Current-State Assessment of Application Programming Interfaces (APIs) in Health Care
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Executive Summary

This report summarizes the Application Programming Interface (API) Technical Expert Panel (TEP) meeting, convened on December 7, 2018 to further inform NORC’s current-state analysis of API use in health care.¹

NORC’s assessment explored four thematic areas: 1) use cases and standards for APIs; 2) challenges, technical concerns, and facilitators for read and write capabilities; 3) outlook for future development of write capabilities; and 4) costs associated with API development, implementation, and use. NORC developed the API landscape assessment by reviewing published and grey literature, conducting a series of expert interviews with health care stakeholders operating in the API landscape, and thoroughly reviewing EHR app galleries.

The API TEP meeting provided a forum for a multidisciplinary group—representing electronic health record (EHR) vendors, API providers, application (app) developers, third-party platforms, large health care organizations (HCOs), and academic institutions—to provide insights into the development and use of APIs in health care. The API TEP’s goals for the meeting were fourfold: 1) discuss findings from the API landscape assessment developed by NORC; 2) identify near-term opportunities to advance API development and use with a focus on write APIs; 3) identify challenges to the development of patient-facing apps; and 4) discuss considerations related to the costs associated with API development, implementation, and use.

To begin the day, TEP participants provided feedback on the current API landscape assessment conducted by NORC; the TEP then participated in three deep-dive discussions related to the future of: 1) write APIs, 2) patient-facing apps, and 3) cost and pricing approaches that promote a robust API marketplace.

In the initial session discussing the results of NORC’s current API landscape assessment, TEP participants offered the following perspectives:

- Provider-facing apps are a primary focus for health data API access and exchanges.
- In defining API-related terminology for purposes of discussing, developing, and reporting findings of this current-state assessment, the term ‘API Users’ represents a broad swath of stakeholders—encompassing app developers, HCOs that develop their own apps, middleware vendors, third-party app marketplaces, providers, and patients.
- Replacing the term ‘Open APIs’ with ‘standards-based APIs’ would be preferable, to make clear that the focus is on APIs that are broadly available for developers to use, as opposed to proprietary APIs.

¹ This analysis was performed under contract to the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS). The opinions, findings, and conclusions or recommendations expressed in this report and/or its supporting materials are those of the author(s) and/or key informants who participated in the project and do not necessarily reflect the official policies or other views of HHS; nor does any mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.
Continued reliance on proprietary solutions would have the potential to increase the cost of API development and use, which ultimately is contrary to the goals of standardization and interoperability.

Encouraging adoption of an industry code of conduct among app developers could improve the information available to stakeholders—to help inform their decision-making around app use and provide a rubric against which apps could be evaluated. This approach, in turn, could help alleviate privacy and security concerns and increase the efficiency of the app vetting process.

In discussing the challenges associated with write APIs and opportunities to advance their development and use, given that the current landscape is dominated by read capable APIs, participants noted both concerns and opportunities.

Concerns participants raised about write APIs included:

- Risks associated with incorporating non-validated data into EHRs, from a patient, provider, and vendor perspective;
- Challenges in defining, standardizing, reconciling, and integrating incoming data from external systems into vendor EHRs with years’ worth of internal, proprietary information whose meaning, format, and use in context may differ substantially among EHRs;
- Interoperability challenges from variations in standards implementation (Fast Healthcare Interoperability Resources (FHIR), CCDA, etc.) that highlight the need to expand the range, types, and contexts of data available for exchange.

Opportunities participants suggested to promote the development and use of write APIs included:

- Focusing on write capabilities within high-value use cases;
- Pursuing data governance standards that offer patients and providers the right and capability to review patient-generated health data (PGHD) and patient reported outcomes (PRO), while preserving providers’ rights to approve data from trusted sources;
- Improving data provenance standards—covering inclusion of the necessary metadata, allowing the tracking of integrated data back to their original source using digital signatures from the patient and/or provider, and ensuring the data were not altered during transmission without prior permission.

In discussing the challenges and barriers to the development of patient-facing apps, participants surfaced several central themes:

- A need for aggregated patient health records and other strategies, both to increase patient access to health data and to reduce the patients’ burden of logging into multiple systems to access all their data;
- The potential for leveraging FHIR standards to facilitate interoperable access to, and aggregation, of patient health data from multiple sources;
Increasing visibility into the limits of Health Insurance Portability and Accountability Act (HIPAA) protections for aggregation and/or sharing of records via direct-to-consumer applications. In this context, participants made the point that—prior to agreeing to an application’s terms of use and trusting the application with their information—patients’ consent opportunities should make clear that when they use the application to access, store, or share data, the applications can (under those terms and based on that consent) access and share those data with third parties. The consent opportunities should also make clear to patients the uses to which their data may be put by the application developer or third parties, once patient consent has been given.

The need for caution in integrating PGHD/PRO directly into the EHR. The TEP discussion highlighted that, while PGHD/PRO has the potential to improve care for certain issues, these data also have the potential of being overly burdensome to manage and use. If this information were integrated into the EHR, it must be available in a context that is meaningful and actionable for clinicians and patients. Strategies participants brought up to address this issue include development of apps that aggregate, summarize, and interpret PGHD/PRO data. These apps would share concise information and specifically relevant or summarized data points with the EHRs, rather than reams of ‘raw’ patient data. It was noted that the increase of PGHD/PRO data integration into an EHR brings the demand for third-party groups to manage applications that are aggregating the data.

The meeting ended with a discussion of costs—which included not only the costs of API development and use, but also the pricing structures emerging in the market. While several TEP participants expressed general preferences for market-driven approaches to pricing, they also recognized the pressures that could result. Requiring EHR developers to offer API functionality without an opportunity to recoup their development costs could impose a burden that some, particularly smaller or start-up developers, might not be able to absorb. The TEP offered suggestions for protecting smaller or start-up developers:

- Enabling API developers to at least recoup their development costs, which would also help fuel innovation beyond what is required to meet a minimum standard;
- Providing increased transparency on available API functionality and API-related services and associated costs, which would help create a competitive and fair marketplace.
Introduction

This report summarizes the Application Programming Interface (API) Technical Expert Panel (TEP) meeting convened on December 7, 2018, to inform NORC’s current-state analysis of API use in health care. The information gathered during this session will be used to supplement the information NORC collected from the literature and the key informant interviews. All views expressed herein are TEP participant opinions, and do not constitute official positions on the part of the ONC.

The meeting began with opening remarks from Steve Posnack, Executive Director of the Office of Technology at ONC. His opening remarks were followed by introductions of the TEP participants, NORC research team, and ONC team. Prashila Dullabh (NORC) and Dean Sittig (University of Texas, Health Science Center) led the morning session with a presentation on key findings to date from NORC’s API landscape assessment on the development and use of APIs in health care. Following the morning session, the TEP held three in-depth discussions of three central issues in the field:

- Challenges and opportunities to promote write APIs;
- Challenges and barriers to increasing the development of patient-facing applications (apps);
- Cost considerations associated with API development, implementation, and use.

In the sections that follow, we present a synthesis of the TEP meeting discussion, highlighting near-term opportunities for promoting API use in health care.

API Landscape Assessment

The topics discussed and input provided by TEP participants during the presentation of NORC’s API landscape assessment fall under four major headings: API use case analysis, API landscape, API architecture, and application vetting.

API Use Case Analysis

To explore API use in health care, NORC proposed three high-level uses cases as an organizing construct for describing the exchange of data among different stakeholders, each depicting an example of API use to facilitate clinical document and clinical data elements access and exchange: 1) APIs used for bi-directional data exchange (i.e., write/write); 2) APIs used to contribute data to the electronic health record (EHR) (i.e., read or read/write); and 3) APIs used to aggregate data (i.e., read). TEP participants suggested expanding the use case framing as NORC presented it to include the use of provider-facing

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APIs. An illustrative example of an API rapidly growing in use by provider-facing health information technology (health IT) is Clinical Decision Support (CDS) Hooks, a vendor-agnostic solution that allows providers to pull and integrate useful information from disparate storage locations into their EHR workflow for clinical decision support.

Participants also suggested that it would be beneficial to specify the relevant API stakeholders in each use case description. The NORC team clarified that the key stakeholders were kept separate from the use case descriptions because the same stakeholder can take on different roles depending upon the use case.

**API Landscape**

To understand the health care API and app ecosystem, it is important to have a shared understanding of the various roles of the major players—specifically, who is designing, implementing, and using APIs. NORC presented the meeting participants with three items of terminology that might be used to distinguish API and application stakeholders for purposes of both the TEP discussion and NORC’s final report of findings from the as-is analysis of API use in health care. The three terminology items were: ‘API Technology Supplier,’ ‘API Data Provider,’ and ‘API User.’

- **API Technology Suppliers** were described by NORC as health IT developers and/or those offering solutions that facilitate access to electronic health information—including traditional EHR vendors, ‘middleware’ companies, and other developers/purveyors of solutions to store, access, or transmit electronic health information. Participants accepted that definition as stated.

- **API Data Providers** were described by NORC as holders of data that would be made accessible via an API. This includes health care providers of all configurations, from solo-practice doctors to the largest health care organizations (HCOs), other Health Insurance Portability and Accountability Act (HIPAA)-covered entities, patients themselves, and entities that host PGHD and longitudinal patient records databases. Participants accepted that definition as stated.

- **API Users** were described by NORC as the app developers themselves, including the following stakeholders: HCOs building their own apps, middleware vendors, and third-party app marketplaces. TEP participants discussed potentially modifying the NORC definition of API User to include ‘providers’ and ‘patient’—noting that patients and providers are routine users of API software; they determine and influence the flow of health data and, therefore, should also be considered API Users.

Participants also suggested an additional terminology change—replacing ‘Open-APIs’ with a term such as ‘standards-based’ APIs. Participants favored this change for two reasons: 1) to reduce confusion about the meaning of openness, and 2) to represent APIs that include comprehensive documentation and code examples for developers to use. Participants also described cultivating and maintaining an easy-to-use API as a potential way to encourage developers to produce innovative applications.

Following this discussion, NORC provided an overview of the major stakeholders in the movement of health information via APIs (Exhibit 1).
One TEP member brought the group’s attention to ongoing standards development project by CARIN Alliance to develop the CARIN Common Payer Consumer Data Set,³ which specifies the data elements and offers an implementation guide commercial payers could use to create a FHIR-based API to develop patient-facing apps. The goal of the Common Payer Consumer Data Set is to provide a set of consensus-based data elements analogous to or exceeding the Centers for Medicare & Medicaid Services’ (CMS) Blue Button API.⁴ This standardized data element set could be released to API Users for standards-based APIs. TEP participants also discussed standards developed by the Health Level Seven (HL7) initiative known as The DaVinci Project,⁵ which grants payers access to granular clinical data from multiple patients. The DaVinci Project is a way to align stakeholders around ways to improve payer access to big data to support better analytics and the reduction of administrative burden.

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³ https://www.carinalliance.com/our-work/health-plan/
⁵ http://www.hl7.org/about/davinci/index.cfm
API Architectures

In this part of the TEP discussion, NORC presented a diagram illustrating how different API architectures are designed and implemented to support the exchange of data from the data source (EHR database), to the presentation of the data, to the end-user, in different app configurations (Exhibit 2).

Exhibit 2. API Architectures

Apps can run in different configurations:

Multiple TEP members commented that the API architecture diagram as shown may be too narrowly defined for optimal use. They suggested the following enhancements:

- **Replacing the term ‘EHR database’ with ‘Data Source,’** to indicate that EHRs are not the only data source, but there is a wide variety of health data holders. Data Source was considered a clearer definition of the function of the stakeholder group API Data Provider.

- **Questioning the policies currently governing API Technology Suppliers.** Participants noted that, although API Technology Suppliers function as data access points and therefore control access to data, they are not necessarily responsible for implementing data authorization and access policies. This is potentially problematic, because creating data access points without clear authorization policies raises concerns about data security, with concerning implications for how data might be used.

- **Replacing the term ‘Proxy’ with ‘Data Aggregator,’** because the term proxy has multiple meanings that are context specific (e.g., an application that retrieves data from multiple sources or the remnants of the transactional processes). One TEP member cautioned that the growth of data aggregators that rely on proprietary solutions could have perverse effects on standardization and
the introduction of fees to API Users. The same TEP member cited an illustrative current example a Prescription Drug Monitoring Plan (PDMP) platform that charges for access.

- **Noting two new provider-focused use cases in which apps can be configured:** 1) business-to-business exchanges among HCOs, and 2) surveillance and predictive modeling applications to assist providers with care delivery optimization, population health management, and risk calculation. The former use case represents an example of apps with no user interface and/or apps that either do not use clinical data or do not have direct applications for patient care (e.g., administrative functions). As an example of the latter use case, one TEP member described a predictive modeling app that can be applied to better understand delays in the operating room by combining real-time location data with an event-processing algorithm, to increase visibility into what causes delays and how to intervene in real time to improve workflows.

### Application Vetting

NORC’s findings from the API landscape assessment indicated that provider-facing apps undergo more rigorous vetting procedures than direct-to-consumer apps. Typically, provider-facing apps undergo a two-tier vetting process for which similarly robust analog(s) do not yet exist in the direct-to-consumer space. First, apps are vetted by the EHR vendors considering an app for their galleries. Then, HCOs also vet apps before deciding whether to make an app available to their providers. TEP participants engaged in a robust discussion about the app vetting process, in which two themes emerged that centered on limitations to current vetting processes. First, the EHR vendor app vetting processes does not currently address workflow integration. As a result, HCOs expend significant resources on integration—costs that are not borne by the app developer. Second, current vetting processes do not scale, because the two-tier vetting process has individual HCOs vetting individual apps. To address the challenge of scalability, one TEP participant suggested an external validation process for apps, rather than the current two-tiered vetting process. Validation differs from vetting in that it is the process of checking whether the application satisfies the intended clinical use. The goal of validation would be to set criteria or benchmarks (e.g., a code of conduct) that API users could use to assess the security and privacy protections of different apps. Some TEP participants suggested there be transparency for API users on how a given app has been vetted (e.g., whether the apps has been subject to safety, usability, and/or security assessments.

Finally, a few TEP members suggested it would be beneficial for appropriately situated and skilled organizations to: 1) set standards on data use and privacy policy transparency for trustworthy applications; and 2) properly communicate this information to patients, along with how patients might begin to assess which applications meet or exceed such standards. HIPAA’s right of access, per existing regulations and Office of Civil Rights (OCR) guidance, does not permit a covered entity to refuse to release data to a third party of a patient’s choice if the covered entity does not approve of the third party or its practices. However, many HCOs are uncomfortable with releasing patient information to an app that may not serve the patients’ best interests (e.g., sharing data with bad actors). The TEP members referenced existing frameworks to guide app validation and/or informed consent. For example, the CARIN Alliance has developed a trust framework and voluntary code of conduct for stakeholders and organizations entrusted with Personally Identifiable Information (PII). The goal of the trust framework

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and code of conduct is to provide greater visibility into the obligations, risks, and best practices for managing PII outside HIPAA protections. One technical solution TEP participants discussed, as a way to protect and inform consumers, was a system that would allow digital endorsements of apps. As consumers consider which apps to trust, this system would provide health systems, consumers, and federal entities with additional information on whether, and by whom, the apps have been vetted and validated.

Summary of the API Landscape Assessment Discussion

TEP participants highlighted the following points to refine the findings from NORC’s API landscape assessment:

- *The importance of use cases for provider-facing apps.* Participants noted the emergence of specialty APIs in general, and cited CDS Hooks in particular as a high-value, standards-based API;
- *The potential of health-plan–specific API uses cases* for patient-facing and business-to-business apps as accelerators of minimum common data sets;
- *The utility of modifications to the API terminology* for purposes of NORC’s final report, and in the event the terminology was considered for other purposes: 1) adding patients and providers to the ‘API Data Users’ definition; 2) using ‘Data Source’ as a more encompassing description of the multiple entities from which data can originate; and 3) replacing the term ‘Open APIs’ with ‘standards-based APIs,’ to make clear that the reference was to APIs available to developers.

One near-term opportunity emerged in the TEP meeting regarding the challenges of app vetting and the need for greater efficiency in bringing provider and patient apps to market—namely, to explore, identify, and promote app developer Code(s) of Conduct or third party validators. This approach was described as a potential way to: 1) decrease the need for a two-tier app vetting process, and 2) reduce the burden and cost of entry.

Deep Dive Discussion 1: Challenges and Opportunities to Promote Write APIs

The goal of the first deep dive discussion was to understand the challenges and opportunities associated with write APIs. The conversation focused on three topics:

- Promoting standardization to accelerate the development of write apps;
- Data governance;
- Data provenance;
- Opportunities to promote write APIs.
Promoting Standardization

The discussion of write APIs began with participants noting that read applications dominate the current market. A number of factors were noted that contribute to this domination—the relative maturity of standards for read versus write, limited demand for write capabilities, and the pervasiveness of legacy EHR systems that continue to rely on proprietary APIs. Three concerns emerged around the challenges associated with write APIs:

- **Potential unintended consequences of writing large amounts of non-validated data, specifically PGHD, into the EHR.** Suggested approaches focused on mechanisms to aggregate, summarize, and validate incoming data prior to writing, such as using machine learning to summarize and interpret large volumes of data.

- **Uncertainty regarding the completeness of data that may be written to EHRs.** For example, an app might want to write an order for aspirin to a patient’s chart. However, that app may not provide the dose, frequency, route, start time, or charge code—leaving potential gaps in the record that would need to be filled in through other means.

- **Data mapping challenges from the lack of consistency in data meaning and formats among independent HCOs.** As one participant stated, “We are dealing with decades of proprietary information documented in different ways, which can be difficult to standardize.” TEP participants identified one approach to address data heterogeneity as developing code sets to constrain vocabulary for common use cases. Participants also noted variability in the versions of FHIR implemented by EHR vendors, which is further complicated by the use of local fields, among other customizations. For this reason, as noted in the discussion, EHR vendors have an easier time managing apps that use their proprietary APIs rather than FHIR APIs—which creates a challenge for third-party apps that want to write data into multiple EHRs.

**Potential Write Use Cases.** Due to the challenges described above, TEP participants acknowledged the difficulties of expanding the use of write APIs. However, they also noted opportunities to promote write APIs by taking an incremental approach that focuses on developing standards for certain high-value, low-risk use cases. Participants noted that, over time, interest in and technical capacity for higher complexity use cases is likely to increase as a consequence. There was also a conversation around the merit of prioritizing certain write use cases, such as a smoking cessation questionnaire. Other high-value use cases discussed at the meeting included:

- **Writing simple documents to the EHR from third-party apps that serve as an information filter.** For example, an API User could implement an automated method of incorporating data on a patient’s daily exercise activities in the form of a concise, textual summary of monthly accomplishments, rather than sending daily raw step counts to the EHR.

- **Writing questionnaire responses back into the EHR (e.g., smoking cessation questionnaires) and better leveraging PGHD and PRO data collection.** This could include:
  - Defining FHIR resources to assist in using PGHD and PROs in the calculation of clinical risk scores;
Innovating on the level of machine learning and predictive analytics, so that PGHD and PRO data are presented in an actionable format to providers at the point of care.

- Developing an app that enables patients to contact their providers and request edits to their record (e.g., medication lists). Participants noted that care must be taken to ensure that requested changes are corrections, rather than attempts to expunge potentially stigmatizing information (e.g., medications prescribed to treat HIV, mental health disorders, chronic conditions), which would be more appropriately addressed through consent-management standards.

- Leveraging specialized APIs (i.e., using CDS Hooks) that process data and provide clinical decision support, such as medication management.

Some participants also noted that several write use cases have been submitted to the Argonaut Project for consideration in the work to be prioritized for 2019. The suggestion was also made to focus on write use cases that may be part of the soon-to-be-released list of 2019 Argonaut Project priorities. Yet another suggestion that surfaced in the TEP meeting was to set priorities centered on ONC, wherein the TEP participants envisioned the agency establishing and promoting a vision that guides the market towards certain high-value, high-priority use cases.

Data Governance

This segment of the TEP discussion began with participants discussing how to define data governance as it relates to write APIs—that is, who has the authorization to write data into an EHR. Participants’ main concerns centered around three issues: 1) how HCOs would evaluate and validate external data, 2) how that information should or would be used, and 3) what new obligations might be placed on HCOs to act upon external data received. TEP participants noted that, since not all data are actionable or clinically useful, the provider should be responsible for approving clinical data before data are written in from outside sources. A proposed near-term solution would be to enable bi-directional (e.g., publish/subscribe) data exchange between a provider and a patient. This would enable a provider to flag data they want to request or review from their patient (e.g., specific questionnaires) and reject data they do not want sent/written (e.g., pedometer data).

Data Provenance

Participants noted the importance of data provenance, given the need to understand the source and quality of the incoming data. Since a patient’s electronic health data travel through many avenues, the associated metadata needs to reliably answer such key questions as: Who created the data? When were the data created? Were the data altered at any point, for what purpose, and by whom? One possible approach to facilitate source identification and prevent tampering would be the use of digital signatures to indicate whether data have been edited (or tampered with) and by whom, as the data were shared and re-shared across the various avenues of exchange.
Summary of Deep Dive Discussion 1

During the discussion of challenges and opportunities for write APIs, TEP participants identified several central themes: the need for increased standardization, the need for increased attention to data governance, and the capture and sharing of data provenance information. Together, development in these areas is necessary to create the conditions in which write APIs can be used by patients and providers with confidence. TEP participants generated a list of use cases for which write standards for APIs, and data governance and data provenance guidelines should be developed, concentrating on near-term opportunities:

- **Standards for questionnaires and questionnaire responses.** For example, taking a community-driven approach in which to develop standards for capturing smoking status as a discrete and high-value clinical use case example, and to demonstrate the feasibility of questionnaire functionality;
- **Development of limited common code sets to constrain vocabulary** for the most common medications, procedures, observations and document types;
- **Build out of data governance policies and procedures** through a use case–focused approach;
- **Use of digital signatures** as one mechanism for documenting and verifying data provenance.

Deep Dive Discussion 2: Challenges to the Development of Patient-Facing Apps

The focus of the second deep dive discussion was to understand the challenges and barriers related to increasing the development of patient-facing apps. The discussion focused on four topic areas:

- Use cases and challenges for patient-facing apps with write capabilities;
- Challenges regarding patient access to health information;
- Gaps and challenges related to apps facilitating patient access;
- Writing PGHD or PRO into EHRs.

Use for Patient-Facing Apps with Write Capabilities

Given the growing interest in write capabilities, the TEP participants identified a list of important common use cases for patient care, for which data could be collected via patient-facing apps and then potentially written into the clinical record:

- **Smoking cessation**—questionnaire-based monitoring and support;
- **PGHD/PRO**—e.g., home blood glucose monitoring;
- **Social determinants of health data** for more accurate and targeted capture of these variables, depending on the clinical concerns;
- **Identification of care gaps**—e.g., monitoring medication adherence;
- **Care plan creation and adherence**—e.g., scheduling and reminding patients about preventive care screenings, follow-up visits;
- **Lab results**—app-based tracking of the status of lab results, similar to shipping information and order tracking of packages;
- **Price comparisons**—using an app to compare charges for routine visits, procedures, prescriptions, etc.

Discussion of these use cases raised several specific challenges with regard to write functionalities, as discussed in the next section.

**Patient Access to Health Information via Portals**

As participants emphasized, ensuring patient access to their clinical data is vital for improving patient engagement, and a necessary component of ensuring EHRs provide value to patients. Participants centered their discussion of patient access challenges on the difficulty patients currently have, *via existing portals*, in gaining access to their health records and managing their information. Patients typically receive health care from multiple providers working in multiple health systems, which may or may not use the same EHR and may not share information in an interoperable way. EHRs are assigned to a specific portal, and portals enable authentication for the patient to have app and API access to their personal health information (PHI) (e.g., medications, lab results, discharge summaries). While patients have access to their PHI through portals, there are two main sets of challenges.

The first set of challenges comes from the patient perspective. Patient access currently requires special patient effort. Patient portals are generally tethered to a particular EHR, and apps generally rely on patient authentication via a portal. Therefore, if an EHR does not have an assigned portal, patients are unable to use apps to access their health data in the EHR without special effort (such as calling to request a paper copy of records). One scenario in which this authorization problem arises is when patients receive care from more than one provider entity across inpatient and ambulatory settings, which may lead to a patient having to contend with multiple portals. This can make it difficult for patients to manage their logins and to know which portal to access for a given piece of health information. In addition, for patients who see certain providers intermittently or rarely, it may be difficult for them to recollect their login information to access the portal.

One suggested solution to the patient access problem was the use of knowledge-based or two-factor authentication. This would allow patients to log into any portal that houses their health data, thereby substantially reducing the burden of accessing health data. According to TEP participants, the United States Department of Health and Human Services (DHHS) and the National Institute of Standards and Technology (NIST) have identified use cases for knowledge-based authentication. Another suggested solution, in which APIs can play a role, was to develop a ‘catch-all’ patient record, in which the patient’s health data are aggregated from multiple patient portals. This would necessitate the use of standards like FHIR and the sharing of FHIR endpoints among vendors, which would require vendor cooperation and maintenance. The benefit to patients would be a centralized record and interface displaying information from disparate health sources.
The second set of challenges TEP participants discussed was associated with the above type of solution: data discoverability and record security. FHIR standards alone do not guarantee interoperability. Implementation variability, lack of discoverability of FHIR endpoints, corruption of endpoints, etc. all necessitate vendor commitment to supporting a centralized record. In addition, it is difficult to ensure an aggregate record is correct in an environment of patient matching and provider matching across networks and portals. To do so effectively requires governance and portal technical specifications. One participant cited Qualified Health Information Networks as an example of a successful model of providing for record location and aggregation.

**Patient Access to Health Information via Apps**

Record aggregation by third-party companies via personal health records and/or direct-to-consumer apps was raised by TEP participants as another potential solution to patient access challenges. Participants were particularly concerned that, when patients are choosing and using the solutions discussed above, they may not have clear and understandable information regarding: 1) how the apps will protect the security of their data, and 2) how the third party’s terms of use or privacy policy might permit the company to use or disclose the patient’s information to others without seeking further, specific approval from the patient.

TEP participants discussed the ‘fine line’ between a patient’s right of access and autonomy in choosing an app, regardless of its trustworthiness, versus the benefits and complexities of designing a system for reviewing and approving apps. It was noted that little vetting is conducted for direct-to-consumer apps available through app galleries, but there are models elsewhere. CMS Blue Button 2.0 was discussed as an example of an API that has a thorough vetting process. However, one participant noted that app vetting for the broader community might not be a suitable role for CMS, as they do not have the infrastructure to support such vetting at scale.

TEP participants also noted that, while patients have the right to access copies of their medical records under HIPAA, patients may not be aware that HIPAA rights and protections do not apply if patients choose to share their health information with non–HIPAA covered entities. Sharing health information with apps that do not have a Business Associate Agreement with a HCO, in particular, can mean that HIPAA protections are no longer applicable. The Federal Trade Commission (FTC) oversees the information and responsibilities of the app developer. Although a code of conduct is being developed to guide companies who become stewards of health data, any such code would be voluntary and unenforceable. As such, lack of knowledge about patient rights and protections of their health data has become an increasingly problematic issue as more patients are interested in using apps to record PGHD, for example, and/or manage their health information.

TEP participants also expressed concern about the lack of transparency as to who is viewing patient data (including but not limited to PGHD), and how those data might be shared with other entities (e.g., research organizations, companies). This becomes an issue when patients inadvertently consent to secondary use of health information, including the selling of their protected health information (PHI). One TEP participant put it this way: “The government must provide clear guidance, so we do not have a Facebook situation down the road.” Another participant said, “The secondary use of health data is poorly disclosed to patients, and unethical.”
TEP participants emphasized the importance of patients knowing what they are agreeing to and what risks they are choosing to accept as they make decisions about the health IT solutions available for managing their data. In particular, TEP participants noted that patients must have understandable information on whether apps share and/or sell health data— and that this should not involve reading multiple pages of a consent policy or a policy stated in complex legal or technical language instead of plain, consumer-friendly terms. In addition, participants stressed that patients may not have a full understanding of all the different types of information contained in a particular FHIR resource (e.g., observations may include laboratory blood test results along with sensitive sexually transmitted disease information). TEP participants suggested that, within the health system environment, patients should be explicitly offered the option to opt-out of sharing their PGHD with individuals other than their health care providers.

The discussion then turned to issues of patient rights in choosing apps to manage their health information and ease of access to the same. Participants noted that, while there are risks associated with sharing health information with apps, which must be articulated to consumers, the Office for Civil Rights has made it clear that patients have the right to choose with whom they will share their data and for what purposes. Thus, one of the challenges patients encounter using direct-to-consumer apps to manage their care is the reluctance of their HCO to transmit patient health information to an app that has not been vetted by that organization.

Writing Patient-Contributed Data into EHRs

TEP participants flagged two concerns regarding the incorporation of PGHD/PROs into EHRs. Their first concern was the accuracy of the data generated by patients. Most patient-generated data are gathered from wearable and smart devices (e.g., Fitbit, Apple Watch, electronic scales, and blood pressure monitors), many of which are not approved by the Food and Drug Administration for clinical use or as medical grade equipment. It is unclear how accurate and reliable these data are, or the extent to which they should factor into a patient care plan or provider decision-making (e.g., the need to prescribe a medication). The second concern TEP participants expressed in this connection was about the preparedness of providers and HCOs to manage an influx of raw PGHD/PRO data, in addition to lack of mechanisms to incorporate these data into their clinical workflows in an efficient and meaningful way. Without a simplified means of reviewing PGHD/PROs, TEP participants stressed that providers may struggle to take action on information shared by patients.

One suggested solution was that specific apps be developed to provide a meaningful summary of the raw PGHD/PRO data, which should then be written to the EHR. Several TEP participants described a possible future in which EHRs and CDS systems could be made to function like data repositories that are leveraged to provide concise and customizable PGHD/PRO summaries to providers at the point of care (e.g., dashboards). This kind of automated system for PGHD/PRO summary and transfer would be preferable, in their view, to the burden associated with manual review of real-time or near real-time PGHD/PROs; and would, therefore, help facilitate appropriate use of these data in clinical decision making.

TEP participants stressed that the utility of incorporating PGHD or PROs into the EHR varies based on the use case. This led to a discussion around the potential for PGHD/PROs to have significant value in identifying care gaps, such as medication adherence. It was noted that PGHD/PRO patterns could provide
additional context to a provider, helping them see or prompt for more information on why a patient is not taking the prescribed medications (i.e., patient experiencing side effects, patient cannot afford the medication). In contrast, raw data (such as daily steps) may be of use in a patient’s weight management regime, but do not tend to be useful to a primary care provider.

Summary of Deep Dive Discussion 2

The main challenges raised by the TEP discussion of patient-facing apps and write capabilities centered on technical, operational, and workflow challenges to patient access to their health information, through both portals and apps. Patient options to create an aggregated health record are needed, coupled with the need to improve the discoverability of data and record security. In addition, more transparency into how apps use PHI for secondary use is necessary, as is patients’ informed consent for its use. Potential policy and technical opportunities include:

- Development of apps that summarize raw PGHD/PRO data;
- *More widespread use of knowledge-based or two-factor authentication* to ease the burden of logging into multiple portals to access health information (e.g., HHS and NIST offer current use cases for knowledge-based authentication);
- *Greater use of standards* like FHIR and the sharing of FHIR endpoints among vendors, which would facilitate patient use of a centralized record;
- Development of security-related protocols developers can use with FHIR standards;
- Patient education on their rights of access and on risks of health information sharing;
- Development of, and industry adherence to, codes of conduct for non–HIPAA-covered entities receiving health information from patients (e.g., through app use, PGHD).

Deep Dive Discussion 3: Cost Considerations Associated with API Development, Implementation, and Use

The focus of this deep dive discussion was to understand both: 1) the costs a developer incurs during development and operation of the API, and 2) the pricing of the products or services that use these APIs. The discussion focused on two topic areas:

- Reasonable costs associated with developing, operating, and maintaining APIs;
- Strategies to reduce costs and to promote a more open app marketplace.

Costs Associated with Operating and Implementing API Software

TEP participants discussed as an open question the issue of reasonable costs associated with development and operation of APIs. The discussion oscillated between the cost inputs needed to develop, implement, and operate API technology versus the prices developers/vendors charge their customers for software and associated services. As the discussion unfolded, however, a majority of TEP participants tended to focus
more on the pricing, or cost to customers such as HCOs, to obtain software and support needed to implement and access data via APIs.

Participant sentiment predominantly favored allowing market-driven approaches to set pricing. For example, participants felt that developers should manage the pricing structure for their API technology and API technology support services. Participants also agreed that APIs have costs associated with their development, and that more widespread use of these solutions would likely drive down the price of using APIs. It was noted, on the one hand, that these market forces are already visible, as prominent EHR vendors have recently modified their pricing structures. App developers, in most cases, currently pay for API usage in order to drive their business ventures. But participants also noted, on the other hand, that offering free APIs (i.e., API access offered without additional charges to the consumer or consumer app developer) could drive adoption of APIs and loyalty to the health system, although this would be of little direct business benefit to EHR vendors.

TEP participants expressed the belief that if APIs are mandatory, and not a source of at least gross revenue and cost recoupment, developers may do only the bare minimum to meet federal requirements, which could prevent an innovative and a competitive environment among apps. Participants also noted that costs associated with API implementation and operation vary based on characteristics of the apps and the exchange environment. Absent uniform standardization, custom development is often needed—both to enable connection with each specific app, and to deal with data variations among the underlying sources. It was also acknowledged that, while market forces may reduce the costs of API development, they do not address the implementation costs borne by HCOs.

One near-term opportunity proposed during the TEP discussion included charging a transactional fee, for which pricing is dependent upon the value of the transaction, along with a price cap, particularly for applications that are themselves free to their end users (such as patients or clinicians). Another proposed solution was pricing based on usage and/or volume, such as API calls. Taking into consideration the costs for bulk data APIs, participants suggested using a tiered costing model, in which app developers pay for a particular amount of data usage based on the volume of API calls over a fixed period. The cost would increase per tier, but the cost per API call would drop as consumption increased. Participants cautioned, however, against ‘nickel and diming’ people for transactions. A few TEP participants also called attention to the potential for pricing structures to create perverse incentives. For example cases where pricing is based on volume of calls—when API users, in an effort to reduce the number of API calls initiated, may try to request all of a patient’s information in a single call, rather than requesting only what is needed.

**Strategies to Reduce Costs and to Promote a More Open App Marketplace**

Participants highlighted a need for consistency among pricing models for APIs, stating that how much is charged currently for access to APIs varies, with large companies potentially able to negotiate better pricing. One approach participants proposed to promote cost consistency was to encourage transparency from companies on pricing models for APIs, as opposed to determining costs based on closed negotiations. This might include extending transparency beyond pricing, to clear descriptions of what services are associated with different pricing models (e.g., sandboxes, app testing and validation, service support). Participants also mentioned the possibility of declining overall API costs, as the supply of APIs increase and interoperability standards are refined and more widely implemented, with less unnecessary
variation across implementations. In order to promote a more open app marketplace, participants suggested that ONC might provide consumers with their own app marketplace, similar to the SMART on FHIR application gallery—which should allow users to easily distinguish the audience for whom the app is designed (e.g., clinician, patient).

Summary of Deep Dive Discussion 3

Three common themes emerged from the TEP discussion of API costs:

- **Transparency is essential** to establishing a fair and competitive app marketplace.
- **Use of transaction-based models for pricing is an ongoing challenge** when defining ‘reasonable’ pricing. Other models are available, all with pros and cons.
- **It is essential to include the burden to the health care system** when considering total system costs.

Acknowledgements

The TEP meeting provided a wealth of information to help inform the current state of APIs in health care. Participants represented a wide swath of the health care industry—from EHR vendors, API providers, app developers, and third-party platforms, to HCOs and academic institutions. NORC would like to thank all the participants for their support and valuable input.