



March 13, 2023

Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-0057-P  
Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850

***RE: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program***

Dear Administrator Brooks-LaSure:

On behalf of the CARIN Alliance, we want to thank you for providing the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule on Interoperability and Prior Authorization. We are excited about the efforts you have made to advance interoperability, reduce administrative burden, and accelerate consumers' access to health information.

As you are aware, the CARIN Alliance is a multi-sector group of stakeholders representing numerous hospitals, thousands of physicians, and millions of consumers and caregivers. We are committed to providing consumers and their authorized caregivers access to health information. Specifically, we are promoting the ability for consumers and their authorized caregivers to gain digital access to their health information via the open APIs mandated under MIPS/Stage 3 Meaningful Use (MU) ACI objectives and the use of 2015 Edition CEHRT to use that information in any third-party application they choose.

We are very supportive of many of the proposal included in CMS's rule to promote and encourage patients to get and use a digital copy of their own health information, specifically the expansion of the patient access API to include prior authorization information. We are especially encouraged by this addition as information about prior authorizations is critical for individuals as they navigate their care.

Again, we appreciate your consideration of our comments. Please do not hesitate in contacting me if you have any further questions.

Ryan Howells  
Leavitt Partners  
On behalf of the CARIN Alliance

## Patient Access API

CARIN Appreciates CMS's ongoing support of consumer access to information and the expansion of information within the Patient Access API to include prior authorization information. We support your efforts and provide some brief recommendations for advancing patient access in implementation.

### **Prior Authorization Information**

As noted above, we support CMS's ongoing focus on patient access to information. The primacy CMS has given to facilitating patient access, even in a rule focused on several business-to-business data interoperability requirements, is laudatory. We support the critical work of making sure patients, caregivers, care-partners, and consumers have access to information about prior authorization information. Nonetheless, we have several recommendations on how CMS can support endpoint discovery for the Patient Access APIs at regulated payers, recommended standardization of application onboarding, expansion of prior authorization information to include drugs in addition to services, and making sure that new requirements for payers and providers in the interoperability space does not crowd-out needed improvements and needed implementation support of the Patient Access API. CARIN has outlined many of our recommendations for registration in our draft Application Registration Implementation Guide.<sup>1</sup>

- *Endpoint discovery and application registration*
  - **Endpoint Discovery:** As noted in CMS's previous request for information on a National Directory for Health Providers and Services, "there is neither an authoritative source for digital contact information nor a consistent method for locating such information." This lack of an authoritative source, or even a consistent method to locate information, has created a challenge for many of the consumer-facing applications in the CARIN community. While a number of fee-based and free endpoint directories are beginning to emerge in the market, and this is a topic of discussion for the Trusted Exchange Framework and Common Agreement (TEFCA), the current process by which consumer-facing applications connect to FHIR endpoints is incredibly manual and tedious. While some providers, payers, and technology vendors are working to streamline endpoint discovery and registration, CARIN members describe the ongoing need to telephone many individual providers or payers, or even use their personal or professional social networks, to escalate their requests for discovering endpoints or initiating their application registration process. As we have previously commented, we strongly encourage CMS to work with the private sector in order to develop a free, publicly available endpoint directory that allows applications acting on behalf of consumers to easily access endpoint information. This could be done using EPCS data connected to digital identity work currently underway across CARIN, federal agencies, and the private sector.<sup>2</sup>
  - **Endpoint Registration:** Even after discovering API endpoints, CARIN members report a number of operational challenges throughout the registration and onboarding process. Incorporating operational standards into the national provider directory (NPD) could alleviate these challenges. For example, while registration may begin with either an email request or online form submission by an app developer, response times can extend

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<sup>1</sup> [https://www.carinalliance.com/wp-content/uploads/2021/07/CARIN-Alliance\\_App-Registration-IG\\_07222021.pdf](https://www.carinalliance.com/wp-content/uploads/2021/07/CARIN-Alliance_App-Registration-IG_07222021.pdf)

<sup>2</sup> See: <https://www.carinalliance.com/our-work/digitalidentity/>; ADD CARIN COMMENT ON NDHPS

to months, and require multiple follow ups. In more unusual cases, registration requires a login, but the endpoint does not direct app developers how to create or request one. Even when registration requests are acknowledged, CARIN members report waiting weeks or months for registration requests to be acted upon. In more unusual cases, implementers under CMS-9115 refuse to act upon a request unless and until a plan member or beneficiary affirmatively requests access to their data through a specific application.

- **Onboarding and Authorization:** CARIN members also report that the syntax and structure of capability statements for patient access APIs is variable, and often includes incomplete or out-of-date information, requiring email and telephone exchanges between connectors and implementers. Establishing a standard for these capability statements, along the lines of what Argonaut has done with branding guidelines<sup>3</sup> at patient access APIs would improve the onboarding workflows. In addition, capability statements should make clear when CMS covered payers support access to USCDI clinical information and members from their commercial lines of business.

As you know, certified (g)(10) APIs must be registered within a 15 day period. No such time requirement applies for CMS-9115 APIs. CARIN encourages CMS to consider imposing a reasonable registration time period to address delays reported by CARIN members throughout the onboarding and authorization process; for example, when requesting test accounts and sandbox access to implement and test API connections, when requesting troubleshooting support, or when requesting authorization to sandbox, and later, to production environments. We also recognize any reasonable timeframe would have to balance cybersecurity and related protocols plans must follow.

- **Consumer Education, Disclosures and Disclaimers:** CARIN members report significant variability in the data use and security questionnaires that app developers are asked to complete, and how these responses may be used in consumer education. CMS-9115 requires the questionnaire to be consistent with an appropriate security risk analysis of PHI in covered payers' own systems, and encourages covered payers to adopt an attestation framework to support consumer education. Our Application Registration Guide<sup>4</sup> encourages implementers not to interpose their own interpretations of an application's privacy, data and security practices. We believe CMS is best positioned to provide a trusted source of privacy education to consumers across their healthcare journey and would also be best positioned to evaluate the outreach of their consumer educational materials. We encourage plans and endpoint intermediaries to allow app developers to review and discuss potential privacy notices and characterizations a plan intends to make about each application.

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<sup>3</sup> Argo 22: Patient-access Brands and Endpoints, accessed on December 2, 2022 at <https://hackmd.io/@argonaut/patient-access-brands>

<sup>4</sup> [https://www.carinalliance.com/wp-content/uploads/2021/07/CARIN-Alliance\\_App-Registration-IG\\_07222021.pdf](https://www.carinalliance.com/wp-content/uploads/2021/07/CARIN-Alliance_App-Registration-IG_07222021.pdf)

- ***Prioritization of Patient Access API Implementation***
  - As noted previously, CARIN is exclusively focused on consumer access to health information. CARIN does not take a position on several of the proposals in the Provider Access API section, Payer to Payer Data Exchange on FHIR section, or Improving Prior Authorization Processes section of this proposed rule, although many members are supportive of these changes and are pleased to see the repurposing of the CARIN IG for Blue Button for various non-B2C use cases. Nonetheless, many CARIN members are concerned with the number of initiatives currently contemplated in CMS rulemaking and the impact these may have on implementation activities around Patient Access. As noted above, there is significant work that can and should be done to help impacted parties implement.
  
- ***Privacy Policy***
  - As we have noted in previous comments to CMS, CARIN and its members are committed to robust patient, caregiver, care-partner, and consumer privacy. CARIN has developed, and seen implemented widely across the sector, the CARIN Code of Conduct. We appreciate the CMS continued recommendation to look to the Code as an industry best practice.

CARIN also believes that additional clarifications for data holders are important as CMS moves forward with Patient Access implementation. Additional education is needed for regulated payers on what member education should include and how information is best presented to members. Additional education is needed for patients, caregivers, care-partners, and consumers about what it means to access information through a consumer-facing application, how to best protect data outside of HIPAA, the benefits of accessing and using your health data, and how to choose an application that works best for their individual situation. We encourage CMS to continue to provide educational resources and point to industry best-practices to provide all relevant parties with the needed education to ensure that privacy is protected while patient, caregiver, care-partner, and consumer access is advanced.

- ***Patient Access API Amendments***
  - CMS suggested that industry consider using the CARIN for Blue Button Implementation Guide (IG) for the Patient Access API.<sup>5</sup> CMS noted in their FAQs that while the previous version of the CARIN for Blue Button IG (STU 1 V1.0.0) did not include dental and vision claims, when an updated version of the CARIN for Blue Button IG is available which enables inclusion of additional claim types, impacted payers may use the updated version. We ask that CMS provide guidance on when they expect to update their guidance and proposed rulemaking to support oral and vision claims using the STU 2 (V2.0.0) version of the IG and to provide a date when CMS expects it will be enforced.

We ask that CMS update their guidance<sup>6</sup> to point to the latest version of the CARIN

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<sup>5</sup> <https://www.cms.gov/about-cms/obrhi/faqs>

<sup>6</sup> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>

for Blue Button IG STU2<sup>7</sup>.

We suggest that CMS develop a National Directory for Health Providers and Services as a way to establish easily discoverable HL7® FHIR® endpoints.

As the largest payer in the country, CMS should be included in the National Directory for Health Providers and Services and adopt TEFCA, which will provide a blueprint for other Payers to follow. As part of adopting TEFCA, CMS could offer its latest APIs (e.g. CMS Blue Button 2.0 API) through the National Directory to encourage Apps to discover endpoints and trusted entities to connect with.

CMS should also work to ensure that updates required as part of the Patient Access API amendments are consistent with ONC updates and requirements for Certified Electronic Health Record Technology and other Certified Health IT. Standards development updates should be consistent across agencies.

#### Payer to Payer Data Exchange on FHIR

- Medicare FFS:
  - While not explicitly addressed in this section of your proposed rule, CMS indicates intent to ensure that people with FFS Medicare benefit from the policies proposed and seeks comment on how these proposals could apply to Medicare FFS in the preamble. To accelerate interoperable data exchange, we recommend that CMS develop a Medicare Part A and B to C or “AB2C” API, enabling Medicare FFS to share data with MA plans. We urge CMS to align access to a new AB2C API with the ONC’s emerging FHIR-enabled Trusted Exchange Framework and Common Agreement (TEFCA). Making TEFCA the path for MA plans to access Medicare fee-for-service data could be a huge accelerator to TEFCA adoption overall while further accelerating the US toward health data interoperability. This will enable MA carriers to serve beneficiaries better, improve health outcomes and ensure that the patient data MA carriers provide to patients and providers includes the patients’ data from periods when they were beneficiaries of FFS Medicare.
- Identifying Previous and Concurrent Payer and Opt-in
  - Since Payer to Payer data exchange using FHIR is for the purpose of allowing a patient to easily facilitate the right to access their data from past and current payers with one request, consent should be an important feature of payer technology builds and CMS regulation. Patients should be able to provide consent through multiple modalities, such as OAuth 2.0, portal access, or other consumer interface that facilitates their ability to express their consent preferences. Technical guidance should be clear on what consent modalities are supported. As with other areas, consent should be consistent with other guidance, including those from ONC and the Office of Civil Rights.
- Leveraging the CARIN Implementation Guide for Blue Button for Payer-to-Payer and Provider Access Exchange:
  - As you know, the Proposed Rule requires the publication of Claims and Encounter

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<sup>7</sup> <https://build.fhir.org/ig/HL7/carin-bb/>

data without the financials. The CARIN IG for Blue Button already produces EOBs for In-Patient, Out-Patient, Professional, Pharmacy, Dental and Vision through a set of FHIR profiles. These same profiles could provide the required Non-Financial view of the EOBs to meet the requirements of the Proposed Rule by using the Summary view returned by FHIR's Summary parameter Search.

- A Non-Financial view of a CARIN IG EOB can be produced by applying the following updates to each of the CARIN IG EOB profiles:
  - Add a Summary flag ( $\Sigma$ ) to all non-financial elements or structures with MustSupport flag.
  - Remove the Summary flag ( $\Sigma$ ) from all financial elements or structures with MustSupport flag. Any mandatory cardinality constraint (i.e. minimum cardinality > 0) on such financial elements or structures would be relaxed (i.e. minimum cardinality = 0) and an invariant rule would be added instead to enforce this constraint on all EOBs except ones from the Summary parameter searches.
- The current guidance in the IG will be updated to reflect the Summary view of the profiles for the Non-Financial requirement.
- The benefits of this approach are:
  - Payers do not need to build and maintain more than one set of EOB Profiles
  - These Non-Financial Summary views of the CARIN EOBs would leverage the existing validation, testing and data extract work already invested in the Patient Access API.
- We encourage CMS to reference the potential of leveraging this IG for this purpose.

### Interoperability Standards for APIs

- Modifications to Required Standards for APIs
  - We encourage CMS to develop a strategy for how they decide which version of implementation guides or standards that they are enforcing at any given time. One opportunity in which to do that is by ensuring the latest version of the required IG is included in an openly available, free test harness such as the ONC's Inferno<sup>8</sup> testing tool. We are actively working with both ONC and CMS to build test scripts on the Inferno test suite to ensure CMS payers have a transparent and readily accessible way to test their compliance with the CMS interoperability requirements. We believe a model for compliance where CMS points to ONC's Inferno test tool for the latest version of the IG, while ensuring adequate time for the industry to meet the requirements of latest version of the IG is an effective way to help the industry remain up to date with the latest version of FHIR IGs over time and ensure a fully interoperable health care data ecosystem over time. Otherwise, the industry will become fragmented by having different version of different IGs that remain out of date and out of compliance with federal regulations and industry advancement of standards.

RFIs:

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<sup>8</sup> <https://inferno.healthit.gov/>

- Electronic Exchange of Behavioral Health Information
  - We appreciate the focus across HHS and the administration on behavioral health and on the exchange and use of behavioral health information. CARIN has previously commented on the need to ensure consumer access to Part 2 data and reiterate those comments here. We further encourage CMS to make sure any new requirements for electronic exchange of behavioral health information align with final rules from OCR and SAMHSA related to substance use disorder data.
- Improving the Electronic Exchange of Information in Medicare Fee-for-Service (FFS)
  - We believe there is an opportunity for the Medicare FFS team to adopt many of the artifacts we have implemented in CARIN. We think the Medicare FFS team can lead on the implementation of a NIST IAL2 Digital Identity solution consistent with the NIST 800-63 requirements. They can also add attestation to the CARIN code of conduct to the application registration process similar to what the Veteran's Health Administration and numerous other payers have done. Finally, they could implement the CARIN IG for Digital Insurance Card and the SMART Health Card specification so millions of Medicare FFS beneficiaries can have a secure, portable, and digital way to share their coverage information.
- Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)
  - Generally, TEFCA enables connectivity across a wider range of stakeholders holding patient data, thus being able to facilitate access to a more complete patient record for those with authorized access to those records. Such access has the opportunity to improve on patient care and overall management of one's health.
  - The Trusted Exchange Framework provides a number of capabilities that have the ability to advance the payer-patient interactions specifically:
    - A Common Agreement that reduces the need for individual agreements between Individual Access Services (IAS) providers and payers based on a common trust and privacy framework consistent with the HIPAA provisions applicable to covered entities and their business associates.
    - A patient discovery and record location established by the QHIN that would include record location with payers participating in TEFCA, thus enabling a patient to find their records across both providers and payers.
  - Additionally, as TEFCA expands beyond the treatment and individual access services into other use cases, the ability to share data more efficient would generally reduce the friction resulting from missing data and gaps in point-to-point data sharing agreements.
  - These opportunities create a valuable opportunity and need for payers to join TEFCA streamlining their ability to support connections with multiple IAS providers and reduce friction for patients to access their complete record across multiple providers, payers, and other stakeholders.
  - Considering the advances in technologies, we encourage CMS to work with ONC to explore and clarify how FHIR based exchange, as proposed for the Patient Access API can be fast tracked with minimal QHIN infrastructure requirements, thus taking advantage of the Common Agreement to start and expanding use over time as QHINs enable patient discovery and record location as well as advance facilitated FHIR based exchange.

- *Expansion of Prior Authorization Information to Drugs*
  - CARIN recognizes the regulatory and operational challenges of requiring drug-related prior authorization information flowing to patients, caregivers, care-partners, and consumers. We also acknowledge, as CMS notes, that other regulatory paradigms, as well as different data standards, may exist for drugs. However, we believe that it is critically important for patients, caregivers, care-partners and consumers to have access to that information. Several CARIN members, patients and caregivers, have had challenges with drug prior authorizations, including situations where formularies change without notice and where information about timelines and appeals is not forthcoming. One caregiver advocate experienced a particularly stressful situation with her son in refilling a necessary medication that unexpectedly required a prior authorization. During the days between notification of the PA need and the resolution of the PA, she was left without information about the status of that prior authorization,

This information asymmetry could be eliminated if drug prior authorization information were included in the Patient Access API. While the CARIN community, and other FHIR accelerators, will continue to advance private-sector solutions, we encourage CMS to consider ways it can support all actors in facilitating better data flow for drug prior authorizations.