting a variety of data quality issues. For example, an improperly entered birth date year in the EHR cannot be automatically corrected. Instead, it is flagged as a potential error. Discussion participants said that the goal for every app should be sharing only complete and useful information. They supported the adage that "the right app at the right time distributed widely could reshape clinical practice."[31]

PRIVACY AND SECURITY CONSIDERATIONS

While HIPAA provides a federal framework to support a patient's right to access and control where their health data is sent, the Final Rule outlines a technical capability that can be used to support that right of access. As previously mentioned, EHI incorporates terms (ePHI and DRS) defined by the regulations (Rules) issued under HIPAA through the use of APIs and apps of a patient's choosing.[32,33] The Final Rule requires health IT systems to provide access to the USCDI (data set) via APIs, and providers must allow patient-authorized apps to access an API. That access is authorized by the patient using authentication and authorization processes that are fully under the provider's control. Providers must allow any patient-authorized app to access an API to fulfill the right to access requirement.

Discussions with participants reflected the willingness by organizations to not only accept, but embrace, the integration of APIs and apps with their health IT systems for various purposes such as supporting clinical care and for patient access. In addition, under HIPAA, organizations and other data users may disclose de-identified data sets for research, population health, creation of real-world data (RWD), and other related purposes. However, this de-identified data still requires adequate privacy and security protections because it is possible for patients to be re-identified, even when certain data elements have been removed.

Organizations are interested in the gained functionality APIs and apps provide while also ensuring they comply with the HIPAA privacy and security requirements, prevent data breaches, reduce their liability, and maintain consumer trust. Organizations continue to be highly dependent on the existence of strong security programs, processes, technical safeguards, and assurances from third-party app developers.

Discussion participants agreed that strong privacy and security protections are critical for the successful implementation of APIs and health apps in the marketplace. While the ONC Final Rule does not allow providers or EHR vendors to impose security assessments that impede patient access to EHI through the app of their choice, providers expressed their privacy and security concerns and described their approach to preventing data breaches and ensuring the trust of third-party apps:

- Large organizations often employ a lengthy security risk assessment process to ensure that third-party apps requested by patients or providers can be trusted. Smaller organizations do not have the bandwidth to conduct security risk assessments for outside vendors and tend to consider apps an unnecessary security risk that they are unwilling or unable to manage.
- Provider organizations are concerned about the risk of data breaches associated with apps that are not approved by the health IT developer. These organizations limit the implementation of APIs and apps to those provided by the health IT developer and are included in its pre-approved app gallery to reduce the risk of a breach.
- Provider organizations are concerned that consumers lack understanding of how their data may be used, disclosed, and even sold without their knowledge.

Security Risk Assessment Process

Discussion participants noted that organizations may lack robust security risk assessment processes and trusted frameworks to manage data in third-party apps. Furthermore, many organizations do not have a governance structure in place to determine the necessary privacy and security workflows for apps.

However, participants said it is the responsibility of the organization to develop a process to test and monitor the app developers with whom they have a relationship. For third-party app developers who are not considered business associates of the provider organization, consumers must understand that the organization is not liable for how patient data is used or disclosed once it leaves the provider's secure environment.

Risk of Data Breaches

Recent security incidents, such as the September 2021 reported breach of over 61 million records[34] involving fitness trackers, wearable medical devices, and health apps, further highlight the need for organizations to carefully consider how to safely expose their sensitive and personally identifiable health information to technologies using APIs and apps.

Security research conducted in 2021[35] used penetration testing in a simulated cyberattack against several APIs and mobile apps and found that, apart from the two APIs built by EHR vendors, they were able to expose vulnerabilities in the systems, primarily due to implementation issues with third-party apps and middleware rather than the API technology itself. FHIR® uses best practice security standards, but just like any technology this does not entirely prevent a bad actor from exploiting it using tools that may expose sensitive data in unmanaged mobile devices and application logic. The 2021 security research identified five attack surfaces that bad actors could exploit:

1. User credentials,
2. App integrity,
3. Device integrity,
4. API channel integrity, and
5. API and service vulnerabilities.

Discussion participants agreed that standardized APIs allow for secure data exchange between relevant stakeholders and health apps. However, several discussion participants shared concerns about the risk of data breaches when using third-party apps. Provider organizations were willing to trust health apps widely accepted by the health care industry, such as Apple Health (iOS) and Common Health (Android). These apps have been deemed "safe" because they store patient data on users' devices, rather than in the cloud or on app developers' managed servers.

Consumer Understanding

Liability for breach, improper use, and disclosure falls to the covered entity or its business associates under HIPAA.[36] However, app developers are not considered covered entities or business associates. Discussion participants' expressed concern that despite this difference patients and consumers will hold an organization responsible for a breach in other ways such as affecting publicity, reputation, and resources required to resolve the complaint. Until consumers have a greater understanding of their responsibilities, these liability concerns have made many organizations risk averse when implementing APIs and apps. Once PHI leaves the protected environment of the organization, information may be at risk from third-party apps that store data on consumers' unmanaged mobile devices. Consumers are required to accept privacy policies when installing a third-party app, but they may not clearly understand all the privacy and security implications contained within the privacy policy. Discussion participants wanted app developers to provide users with clear, plain-language privacy policies regarding the future use and disclosures of health data with third parties (e.g., other healthcare providers, pharmaceutical companies, researchers, consumer product companies).

One discussion participant noted that consumers may not fully understand that, when they consent to data exchange via a third-party app, the app may continuously extract data for an extended period until the consumer revokes their consent. In addition, the consumer may not understand the specific data elements and volume of data that will be shared with that third party. This discussion participant said that more granular levels of consent are needed to provide consumers with additional transparency about specific data elements and explicit timeframes when their data will be stored and shared. Data sharing agreements may protect providers against liability, but consumers do not have any recourse in the case of a breach other than what the federal government may impose as a penalty on the third-party app developer.

REGULATORY COMPLIANCE

Under the Final Rule, providers must support consumers' rights without interference, consistent with information blocking provisions. Provider organizations are already required by HIPAA to provide access to PHI and required by CMS through the Promoting Interoperability Programs to show meaningful use of health IT systems.[37,38] The Promoting Interoperability Programs promote and prioritize interoperability; the exchange of healthcare data that extends beyond the existing requirements of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information.[39]

To comply with the Final Rule, providers and healthcare organizations must make patient data requests for information easy and inexpensive, including through the use of apps of their choosing.[40] Most discussion participants said their organizations are meeting both the Final Rule requirement to use standardized APIs and apps and a patient's HIPAA right to access PHI via their patient portal, but expressed several concerns related to regulatory requirements and potential liability issues, represented in the following key themes:

- The Final Rule's "information blocking" provisions continue to be a major driver for the adoption of standardized APIs that support consumer access to EHI under the Final Rule. Provider organizations want to maintain compliance and avoid being seen as "information blockers."
- Provider organizations want strategic alignment of health IT policy with incentives to support the implementation of policy-mandated new technologies. Moreover, organizations that are internally developing apps want additional policy guidance regarding reimbursement.

Information Blocking Provisions

Although a portion of the Final Rule focuses on health IT developers for certification of health IT systems, documentation, and costs, the "information blocking" provisions of the Final Rule are key to provider organizations achieving compliance with the Final Rule. Information blocking, as defined by ONC in their report to Congress in April of 2015, occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of EHI.[41] The Final Rule defines information blocking as: "an act or omission by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that:

- is likely to interfere with access, exchange, or use of EHI,[42]
- is not required by law or covered by an exception,[43] and;
- if the act or omission is conducted by:
  - a health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that the act or omission is likely to interfere with access, exchange, or use of EHI.
  - a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of EHI."[44]

When asked how the Final Rule and information blocking provisions affect their organization's health IT and digital health policy, four discussion participants directly acknowledged that the new information blocking provisions played a major role in shaping their organization's health IT and digital health policy. Overall, discussion participants said that their organizations were meeting ONC's requirement to grant patients access to their health information under HIPAA and the Final Rule. One discussion participant believed that organizations complied as long as they took the steps necessary to meet the needs of the population through the EHR's patient portal. Another discussion participant expressed the opinion that, if their EHR did not yet include the required standardized API functionality, they would need to wait to implement future functionality to meet Final Rule compliance deadlines. One participant also discussed the use of a single developer's EHR product by all organizations within a large urban geographic location, which reduced the need for apps to exchange health information because the organizations had enabled cross-organizational data sharing within the EHR. Another participant felt it would be difficult to meet the requirement of an "app of the patient's choice" because patients do not have the knowledge or understanding of which apps may provide them additional benefits.

Strategic Alignment and Incentives

When asked about the kind of support and guidance that could be provided from the federal government related to API and app implementation, four discussion participants emphasized the need for strategic alignment between the health policies enacted, such as the Cures Act and the Final Rule, and incentives so that organizations can obtain resources to implement newly required technologies and standards.

For organizations that are internally developing apps, three discussion participants cited the lack of reimbursement and payment programs in the health IT and digital health space as a barrier to the development of internally developed patient-facing and provider-facing apps. One discussion participant used RPM as an example. The provider organization is interested in implementing RPM technologies, but struggling to decipher the various business models among health IT developers and app developers and to understand the costs associated with the development, testing, and deployment of RPM technologies. Moreover, three discussion participants emphasized that their organizations are uncertain of the costs related to internal app development versus using existing apps from a health IT developer's app gallery. Such lack of clarity has resulted in organizations being more conservative in developing and implementing new apps.

> **"But [API and app development] almost needs some sort of guidance and some narrowing. To say to [us], now you have to support Fitbit, you have to figure out how to support Apple Health, you have to figure out how to support Garmin. I think that's a bit of a stretch because [we] are just making sure we do one thing right."**

Conclusion

Passage of the Cures Act and the Final Rule highlight the need for greater interoperability of health IT systems to promote advances in scientific discovery, clinical care, and consumer access to health information. This project, conducted in 2021 before some of the Final Rule compliance deadlines in 2022, sought to understand the perspectives of provider organizations as they work to implement the new standardized API functionality that is meant to increase interoperability and exchange of health information through the use of both provider-facing and patient-facing apps. Through discussions with participants about their experiences working with different health IT developers, use cases, resources, timelines, and strategic objectives, we gained a better understanding of the experiences, considerations, barriers, and challenges each organization faces as they strive to meet the goals of the regulations.

Providers are generally enthusiastic and supportive of using standardized APIs to extend core EHR functionality through the use of apps. Participant discussions focused on their motivations, regulatory and liability issues, governance models, implementation challenges, and privacy and security considerations for adopting the new API standards. As the industry moves toward implementing new standards and increased functionality of APIs and apps, provider organizations will need to modify their internal processes to adhere to regulatory requirements. The findings in this report provide insight into organizational successes, challenges, and barriers encountered as they work to implement APIs and apps in their environment.

- Primary motivations for using provider-facing apps include extending core EHR functionality, providing a more seamless user interface for clinicians, and using tools such as risk calculators to improve clinical decision support.
- Primary motivations for using patient-facing apps include meeting regulatory requirements, giving patients greater access to their electronic health information, and avoiding Information Blocking violations.
- The most cited regulatory challenge for providers was complying with new standards and Information Blocking rules, while also struggling to balance limited resources to implement new systems in their already complex environments.
- Frequently cited challenges and concerns with implementing patient-facing apps were protecting the security of data once it leaves the EHR, and educating consumers on the risks they take when sharing health information with third parties.
- Encouragingly, providers also shared some successes with implementing provider-facing apps that exchange data using standardized APIs for purposes such as completing patient questionnaires, collecting information from RPM devices, and using risk calculators to prevent certain diseases and assist in clinical decision support.

The report also reveals opportunities for ONC to support organizations by addressing current issues and providing additional policy guidance and consumer education to promote future use of APIs and apps. Key themes shared by the discussion participants highlighted the need for policy initiatives to be grounded in practical, usable, and beneficial tools for clinicians and consumers. Specifically, discussion participants

recommended that ONC consider the following when issuing future regulations or implementation guidance:

- Provider organizations have varied, and generally limited, resource capacities, technical capabilities, funding, risk tolerance, and internal processes to implement APIs and apps.
- Considerations for implementation and enforcement deadlines should allow for flexibility between different types of organizations and varying levels of EHR software readiness.
- Improved consumer understanding of privacy policies and security practices of app developers are needed to reduce the liability concerns of organizations as they share more data with third-party apps.

Useful information and a variety of insights were gathered from stakeholder interviews despite the small sample size and limited number and type of stakeholder groups represented across the discussion participants. These perspectives represent organizations that are relatively technologically advanced and early adopters of standardized APIs and apps. The opinions of individual participants may not necessarily reflect the perspectives or positions of their respective organizations. The open-ended nature of the discussions facilitated gathering valuable individual insights that may be able to be aggregated and synthesized across all stakeholder groups.

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