Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-9123-P

Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications

Dear Administrator Verma,

On behalf of the CARIN Alliance, we thank you for the opportunity to comment on the proposed rule for promoting patient access and interoperability. We appreciate your consideration of our comments.

The CARIN Alliance is a multi-sector group of stakeholders representing numerous hospitals, thousands of physicians, millions of consumers, individuals, and caregivers. We are committed to enabling consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals. Specifically, we are promoting the ability for consumers and their authorized caregivers to gain digital access to their health information via open APIs.

We want to thank CMS for the number of advancements that you have made and the focus that you have brought to empowering consumers with access to their digital health information. Through MyHealthEData, Blue Button 2.0, the Promoting Interoperability Program, CMS-9115-F, and other initiatives, CMS has significantly advanced industry efforts to empower consumers and their authorized caregivers with access to their health information.

Overall, we are supportive of the proposed rule, **but want to emphasize that as a CARIN community we have not had enough time to develop consensus on many of these important topics given the short comment period and would request extending the comment period.** We've done our best to indicate where we have support and areas where we need more clarification from CMS and/or discussion within the CARIN community before commenting further.

Again, we appreciate your work here and your consideration of our comments. If you have any questions or additional follow-up, please contact me at ryan.howells@leavittpartners.com.

RR Ryan Howells

Ryan Howells
Leavitt Partners
On behalf of the CARIN Alliance

Comment Structure and Format: Our comments below follow a consistent pattern. We first list the CMS preamble and/or regulatory language in **black text** followed by our CARIN Alliance response in **blue text** while trying to group similar themed comments together. We also generally try and list the topics in the same sequential order that is outlined in the proposed rule.

CMS preamble language:
We believe aligning these policies across all payers would benefit all payers alike.

While we currently do not believe it is necessary to apply these policies to Medicare Advantage organizations at this time, we intend to further evaluate the implementation of these policies to determine whether they would also be appropriate to apply to Medicare Advantage organizations for future rulemaking.

CARIN Response:
The CARIN Alliance strongly believes CMS should apply the finalized requirements in CMS-9123 to the same set of payers listed in CMS-9115-F, this includes Medicare Advantage payers. The CARIN Alliance agrees with CMS that aligning these policies across all regulated payers and product types would benefit both payers and members alike. Practically speaking, it would be incredibly difficult, time consuming, and unduly costly to the health care system for payers to implement two different technology approaches for patient access based on which specific line of business the member has enrolled in. It would also be extremely confusing, frustrating, and inconsistent for members to have different experiences across different lines of business. CMS has applied a consistent approach to all government-regulated payers as part of CMS-9115-F and should do the same for CMS-9123-P whether in the final rule or in future rule making.

CMS language:
When we first finalized the CMS Interoperability and Patient Access final rule [CMS-9115-F] and suggested IGs payers could use to implement the APIs, we only suggested the US Core IG; however, some payers informed us that they preferred to leverage the PDex IG because it offered additional resources for payer-specific use CMS-9123-P cases and was compatible with the US Core IG ensuring interoperable data regardless of which IG was used. We seek comment on the pros and cons of requiring the use of either one of these IGs or if only one of the two proposed IGs should ultimately be required and why.

CARIN Response:
The payers within the CARIN Alliance are split between using US Core IG vs. the PDex IG to exchange clinical data between payers. There are pros and cons related to both approaches depending on the individual payer's data retention and exchange strategy. As such, the CARIN Alliance appreciates the option CMS has provided to payers to use either the US Core IG or the PDex IG to exchange clinical data payer-to-payer.

CMS language:
We did not include information about prescription drugs and/or covered outpatient drugs in any of the proposals in this rule. However, we are interested in better understanding the benefits and challenges of potentially including drug information in future rulemaking. For example, what specific considerations should we take into account? Are there unique considerations related to the role Pharmacy Benefit Managers (PBMs) play in this process? Overall, we do think it would be very valuable to payers, providers, and patients to have information about a patient's prescription drug and/or covered outpatient drug

pending and active prior authorization decisions, and we would like to better understand how to most efficiently and effectively consider including this information in these API provisions in the future.

CARIN Response:

We appreciate the interest CMS has in potentially including drug information in future rulemaking. The CARIN Alliance has done extensive work in this area and has commented to CMS when CMS-9115 was being proposed on the benefits of providing the member with information on their formulary and pharmacy benefit information.[1]

The CARIN Alliance believes that individual consumers have a right to know about the real-time cost of their prescribed pharmaceuticals so they can engage in shared decision-making with their provider to find the drug that is more economical or efficacious for their specific situation. We believe patients can help in proactively being able to work in conjunction with their provider to determine which drug would work best when considering a member's formulary and benefit information, out-of-pocket costs, therapeutic alternatives, and cash price.

Last summer, the CARIN Alliance worked within the HL7® FHIR® community as one of their accelerator programs to ballot and publish the STU1 version of the CARIN Consumer Real-Time Pharmacy Benefit Check IG.[2] This implementation guide provides the ability for a consumer to use an application of their choice to access real-time formulary and benefit information via an HL7® FHIR® API so they can know how a prescribed drug will affect their out-of-pocket costs. CARIN supports and appreciates the work CMS has done to promote the adoption of the Payer Data Exchange US Drug Formulary IG which allows a member to select a plan that covers the prescribed drugs a member is currently taking.

CMS[3] and Congress[4] have both recently discussed the benefits of a real-time pharmacy benefit check tool for physicians. In fact, CMS has recently required a real-time pharmacy benefit tool be available to physicians in final rule making but has stopped short of making that same information available to patients via an API accessible to a consumer in an application of their choice. The CARIN Alliance believes it is important to provide the same information to patients as we do to providers today. **As such, the CARIN Alliance suggests CMS include the CARIN Consumer Real-Time Pharmacy Benefit Check IG to meet the Beneficiary real-time benefit tool (RTBT) requirement discussed as part of the requirements CMS has identified that will be addressed later in future rule making.[5]**

CMS language:

As we discussed in the CMS Interoperability and Patient Access final rule (85 FR 25550), payers can look to industry best practices, including the CARIN Alliance's Code of Conduct and the ONC Model Privacy Notice for other provisions to include in their attestation request that best meet the needs of their patient population. In particular, we believe that explaining certain practices around privacy and security in a patient-friendly, easy-to-read privacy policy would help inform patients about an app's practices for handling their data. It helps patients understand if and how the app will protect their health information and how they can be an active participant in the protection of their information. Also, as explained in the CMS Interoperability and Patient Access final rule (85 FR 25517), if an app has a written privacy policy and does not follow the policies as written, the Federal Trade Commission (FTC) has authority to take action.

[1] https://www.carinalliance.com/wp-content/uploads/2019/06/CARIN_Patient-Access-and-Interoperability_Final.pdf
[2] Link to the HL7® FHIR® STU1 published version of the CARIN Consumer Real-Time Pharmacy Benefit Check IG: http://build.fhir.org/ig/HL7/carin-rtpbc/
[3] https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-02085.pdf#page=560
[4] https://docs.house.gov/billsthisweek/20201221/BILLS-116HR133SA-RCP-116-68.pdf
[5] https://www.govinfo.gov/content/pkg/FR-2020-06-02/pdf/2020-11342.pdf

CARIN Response:
We greatly appreciate that CMS references the CARIN Alliance Code of Conduct as one of the industry standards for how third-party applications who are not covered by HIPAA should handle and protect health data. Since the CARIN Alliance first released the Code of Conduct in 2018 with the input of over 60 different stakeholders[6], it has become the industry standard set of best practices for applications to attest to when accessing personally identifiable health information from HIPAA covered entities or their business associates.

For years, the FTC has suggested industries adopt best practices for how to engage with consumers such as making sure they have 'express, informed consent'[7] or as the CARIN Code of Conduct requires 'informed, proactive consent'[8] whenever an organization is acting on a consumer's behalf. The FTC has held hearings recently on how to protect consumers in the 21st Century by holding industries accountable by encouraging industries to voluntarily adopt industry-specific codes of conduct so there are appropriately tailored, adequate and consistent consumer protections and regulatory enforcement abilities under Section 5a of the FTC Act[9].

On December 1, 2020, we had the opportunity to present at the Office of National Coordinator's Accelerating APIs in Healthcare event and discuss how multiple large national payers use or plan to use the CARIN Code of Conduct in production including: Cambia Health Solutions, CVS Health, BCBS of Florida, Centene, UPMC, Cigna, and the Veteran's Health Administration[10]. We believe other payers will be following their example in 2021 although we are also aware of other codes of conduct that have been or will be developed by the industry.

As such, we believe CMS should support payers adopting the CARIN Code of Conduct as the industry standard for application attestation to ensure appropriate FTC regulatory enforcement and consistency in helping protect consumers no matter which application they choose to access their health information. We believe allowing the industry to implement multiple codes of conduct for applications to attest to could significantly impact the growth of the consumer-facing application ecosystem because those applications would need to customize their applications to meet multiple different standards. It may also impact the ability of the FTC to enforce a single industry standard and therefore leave consumers at risk of their data being used inappropriately.

CMS language:
At a minimum, we propose that the requested attestation include whether:
● The app has a privacy policy that is publicly available and accessible at all times, including updated versions, and that is written in plain language, and the third-party app developer has affirmatively shared this privacy policy with the patient prior to the patient authorizing the app to access their health information.

To "affirmatively share" means that the patient had to take an action to indicate they saw the privacy policy, such as click or check a box or boxes.
● The app's privacy policy includes, at a minimum, the following important information:

[6] https://www.prnewswire.com/news-releases/voluntary-code-of-conduct-developed-by-more-than-60-industry-stakeholders-can-help-facilitate-health-data-exchange-with-entities-not-covered-by-hipaa-300755734.html
[7] https://www.ftc.gov/news-events/blogs/business-blog/2014/07/top-billing-5-best-practices-mobile-industry
[8] https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/
[9] https://www.ftc.gov/news-events/events-calendar/ftc-hearing-competition-consumer-protection-21st-century-february-2019
[10] https://www.youtube.com/watch?v=TI8Kwz17OxE&feature=youtu.be

++ How a patient's health information may be accessed, exchanged, or used by any person or other entity, including whether the patient's health information may be shared or sold at any time (including in the future);
++ A requirement for express consent from a patient before the patient's health information is accessed, exchanged, or used, including receiving express consent before a patient's health information is shared or sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction);
++ If an app will access any other information from a patient's device; and
++ How a patient can discontinue app access to their data and what the app's policy and process is for disposing of a patient's data once the patient has withdrawn consent.

CARIN Response:
We fully support the minimum requirements CMS has outlined above, including their definition for how applications 'affirmatively share' their privacy policies with consumers and a requirement to obtain 'express consent' from a patient before the patient's health information is accessed.

The CARIN Code of Conduct accommodates each of these requirements plus additional best practices that go above and beyond these minimum requirements.

CMS language:
We propose that impacted payers must request the third-party app developer's attestation at the time the third-party app engages the API. Under our proposal, the payer must inform the patient within 24 hours of requesting the attestation from the app developer of the status of the attestation – positive, negative, or no response, with a clear explanation of what each means. The patient would then have 24 hours to respond to this information. For instance, if the app developer cannot attest that the app meets these provisions, or if there is no response to the payer's request for the attestation, the payer can inform the patient there may be risk associated with sharing their health information with the app. The patient may choose to change his or her mind and, at that point, the payer would no longer be obligated to release the patient's data via the API. However, if the patient does not respond or the patient indicates they would like their information made available regardless, the payer would be obligated to make the data available via the API. The patient would have already authorized the app to access their data, as the request from the payer for an attestation could only happen after the patient has already authorized the app to access their information and provided information about their payer to the app. As a result, the patient's original request must be honored. Because the patient has already consented to the app receiving their data, it is important that this process not overly delay the patient's access to their health information via the app of their choice. However, we are interested in comments from the public that discuss this process, and the payer's obligation to send the data regardless of whether or not the patient responds to the payer after notification of the app's attestation results, specifically notification if the app does not attest to meeting the above privacy provisions.

CARIN Response:
While we believe we understand what CMS is trying to accomplish, the CARIN Alliance does not support the CMS proposed requirement that impacted payers must request the third-party application developer attest "at the time the third-party app engages the API". **Instead, the CARIN Alliance recommends that CMS require that the application attestation be requested as part of the application registration process.** We also believe that the content of consumer education should be comparatively high-level. More detailed information that extrapolates from attestation questionnaires can lead to inaccuracies about a particular application's data practices, and different displays for consumers when they request data from different payers using the same application.

For the attestation process, the CARIN Alliance recommends that CMS require payers to ask third party app developers during the application registration process to validate whether or not it has already attested to an industry set of best practices, like the CARIN Code of Conduct. This approach would streamline the attestation process and reduce variability in the consumer education displayed by different payers when consumers give permission to the same application to access their data.

CMS language:

We are particularly interested in hearing feedback on how best to engage available industry-led initiatives, as well as the level of flexibility payers think is appropriate for defining the process for requesting, obtaining, and informing patients about the attestation. For instance, would payers prefer that CMS require the specific types of communication methods payers can use to inform patients about the attestation result, such as via e-mail or text or other electronic communication only? How should CMS account for third-party solutions that present a list of apps that have already attested? In this situation a payer would not need to take action for these apps, but would need to have a process in place for apps not included on such a list.

We recognize that there are many ways that an impacted payer could meet this proposed requirement and we do not wish to be overly prescriptive regarding how each payer could implement this process. For instance, a reliable private industry third party may offer a pathway for apps to attest that they have established a minimum set of privacy provisions to be in compliance with this proposed requirement. A payer could work with such an organization to meet this requirement. Or an impacted payer could establish its own process and procedures to meet this proposed requirement. This process could be automated. We believe it is important to allow the market to develop and make available innovative solutions, and we do not look to preclude use of such options and services. Regardless of this proposed flexibility, impacted payers must not discriminate in implementation of this proposed requirement, including for the purposes of competitive advantage. Whatever method a payer might choose to employ to meet this proposed requirement, the method must be applied equitably across all apps requesting access to the payer's Patient Access API.

CARIN Response:

The CARIN Alliance has developed a website called MyHealthApplication.com, which lists each of the third-party applications that have attested and signed the CARIN code of conduct. We developed this website based on feedback received from the payer community after payers were asking third-party applications to physically sign the CARIN Code of Conduct so payers would have a copy of the application's attestation as part of their records. Rather than having applications sign the Code multiple times or have certain applications not attest to the code, we worked with the application community and had them use DocuSign to attest to the current version of the Code so that any data holder can have access to that information from a centralized location. In the future, we will be working to automate this process using secure technology approaches so data holders will be able to call for and receive a signed certificate or web token from the MyHealthApplication.com website indicating which applications have attested to the latest version of the CARIN Code of Conduct.

For more information on the process we follow for applications to be listed on the MyHealthApplication.com website, please see the footnote below[11].

CMS language:

We also request comment on whether the request for the app developer to attest to certain privacy provisions should be an attestation that all provisions are in place, as it is currently proposed, or if the app

[11] https://myhealthapplication.com/list-your-app

developer should have to attest to each provision independently. We wish to understand the operational considerations of an "all or nothing" versus "line-item" approach to the attestation for both the app developers and the payers who would have to communicate this information to patients. And, we wish to understand the value to patients of the two possible approaches.

We request comment on the proposal to require impacted payers to request a privacy policy attestation from third-party app developers.

CARIN Response:
The CARIN Alliance has always believed that applications must attest to the CARIN Code of Conduct as an "all or nothing" versus "line-item" approach. A few of the reasons we believe this are listed below:

1) Consumer-facing applications are competing based on how they keep a consumer's data private and secure. Therefore, it is to everyone's advantage (e.g., the application, the data holder, and the individual) for an application to attest to everything in the Code rather than following a "line-item" approach.
2) A "line-item" approach would mean someone would need to make a value judgement on individual components of the Code of Conduct and how they may or may not affect the other requirements of the code. This would defeat the purpose of having an interrelated code that addresses each of the areas an application needs to follow and would also require an individual or organization to make value judgements on behalf of the individual which is not in line with the principles of consumer-directed exchange.
3) A "line-item" approach would mean the code would be implemented in different ways by different data holders therefore eliminating the ability for the healthcare industry to have a single common industry code that all data holders will use with all applications.
4) We expect the Code of Conduct to expand and improve over time. Allowing for a "line-item" approach would potentially negate the ability for the industry and individuals to take advantage of these improvements over time.

Therefore, we would ask CMS to ensure that applications take an "all or nothing" approach to attesting to the CARIN Code of Conduct. We also would reiterate our ask for CMS to point to the CARIN Code of Conduct as the industry standard for applications to attest to minimize the risk associated with having multiple different standards in the market that could impact the FTC's ability to enforce those standards and negatively impact the consumer experience when they use multiple different applications across multiple data holders.

CMS language:

Specifically, we propose that these payers report quarterly:
● The total number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app; and
● The number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app more than once. Tracking multiple transfers of data would indicate repeat access showing patients are either using multiple apps or are allowing apps to update their information over the course of the quarter.

Therefore, beginning March 31, 2023 all impacted payers would need to report to CMS the first set of data, which would be the data for October, November, and December 2022.

CARIN Response:

The CARIN Alliance believes measurement and metrics are important to tracking the growth of consumer-directed exchange. Unfortunately, we have not had enough time to discuss the goals and desired outcomes of what and how tracking specific measures would advance consumer-directed exchange and, therefore, have decided not to comment on the specifics of this proposal. However, we look forward to continuing to engage on this topic in the future. We have several questions about what CMS is looking to measure in terms of metrics and believe this topic warrants a more robust conversation between the public and private sectors.

CMS language:
Although Medicare FFS is not directly impacted by this rule, we do note that we are targeting to implement the provisions, if finalized. In this way, the Medicare FFS implementation would conform to the same requirements that apply to the impacted payers under this rulemaking, so that Medicare FFS beneficiaries would also benefit from this data sharing. CMS started to liberate patients' data with Blue Button 2.0, which made Parts A, B, and D claims data available via an API to Medicare beneficiaries. In an effort to align with the API provisions included in the CMS Interoperability and Patient Access final rule, we are updating the Blue Button 2.0 API to FHIR R4, and will begin use of the CARIN IG for Blue Button. If the provisions in this rule are finalized, we will work to align and enhance Blue Button accordingly, as possible.

CARIN Response:
CARIN Alliance supports CMS and their move toward adopting the CARIN IG for Blue Button®. We have appreciated the partnership we have shared over the last few years as CMS led the way in adopting FHIR R3, the CARIN Alliance published an R4 version for the industry to use, and now CMS is adopting the same FHIR R4 version for Medicare FFS claims. We look forward to continuing to collaborate with CMS in the future as new versions of FHIR are developed.

CMS language:
Requests for Information: Methods for Enabling Patients and Providers To Control Sharing of Health Information

CARIN Response:
Unfortunately, the CARIN Alliance was not given enough comment time to adequately address all of the questions CMS asks in this RFI but looks forward to working with CMS on a mutually agreeable path forward in the future.

As a general comment, while the CARIN Alliance wholeheartedly supports the direction the industry, ONC, and CMS is moving to allow consumers more granular access and control over the health information, from a practical perspective and as the ONC has indicated in their final 21st Century Cures rule[12], data segmentation and granular control over health care data is still in its infancy, both in terms of the standards that are being developed and the infrastructure required to make it work across the industry. This does not in any way minimize the importance of granular control, it simply speaks to the fact that we look forward to working with industry and the public sector to advance this type of functionality in the future.

CMS preamble language:
We recognize that while we have proposed to require compliance with the specific IGs noted above, the need for continually evolving IGs typically outpaces our ability to amend regulatory text. Therefore, we propose to amend 431.60(c)(4), 438.242(b)(5), 457.730(c)(4), 457.1233(d)(2), and 45 CFR 156.221(c)(4) to provide that, if finalized, regulated entities would be permitted to use an updated version of any or all IGs

[12] https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf

proposed for adoption in this rule if use of the updated IG does not disrupt an end user's ability to access the data through any of the specified APIs discussed in this rule. This would then amend the process to allow payers to use new standards as they are available, as we finalized in the CMS Interoperability and Patient Access final rule to these proposed IGs.

CMS regulatory language:
§ 431.60 Beneficiary access to and exchange of data
§ 457.730 Beneficiary access to and exchange of data.
§ 156.221 Access to and exchange of health data and plan information.

(iii) Beginning January 1, 2023 be conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified in paragraphs (b)(1) and (2) of this section, 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified in paragraph (b)(3), 45 CFR 170.215(c)(7) for data specified in (b)(4), and 45 CFR 170.215(c)(6) for data specified in paragraph (b)(5) of this section. (4) May use an updated version of any standard or all standards and any or all implementation guides or specifications required under paragraphs (b) or (c) of this section, §§ 457.731, 457.732, and 457.760, where: * * * * * (ii) * * * (C) Use of the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data described in paragraph (b) of this section, or the data described in §§ 457.731, 457.732, and 457.760 of this chapter through the required API. * * * * * (e) * * * (2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which parties seek to access electronic health information, as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

CARIN Response:
The CARIN Alliance supports the CMS recommended approach for the industry to use an updated version of any standard or all standards and any or all implementation guides or specifications referenced in this proposed rule. Although this process for payers does not involve certification of health records technology, the CARIN Alliance would recommend that CMS find ways to leverage and reference the ONC's standards version advancement process referenced in the ONC 21st Century Cures final rule [13] as much as possible especially for APIs that are relevant to both the payer and provider community. Having a common approach that includes input from both the private and public sectors for how standards are advanced is imperative to having an interoperable ecosystem.

CMS preamble language:
We are now proposing to enhance this payer-to-payer data exchange in two ways. First, we are proposing to require that this payer-to-payer data exchange take place via an API. Second, we propose to require impacted payers to make available, at a minimum, not only the USCDI version 1 data, but also claims and encounter data (not including cost information) that the payer maintains with a date of service on or after January 1, 2016, conformant with the same IGs proposed for these data types in sections II.A. and II.B. of this rule, as well as information about pending and active prior authorization decisions, beginning January 1, 2023 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2023) via this standards-based Payer-to-Payer API.

CMS regulatory language:
(b) Coordination among payers— Payer-to-Payer Data Exchange. (1) Beginning January 1, 2023, a State must implement and maintain a standards based API compliant with § 431.60(c), (d), and (e) that makes available to another payer, at a minimum, the data maintained by the state with a date of service on or

[13] https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf

after January 1, 2016, within one (1) business day of receipt, conformant with the implementation specifications at 45 CFR 170.215(c)(5) for data specified at § 431.60(b)(1) and (2) not including remittances and enrollee cost sharing information, 45 CFR 170.215(a)(2) or 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(3), 45 CFR 170.215(c)(7) for data specified at § 431.60(b)(4), and 45 CFR 170.215(c)(6) for data specified at § 431.60(b)(5). Such information received by a State must be incorporated into the State's records about the current beneficiary. (2) With the approval and at the direction of a current or former beneficiary or the beneficiary's personal representative, the State must: (i) Receive all such data for a current beneficiary from any other payer that has provided coverage to the beneficiary within the preceding 5 years; (ii) At any time a beneficiary is currently enrolled with the State and up to 5 years after disenrollment, send all such data to any other payer that currently covers the beneficiary or to a payer the beneficiary or the beneficiary's personal representative specifically requests receive the data; and (iii) Send data received from another payer under this paragraph in the electronic form and format it was received.

(c) Coordination among payers at enrollment—Payer-to-Payer API. (1) Accessible content and API requirements. Beginning January 1, 2023, a State must make the standards-based API specified in paragraph (b)(1) of this section conformant with the implementation specification at 45 CFR 170.215

CARIN Response:

The CARIN Alliance supports the CMS requirement to use the CARIN IG for Blue Button® (minus the remittances and enrollee cost sharing information) as the required implementation guide (IG) to follow when sending payer-to-payer claims data with some suggested changes. Currently, the CARIN IG for Blue Button® requires that all of the member's financial information is 'must support' and should be shared with a third-party application. Therefore, the current IG does not support the requirement to exclude financial information for payer-to-payer exchange. In addition, it's not clear whether CMS is requiring the additional explanation of benefit (EOB) resource information to be shared payer-to-payer or if just the clinical data that is coming from claims. Additional clarity from CMS around this topic would be helpful.

Our comments assume here assume it's the intent of CMS to include EOB information (minus the remittances and enrollee cost sharing information) in the payer-to-payer and payer-to-provider workflows. Therefore, in order to accommodate a situation where payers share claims information with other covered entities minus the enrollee cost sharing information, the CARIN Alliance will be making a recommendation to HL7® to add language to the CARIN IG for Blue Button® as an errata to indicate that payers wishing to use the IG for claims data exchange between covered entities should leave all of the financial fields blank. We believe including $0.00 amounts in the financial fields will impact the quality of the data and therefore is not be a viable option for payers.

We believe this approach will stay true to the requirements in the IG (with some modifications to the must support financial data elements), allow payers to use the same resources for two different purposes, and provide the needed information to know when the data was received from another payer vs. from the current payer. We want to continue to emphasize this recommended approach has not been tested or formally approved by HL7® at this time.

CMS language:

§ 457.730 Beneficiary access to and exchange of data.

CARIN Response:

The CARIN Alliance supports the ability for a beneficiary to receive their prior authorization information via an API to an application of their choice.