June 16, 2025

Stephanie Carlton
Deputy Administrator
Centers for Medicare & Medicaid Services

Tom Keane
Assistant Secretary for Technology Policy
National Coordinator for Health IT
U.S. Department of Health and Human Services

Re: CMS-0042-NC; Request for Information; Health Technology Ecosystem

Dear Deputy Administrator Carlton and Assistant Secretary Keane:

Thank you for the opportunity to provide comment in response to the Request for Information (RFI) on the Health Technology Ecosystem. We appreciate the commitment by CMS and ASTP/ONC to engage stakeholders and gather public input to inform policy decisions that impact the health and well-being of millions of Americans. We look forward to working alongside CMS and ASTP/ONC to make the initiatives presented in the RFI a reality.

Founded in 2020, Zus Health is a shared patient data platform designed to enable data interoperability and accelerate clinical care via normalized, summarized, and actionable health information. Zus Health typically serves risk-bearing provider organizations that are accountable for patient outcomes and total cost of care by arming them with the tools and insights they need to effectively engage patients along their journey.

As a leader in health care data interoperability, Zus Health is uniquely positioned to offer insight into a number of the RFI's questions, including those questions centered around improvement of data quality, expansion of USCDI, changes in the EHR certification process, and enhancement to TEFCA. Our comments aim to inform future policy decisions and identify practical pathways for achieving shared goals related to health data interoperability, with recommendations aimed at improving clarity, accountability, and practical implementation of policies that will shape the healthcare industry for years to come.

Our responses to specific questions of the RFI are below.

Responses to RFI Questions:

TD-2. Regarding CMS Data, to stimulate developer interest – what additional data would be most valuable? What data sources alongside the data? What obstacles? What other APIs?

Zus Health applauds CMS for its investment in modeling market-leading interoperability with efforts such as Blue Button (BB), Data at the Point of Care (DPC), and Beneficiary Claims Data API (BCDA) ("CMS Interoperability Initiatives"). In addition to fulfilling its recently announced commitments to make DPC generally available and to enforce the existing regulatory requirements to expose Patient and Provider-facing APIs, we believe there are additional data types that CMS could offer that would help further stimulate developer interest.

CMS should expand its footprint in two primary ways:

1. Expand the footprint of the CMS Interoperability Initiatives to include key value-based care data types, such as beneficiary alignment information (attribution), risk scores (including contributing diagnoses), expanded demographics, key flags (e.g. dual eligibility, disability, institutionalization) and gaps in care files.
2. Expand the claims data shared through the CMS Interoperability Initiatives to include additional domains. Visibility into dental and vision care can be critical to certain chronic disease management scenarios (e.g. dental care prior to oncology treatment or diabetic eye exams).

TD-4. How can CMS better encourage use of open, standards-based publicly available APIs over proprietary APIs?

To date, CMS has done a tremendous job incentivizing adoption of open, standards-based APIs via enforcement of Conditions of Participation. Going forward, CMS should consider how to both (1) incentivize Health IT vendors that are not yet certified and (2) motivate adoption and expansion of standards-based APIs.

Zus Health would like to propose a tiered, or modular, certification process with corresponding incentive models. This approach would introduce an accessible 'floor' for participating in incentives, encourage more Health IT, and motivate forward-looking developers to prioritize standards-based solutions rather than proprietary APIs.

For example, CMS might consider offering a base-level incentive for meeting the current USCDI via patient-level and bulk FHIR APIs. CMS could offer additional 'market leader' incentives for providers using Health IT that offer additional data, subscriptions, write APIs, and more sophisticated SMART on FHIR launch points (such as in-encounter "cards"). The result would be a base-level of interoperability for a greater set of vendors, with opportunities for market leaders to be recognized for additional capabilities (and command a corresponding premium in-market). Furthermore, this would minimize the ability for EHRs to capture unreasonable fees for access to proprietary APIs.

TD-6. What unique interoperability functions does TEFCA perform?

a. ***What existing alternatives should be considered?***

Zus Health strongly believes that networked exchange founded on a shared trust framework is critical to the future of interoperability in the United States. The average

patient over 65 has seen ~28 doctors over their lifetime.[1] Constructing a complete picture of a patient's individual medical history requires retrieving recent records from most of those providers, each of whom might be operating on a unique instance of a particular EMR. Even with a pristine directory of provider endpoints, the sad fact is that an interoperability vendor supporting this space may need to navigate many registration protocols, authorization systems, and API implementations (all with their own unique quirks and bugs) to construct a comprehensive record for a single patient. Across a population, a model without networked trust simply does not scale – we believe relying solely on an alternative directory of provider endpoints would lead to the demise of the system of data exchange that supports patient care at scale today.

A year-and-a-half ago we would have argued that TEFCA was largely redundant with Carequality, CommonWell, and eHealthExchange for access to patient data. However, since then a lot has happened in the interoperability community. Trust has been degraded, and the status quo found on the existing national networks is no longer sufficient to address the privacy and security concerns of participating organizations. Is TEFCA another national data network / framework? Yes. However, TEFCA is unique in that ASTP/ONC and major EHR vendors in the country have worked to create a national network in TEFCA that specifically addresses the concerns currently plaguing the interoperability community in a way that existing national networks have not or cannot, including increased transparency, elevated evidence requirements proving legitimacy of an organization and its use case, and a clear definition of the minimum clinical information participants are expected to contribute.

Also, in addition to the unique functions of TEFCA, the reality is the industry needs a stable, supported national framework that provider organizations know they can count on, and we believe, with the ASTP/ONC's oversight and support, TEFCA can serve this important role. EHR vendors have spent the last year making clear commitments to TEFCA and have invested heavily in aligned definitions.

For the aforementioned reasons, we support the continuation and expansion of TEFCA.

That being said, to be successful as the primary network of national data exchange, TEFCA requires several operational changes. For example, as discussed below in subsection (b), the vetting process and evidence requirements are burdensome and inefficient, and the use case dispute process allows for denial by a single QHIN (which in some cases may be competitive to the entity requesting approval), escalating an organization and/or use case into a dispute resolution process that is not time-bound.

b. ***Are there redundant standards, protocols or channels or both that should be consolidated?***

As discussed above in section (a), TEFCA serves a unique function compared to the pre-established national networks due to its investment in a trust framework. However, we believe that the onboarding processes within TEFCA are burdensome, inefficient, and in dire need of consolidation.[2]

[1] https://www.fiercehealthcare.com/healthcare/survey-patients-see-18-7-different-doctors-average

[2] Note that Carequality has incorporated some of TEFCA's onboarding processes. The concerns we outline in this TD-6(b) also apply to Carequality's recent incorporations.

In addressing valid concerns about purpose of use abuse and fraudulent Delegation listings, TEFCA set up a laborious Delegation of Authority process. While the basic requirements of these processes are theoretically reasonable, they lack transparency and standardization.

TEFCA identifies Principals as Covered Entity providers who have successfully passed vetting and are authorized to query on the network for the TEFCA Required Treatment purpose of use. Each Principal's QHIN is responsible for activating Delegate listings for that Principal at the Principal's instruction. Although this approach correctly aligns Delegation responsibility with the Principal and their vendor, it currently lacks the necessary standardization and tooling. Each QHIN has established its own delegation process and form. Delegates and their vendors now need to identify which EMR the Principal is using, identify the associated QHIN, track down their unique variation of the Delegation form, and collect e-signatures on a PDF that the Delegate's and Principal's QHINs then need to receive and act on. This process is complicated by the fact that the TEFCA directory is not publicly accessible.

Providers on these networks regularly delegate access to vendors and partners to facilitate care management, data reconciliation, appointment preparation, and other workflows. By making it harder for providers to work with these partners, the current process unnecessarily increases burden on the providers and makes it harder for them to incorporate outside records into their treatment decisions. Through TEFCA, ASTP/ONC and the Recognized Coordinating Entity (RCE) should be prioritizing efficient processes and standards, making it easier for providers to use tools and partners of their choice when accessing these records.

To simplify Delegation of Authority workflows, ASTP/ONC should direct the RCE to:

1. Make the TEFCA directory publicly accessible;
2. Ensure the directory contains clear and up to date contact information regarding Principal representatives that have signatory authority to approve delegates; and
3. Allow authenticated Principal representatives to activate a Delegate listing, or to complete a standard RCE-hosted Delegation form that notifies the associated QHINs.

TD-7. To what degree has USCDI improved interoperability and exchange and what are its limitations?

a. ***Does it contain the full extent of data elements you need?***

A consistent standard for the data set required to be accessible via API has been tremendous for the healthcare industry. USCDI has led to incredible progress in clinical data exchange over the last few years. However, today, USCDI does not have the full set of data elements providers need. There are two key areas that are absent: (1) care management and coordination and (2) a broader range of clinical notes.

1. **Care Management and Care Coordination:** Within the care management and care coordination domains, upcoming appointments are critical drivers of workflow solutions, as care teams often use third party applications to outreach-to and prepare-for patients that are on the calendar. Today, appointment data is available only via proprietary API or interface, driving cost to developers and preventing

seamless experiences for clinicians. Similarly, referral orders are critical moments in a patient's care transition.

While the Draft USCDI v6 enumerates several order types, it fails to include referral orders in the scope. As a result, there is no standard, leading developers for EHR vendors to sporadically include referrals in their proprietary APIs, leading clinicians to resort to eFax as the primary method of interchange.

Separately, note that the "Care Plan" (as distinct from the Assessment and Plan of Treatment) is only introduced in Draft USCDI v6. We believe this clinical data is critical for organizations engaged in proactive, team-based care and should be pulled into an earlier version of USCDI. It is particularly critical if CMS is considering expanding certification requirements to Health IT beyond EHRs [See response to VB-9].

2. **Clinical Notes:** Clinical notes are a critical area of need for providers, particularly as advanced technologies (e.g. language models) make it easier to drive action from unstructured data. While we appreciate ASTP/ONC's efforts to enumerate required note types under USCDI, we worry that notes that do not explicitly fall under existing categories might get left behind. For instance, we note that USCDI does not expressly mention 'pathology reports'. The lack of explicit mention of these types of reports leads to inconsistent manifestation and lack of availability of this critical information for specialists, such as oncologists. We'd encourage requirements that comprehensively cover categories (e.g. a requirement to include ALL clinical notes and reports), with granularity wielded to label and categorize data, rather than build up breadth. A similar pattern can be noted in the Orders category, where the absence of Referrals is a concerning omission.

b. ***If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?***

We believe that the gaps discussed above in subsection (a) are largely due to a limited definition of the USCDI format. However, there are also opportunities to more explicitly tie USCDI to FHIR via a clear implementation guide, including recommended code systems, to ensure the market consistently interprets the translation and avoids preventable inconsistencies.

Additionally, while USCDI and FHIR have introduced a clear standard for data exchange, implementation has been variable across the industry. We note in our response to VB-6 some recommendations for addressing data quality concerns, but enumerate them here as well for completeness:

1. **Completeness:** Zus Health has experienced firsthand vendors that respond with incomplete results despite having FHIR APIs. For example, a heart rate measurement is visible in the EHR, but not available via the API.
2. **Consistency:** Responses do not always adhere to the standard. For instance, we have seen diagnostic reports for a CBC with no Observation resources for the individual results. We have also seen Observation resources with missing codes or the quantitative results buried in an unstructured field rather than adhering to implementation guides. We have also experienced misclassification of a

mammogram procedure as mammogram results. These inconsistencies make it difficult to trust the data, particularly when financial incentives are on the line.

3. **Performance:** In some cases, EHRs can perform a small number of queries consistently, but attempts to use Bulk FHIR or query for results from patients with complex medical histories result in timeouts. Those are the very patients that require innovative solutions!
4. **Friction:** Navigating developer portals, application approval workflows, authentication methods, and app "activation" can be burdensome for developers, as there are a wide range of workflows and solutions.
5. **Support:** Without a consistent mechanism or requirement for support, EHR developers may deprioritize the concerns of third parties in favor of investing in their own solution once the certification "box" is checked.

c. ***If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?***

Adding additional elements would largely add value by increasing the breadth of data available for exchange [See response to TD-7(a) for recommendations]. The one notable risk is when USCDI begins to enumerate multiple sub-categories (e.g. clinical notes, orders). As mentioned in subsection (a) above, notes or orders that do not clearly fall into these categories may be left out in an effort to comply with the standard.

d. ***Given improvements in language models, would you prefer a non-proprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?***

Non-proprietary, but less structured, data should be a *supplement*, not a substitution, for USCDI. USCDI is critical for data that is used in transactional or analytical applications where a common standard is valuable, particularly when consistent coding standards come into play.

CMS might, however, incentivize broader access to unstructured data in the form of unstructured documents, images, PDFs, etc. Today, much of the patient "chart" is in the form of documents that have been transmitted to the EHR via eFax. Buried in this data is a tremendous wealth of insight that would be ripe for language models to leverage. Incorporating these documents into API requirements would be hugely beneficial.

TD-8 What are the most effective certification criteria and standards under the ONC Health IT Certification Program?

Zus Health commends ASTP/ONC's investment in Health IT Certification Programs. This investment has been instrumental in moving the industry towards data interoperability, which in turn unlocks coordinated care and new and innovative care models. While there is much to applaud, the following are a few specific examples that evidence the value of the certification criteria and standards to Zus Health and our provider customers:

- The certification program enables not only FHIR API access to EHRs, but also a consistent authentication and launch experience via SMART on FHIR (45 CFR 170.315(g)(10), 45 CFR 170.315(g)(7)). Forcing providers to navigate "multiple panes of glass" in their workflow leads to a multitude of problems - frustration with logins, countless clicks, and patient safety concerns due to lack of automatic syncing of

patient identity across applications. By introducing a standard for authenticating apps and encouraging EHR vendors to enable in-app launch, ASTP/ONC has made meaningful strides to addressing burdensome and inefficient workflows. As a developer, we are now moving past the era of screen scraping patient context to keep a "side car" in sync with the EHR and, instead, are able to launch applications from within the EHR itself. We hope that ASTP/ONC continues to invest in encouraging EHR vendors to enable seamless provider-facing experiences.

- While the industry is eagerly awaiting the day when FHIR replaces document-based architecture as the standard for exchange, it is worth looking back and commending the successful adoption of the C-CDA. While imperfect, the set of certification criteria associated with this data exchange standard has led us to a place where EHRs readily exchange structured clinical data (either point-to-point or in network-based arrangements). This has been accomplished via a combination of technical standards, reliance on these standards for a variety of use cases, and clear incentives for adoption. We should take the powerful lessons learned on how certification can lead to standards-based adoptions (and also, what we might do differently) and apply these lessons to the next generation: FHIR.

TD-9. Regarding certification of health IT:

a. ***What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?***

Zus Health is supportive of shifting EHR certification requirements to focus on API-enabled capabilities over software functionality. This approach will maximize investment in interoperability, empower EHR vendors (and other Health IT vendors) to innovate to reduce provider burden (instead of investing in required workflows), and offer more Health IT to participate in certification [See response to TD-4].

For this transition to be successful, there must be a set of publicly available API testing tools (such as Inferno, the PIQI Framework[3]) that go beyond evaluating the existence of endpoints. These testing tools should include continuous monitoring of FHIR endpoint availability and performance, with publicly available "service health dashboard" akin to the standard utilized by modern platform companies. In addition, this test suite should accurately reflect the performance of live EHR platforms, not sandboxes or other testing environments as issues often arise outside of these sanitized environments. Furthermore, certified Health IT should be able to host and publish results regarding data quality via a framework, such as the PIQI Framework. Today, Inferno does not meet these requirements of continuous monitoring, performance evaluation, and public-facing status pages.

b. ***What would be the drawbacks?***

The main risk around APIs is that they are available, but not reliable. ASTP/ONC should invest deeply in testing capabilities that can help enforce that the API is performant, consistently returns all data, and offers data that is high quality in terms of its coding and reliability.

Also, it will be critical for ASTP/ONC to quickly develop an intentional and well-documented strategy for expanding the set of APIs required of certified Health IT. We all

[3] https://piqiframework.org/.

agree that basic 'READ' APIs are not enough - developers require the ability to WRITE and UPDATE data in the EHR, to be notified of changes, to interact with data in bulk, and to access data sets (including unstructured data completely). Further, there is industry alignment that there are a number of workflow APIs that could be exceptionally powerful, particularly around scheduling, documentation and sign-off, ordering, and task management.

However, to push forward this broad set of capabilities, ASTP/ONC will need to balance the breadth of requirements and speed of adoption. Go too slowly, and key capabilities are missing for too long. Move too aggressively, and new barriers to entry will be created. Zus Health recommends rapid establishment of "paved pathways" for all of these needs as quickly as possible, along with incentives for expanded API capabilities. A potential solution may be to offer a tiered certification and incentive approach, such that new entrants or innovative platforms can pick the API footprint and levels that are most relevant to their customer bases. This way, there is both an accessible set of requirements for currently non-certified Health IT to get started with, while also offering standards-based paths to higher tier achievements for industry leaders to build certified solutions for writes, subscriptions, etc. (rather than continuing to invest in proprietary systems).

c. ***How could ASTP/ONC revise health IT certification criteria to require APIs to consistently support exchanging data from all aspects of the patient's chart (for example, faxed records, free text, discrete data)?***
First, ASTP/ONC should make a concerted effort to ensure that the structured clinical notes category under USCDI takes a sufficiently comprehensive approach. We note above the concrete example of a pathology report [See response to TD-7(a)].

Once this foundational issue is addressed, ASTP/ONC might also consider a criteria related to exposing all documents stored in the chart. For this to be successful, ASTP/ONC should offer a standard categorization schema of documents that is leveraged as a code system, not as an excuse to partially expose documents. Furthermore, ASTP/ONC should consider how a test suite such as Inferno might be expanded to evaluate this capability for accurate classification, sufficient technical performance, and comprehensive response.

Longer term, ASTP/ONC should consider also including access to inbox documents (not yet assigned to a patient) as part of the certification requirements. Given the availability of comprehensive, bi-directional APIs, there is ample opportunity for innovative technology to help providers (and their administrative teams) manage inboxes more efficiently.

d. ***What policy changes could CMS make so providers are motivated to respond to API-based data requests with best possible coverage and quality of data?***
To motivate providers to adopt certified technology, CMS should continue to wield Conditions of Participation and advocate for enforcement of Information blocking regulations. In addition to existing motivators, CMS should also consider tiered certifications to incentivize laggards and market-leaders alike [See response to TD-9(b)], and should push for transparency of performance, data quality, and complaints to ensure visibility into progress [See response to TD-9(a)].

e. ***How could EHRs capable of bulk data transfer be used to reduce the burden on providers for reporting quality performance data to CMS? What capabilities are needed to show benefit? What concerns are there with this approach?***

As part of this effort to shift Health IT certification to APIs, Zus Health believes there is a significant opportunity to simplify requirements associated with quality reporting. There are three fundamental problems that a bulk data transfer approach would address:

1. **There are currently competing bulk data standards for quality data submission.** CMS should focus on adoption of Bulk FHIR and CQL and aggressively ramp-down QRDA to concentrate Health IT investment in one clear standard.
2. **CMS should consider independent evaluation of Health IT CQL capabilities and not require that every EHR include this capability.** Some provider organizations may prefer third party solutions to serve their quality reporting needs, particularly if their technology strategy combines the use of multiple EHRs. By separating these two certification criteria and creating interoperability between EHRs and CQLs, CMS can encourage innovation in this area.
3. **CMS must encourage the commercial payor market to also adopt these standards.** Most notably, CMS should collaborate with the National Committee for Quality Assurance (NCQA) to ensure that Bulk FHIR becomes the trusted standard, driving down programs such as Primary Source Verification / Data Aggregator Validation that create additional burden and redundant requirements [See response to VB-6].

TD-12. Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?

Today, the MIPS Promoting Interoperability category requires that providers attest either to (PI-HIE-6) participation in TEFCA, (PI-HIE-5) participation in generic bidirectional exchange with an HIE, or (PI-HIE-4) support for electronic referral loops by receiving and reconciling health information. Given how important provider-to-provider communication is in caring for complex patients, and how critical networked exchange is to scaling that communication, we support measures PI-HIE-5 and PI-HIE-6 and recommend that CMS continue requiring such measures. We endorse these measures over PI-HIE-4, which places a higher reporting burden on providers and does not deliver the benefits of a scaled network.

Criteria and metrics that CMS might apply in endorsing specific networks (such as TEFCA) include:

- Basic criteria
  - Support for bidirectional and networked exchange
  - Support for a standard of data exchange named by CEHRT (e.g., IHE, FHIR) that enables transactions across disparate EHRs, vendors, and networks
  - Adherence to security standards
  - Existence of a trust framework (lowercase) to protect patient privacy, align exchange activity with HIPAA purposes of use, and prevent information blocking or exclusionary activity
- Metrics to inform endorsement
  - Number / percent of provider locations participating for Treatment
  - Number / percent of payers participating for Treatment, Payment, and Operations
  - Transaction volume

TD-15. Regarding bulk FHIR APIs:

a. ***How would increased use of bulk FHIR improve use cases and data flow?***

We applaud CMS for continuing to pursue Bulk FHIR as a path for data interoperability. Broad availability of Bulk FHIR APIs would be tremendously beneficial for data exchange and digital app integration. There are two key areas that Zus Health sees value:

1. **Individual Patients.** "Backfill" for individual patients. Digital applications often require a comprehensive view of a patient's medical history in order to deliver comprehensive and accurate insights to patients and providers. Bulk FHIR could be an effective mechanism to ensure this comprehensive data set is available while not overburdening single API endpoints.
2. **Population Health Applications.** Population health applications, such as quality measure calculation or risk stratification, would additionally benefit from Bulk FHIR protocols that can support larger scale data exchange.

b. What are the potential disadvantages of their use?

In pursuit of bulk FHIR API usage, data quality and reliability must be ensured:

1. It is likely that many EHR vendors will rely on external vendors (e.g. cloud providers) to serve this need, as their operational architecture may not be able to perform at scale. While these platforms should be effective in ensuring performance service levels are met (which must be clearly set and measured), such platforms introduce data consistency risks. The fastest way to lose trust with a clinical audience is to show one set of lab results in the EHR or patient-level FHIR API endpoint, and another set via Bulk FHIR API.
2. Population health applications, such as quality and risk, are often tied to payment and, as a result, rigorous audit processes. Bulk FHIR APIs must be set up to both measure data quality (e.g. via a framework such as the PIQI Framework), as well as a highly visible feedback cycle that will incentivize developers to address reported quality issues in a timely manner [See response to VB-6].

TD-17. Given operational costs, what role should CMS or ASTP/ONC or both have in ensuring viability of healthcare data sharing networks, including enough supply and demand, that results in usage and outcomes?

Recently, there have been questions raised about the role of government in funding and/or overseeing a network such as TEFCA. While these questions are reasonable, as discussed in TD-6, the mobility of patient data is critical to outcome-oriented care delivery in this country, and Zus Health believes that networked exchange enables provider access to clinical records at scale in a way that point-to-point connectivity cannot. As we discuss in TD-12, we believe CMS should use programs such as MIPS Promoting Interoperability to incentivize providers in its network to participate in TEFCA. In tandem, ASTP/ONC should provide enough oversight over TEFCA to ensure that QHINs don't block access to records for the currently approved use cases through an onerous vetting process.

Under the previous administration, the ASTP/ONC worked with the RCE and the QHINs to define a vetting process for providers querying for "Required Treatment" purpose of use. Although the vetting requirements are a reasonable foundation on which to re-establish exchange, the process has the following flaws:

1. **The dispute process allows for a single QHIN to dispute a use case or an organization.** A single QHIN objecting to a listing (and maintaining that objection) can place the listing in limbo for an indeterminate amount of time while it is escalated to the ASTP/ONC for review and decision. The current vetting requirements add unnecessary requirements and burden on providers attempting to improve access to care through virtual services, and for providers monitoring patients under an ongoing value-based care relationship. As a result, these organizations are more likely to receive objections as compared to brick-and-mortar fee-for-service facilities that reflect a more traditional model of patient care.
2. **The current vetting tools and process lack standardization and transparency.** Each QHIN uses its own forms to collect vetting documentation, with seemingly arbitrary variation in the data it requires.
3. **As we discuss in TD-6(b), the Delegation of Authority process lacks the technical infrastructure and tools participants need in order to submit and manage delegation requests.**

ASTP/ONC should use its oversight role to continue its prior committed activities, as well as modify existing TEFCA policy:

A. ASTP/ONC needs to continue acting as a final, impartial escalation point for vetting objections. If ASTP/ONC is concerned about budgeting or staffing shortfalls, consider charging a fee to process any disputes. Requiring an escalation fee may prevent objectors from building up an unmanageable backlog.

B. As mentioned in TD-6, to simplify Delegation of Authority workflows, ASTP/ONC should direct the RCE to:

   i. Make the TEFCA directory publicly accessible;

   ii. Ensure the directory contains clear and up to date contact information regarding Principal representatives that have signatory authority to approve delegates; and

   iii. Allow authenticated Principal representatives to activate a Delegate listing, or to complete a standard RCE-hosted Delegation form that notifies the associated QHINs.

TD-18. Information blocking.

b. ***What additional policies could ASTP/ONC and CMS implement to further discourage healthcare providers from engaging in information blocking practices?*** Before implementing additional policies, Zus Health recommends ASTP/ONC and CMS (1) advocate for increased enforcement of existing policies (including CMS Disincentives Final Rule) and (2) prioritize the development of additional guidance to help educate and guide patients and the healthcare community.

1. **Enforcement of Existing Policies.** As of June 2025, HHS has not publicly announced any penalties assessed for information blocking under the 21st Century Cures Act, despite the fact there has been over 1,200 submissions for possible claims of information blocking since September 2023.[4] The absence of enforcement not only weakens the credibility of the regulatory framework but also disadvantages compliant stakeholders and perpetuates data silos that harm care coordination and patient

[4] https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers.

empowerment. Timely, transparent, and equitable enforcement—particularly through OIG investigations and CMS disincentives—is necessary to deter bad actors, encourage consistent compliance, and ensure that the 21st Century Cures Act delivers on its vision of seamless and equitable health information access.

2. **Development of Published Guidance.** While ASTP/ONC has produced FAQs and other documents on what constitutes information blocking, including fact sheets, presentations, and summaries on exceptions to information blocking, Zus Health believes patients and the healthcare community would benefit from additional guidance and education on what information blocking is, how information blocking might present, and what to do if information blocking occurs. In addition, while requiring congressional action, there may benefit in ASTP/ONC having the right to issue formal, binding advisory opinions on whether a specific practice would or would not constitute information blocking. For example, Zus Health struggles from time to time with delayed response times, connectivity challenges (APIs fail or are extremely slow), data availability issues – it would be very helpful to review / rely on an Advisory Opinion (either view our submission or to the extent one exists and the subject matter is substantially similar in nature) in our analysis of whether the responses we receive, or the connectivity we are required to use, comply with the intent of the information blocking regulation.

VB-4. What are the essential data types needed for successful participation in value-based care arrangements?

In our capacity as a data platform, Zus Health serves a wide range of value-based care organizations, from risk-bearing specialties that take specific carve-out risk directly from payers, to Accountable Care Organizations that participate in MSSP and ACO REACH, to provider organizations with shared risk with Medicare Advantage plans. Across the board there are robust data needs and opportunities for CMS to more actively incentivize and model the sharing of such data in the industry.

1. **For value-based organizations, data is mission-critical.** These organizations require robust payer and clinical data to power risk adjustment and quality measure calculations. As the requirements for these measures continue to shift towards clinical data over claims-only calculation, CMS could play a key role in driving data availability, standardization, latency, and trust:

    a. CMS should continue to invest in BCDA API-based exchange for ACOs and incentivize payers participating in Medicare Advantage or Managed Medicaid to follow suit.

    b. CMS should expand the footprint of such API-based exchange programs to include key value-based care data types and claims data from additional domains [See response to TD-2].

    c. CMS should simplify and standardize submission and codification formats for quality measures to fully rely on FHIR and CQL, sunsetting QRDA as an acceptable pathway.

    d. CMS should invest in lower latency methods for exchanging data that would close care gaps and risk gaps. Today, providers endure an immense burden trying to chase down a quality care gap or diagnosis that is deemed “open” by the payer, despite the fact they already addressed such care gap or diagnosis. Faster-moving data, such as real-time clinical data exchange or pre-adjudicated claims files, are likely to help close the lag between care and calculation.

e. Today, the data generated by EHRs via certified means (FHIR APIs, C-CDAs) is not deemed high quality by the auditing entities that oversee fraud prevention for quality programs (e.g. HEDIS) and risk adjustment. The result is a tremendous amount of dual burden related to primary source verification (see NCQA's Data Aggregator Validation program). CMS must aggressively pursue data quality enforcement so that data generated via certified APIs is seen as adequately reliable for HEDIS and other such use cases [See response to VB-6].

2. **Value-based care organizations must operate in a proactive, not reactive, manner.** Proactive care requires early notification of upcoming or active care, allowing providers the opportunity to offer patients the support and engagement needed to mitigate readmissions, guide care navigation, and ensure transitions are seamless. Today, this data is fragmented or unavailable, requiring tremendous technical investment or "boots on the ground" to support patients in real-time. Specifically:

   a. Real-time notification of admission to emergency or inpatient facilities is critical (ADT/ENS). Today, this need is not well-supported for APMs or providers [See response to VB-8].

   b. Expand data exchange to cover other data types that are early indicators of care. This could be accomplished in several ways:

      i. CMS should continue to invest in making data available to providers and value-based care entities that can serve as early indicators of care, both by modeling this via BCDA / DPC and requiring other payers to do the same. This data may include pre-adjudicated claims, prior authorization requests, and even eligibility inquiries.

      ii. Expand the footprint of USCDI to include early indicators of care, such as appointments (currently not explicitly enumerated) and referral orders (currently absent even from USCDI v6 order types).

3. **Value-based care organizations may represent thousands of small providers.** Participation in value-based care organizations empowers these small providers to remain independent while participating in APMs and CMS should continue to encourage such participation. However, participation by these smaller providers presents a tremendous operational challenge for value-based organizations seeking to deeply integrate in their participants' EHRs. There are key efforts that would address this challenge:

   a. CMS and ASTP/ONC should work together to aggressively simplify and standardize the process of establishing a connection between an ACO and their participant providers. For example, ASTP/ONC could simplify the delegation process under TEFCA [See response to PR-6]. Similarly, even when EHRs offer robust FHIR endpoints, the registration and authentication processes vary significantly, creating additional burden [See response to TD-4].

   b. CMS and ASTP/ONC must also continue to enforce SMART App Launch requirements, including provider-initiated EHR launch. Additionally, ASTP/ONC should consider expansion to certification requirements to further expand the footprint of APIs available to developers [See response to TD-10].

   c. CMS and ASTP/ONC should collaborate to pursue the inclusion of Bulk FHIR in certification requirements so that ACOs can efficiently retrieve clinical data from participating providers (and other treating providers') EHRs, reducing the need to wait for the claim [See response to TD-15].

4. **Value-based care organizations nearly ubiquitously invest in care management services and team-based care approaches that support patients before, during, and after traditional appointments.** There are several opportunities to better support this:
    a. Establish API-based certification criteria that might extend to the platforms these users leverage, encouraging more comprehensive interoperability [See response to VB-9].
    b. Ensure key data elements critical to care coordination are available under USCDI, most notably ensure appointments and referrals are required elements [See response to TD-7(a)].
    c. Currently, "Care Plan" is only introduced in USCDI v6. CMS should consider accelerating the inclusion of this data type to USCDI v5 [See response to TD-10].
    d. As CMS pursues a Provider Directory, there is an opportunity to rationalize this directory with the current DIRECT requirements so that true care coordination might occur in the form of real-time messaging. In this pursuit, CMS should evolve the requirements for DIRECT away from point-to-point transmission of individual C-CDA's to check the box on a requirement, and towards collaborative messaging that can facilitate coordinated care [See response to VB-15].

VB-6. What specific health information technology capabilities that could benefit APMs are not currently addressed by existing certification criteria and standards that should be included under the ONC Health IT Certification Program?

Today, the ONC Health IT Certification Program underserves APMs by not enforcing the data quality standards necessary for data generated by Certified Health IT to be considered sufficient for audit purposes under HEDIS and other measures that are critical inputs into value-based payments. Instead, APMs are required to adhere to data quality standards created by organizations like NCQA (e.g. Primary Source Verification), which impose additional point-to-point data connection validations or manual workflows. These programs create a barrier-to-entry for innovative solutions in the quality space. Technologists spend precious resources proving that EHR screenshots match API output, rather than building delightful experiences for clinical teams that improve patient outcomes.

We strongly encourage CMS to prioritize this issue, both by creating pathways to address data quality concerns and by reinforcing adoption of standards such as FHIR and CQL for quality submission.

1. CMS must double-down on Bulk FHIR and CQL as the industry standard for quality measure calculations, allowing the industry to focus on quality efforts.
2. CMS should adopt and incentivize adoption of data quality tools such as the PIQI Framework. All technology certified by ASTP/ONC should be required to publish its data quality performance on an ongoing basis.
3. CMS should make community complaints about data quality or API performance public. We live in the era of social media being the most efficient mechanism for customer support. Why not in Health IT? That would not only allow the broader developer community to vocally support fixing the most critical issues but would also provide clear visibility to enforcing agencies when issues are not resolved in a timely manner.

VB-8. How can other HHS policies supplement CEHRT requirements to better optimize the use of digital health products in APMs? As an example, requirements under the Conditions of Participation for hospitals (42 CFR 482.24(d)) require hospitals to transmit electronic patient event notifications to community providers. What barriers are in place preventing APM participants from receiving the same notifications?

While the CMS Interoperability & Patient Access Rule introduced Conditions of Participation (CoP) related to sending ADT notifications to PCPS, the reality on the ground is that organizations rely on private sector companies or HIEs to create a patchwork of coverage, and, even then, only receive inconsistent notification coverage. We believe the following investments can help address this:

1. **Supplement the CoP with a specific technical implementation.** While FHIR subscriptions seem like a natural choice here, HL7v2 ADT messages are a ubiquitous existing standard that might offer an accelerated path to adoption.
2. **Establish a standard for how providers "subscribe" to the patients for which they provide care.** Ideally, this would be a single endpoint for providers and value-based care entities to "subscribe" to the patients they care for by attesting a treatment relationship, which then might get federated out for notification.
3. **Enforce CoP to ensure hospitals comply with this responsibility.** To do this effectively, the industry needs a consistent, measurable approach. Furthermore, not enforcing this requirement puts patients at risk of not being well-supported during their most vulnerable moments.

VB-9. What technology requirements should be different for APM organizations when comparing to non-APM organizations (for example, quality reporting, and interoperability)?

APM organizations play two key roles beyond providing direct care (which many of them also do). First, they are accountable for quality reporting that directly impacts performance under contracts. Second, they often provide care management services to patients, ranging from transitional care management to chronic disease management and care navigation. CMS should consider these two major functions when considering certification requirements for APMs.

1. With regards to quality reporting, CMS may want to offer certification of Bulk FHIR endpoints and CQL capabilities for platforms used by APMs, such as population health platforms.
2. CMS should allow care management and patient engagement platforms the option to seek certification so that the data generated in such solutions can be accessible via FHIR. We should note that partial adoption of USCDI may be required for this purpose, as certain data types may not be relevant to such a platform (e.g. Procedures). Additionally, as part of the solution, ASTP/ONC should proactively acknowledge that care managers may be in a position where they are documenting patient-reported clinical data without immediate clinical review. Clear guidance regarding appropriate data modeling and provenance should be provided to ensure the integrity of clinical data.

VB-15. How could a nationwide provider directory of FHIR endpoints help improve access to patient data and understanding of claims data sources? What key data elements would be necessary in a nationwide FHIR endpoints directory to maximize its effectiveness?

A nationwide provider directory of FHIR endpoints could be a valuable asset. In order for this to be successful, Zus Health believes that the directory must be optimized for bi-directional FHIR-based use cases. If specific uses are not kept in mind, a generic directory may fail to effectively serve the intended purposes. Specifically, the approach to building a directory must:

1. **Be self-curating, with a path for manual update**. Existing workflows, such as those for listing entities on TEFCA or certifying FHIR APIs ought to be leveraged. Creating net-new requirements for updating a directory increases burden and exposes a new route for non-compliance. Corrections or updates could be made to supplement these auto-curating sources as-needed.
2. **Be mindful of the entities at play**. The word 'provider' might suggest an individual practitioner, while the majority of FHIR-based exchange is done at the organization-level. CMS should clearly model relationships between individual practitioners and the organizations they are tied to.
3. **Offer sufficient context for onboarding.** Today, connecting to an EHR's FHIR endpoints as a non-patient requires navigating custom processes for permissions, onboarding, and variable authentication methods. For a directory approach to work at scale, there needs to be a consistent set of rules applied across participants for gaining connectivity to an endpoint, gaining access to the right subset of patients (e.g. by asserting a treatment relationship), and ensuring developer support is available, if needed.

The requirements discussed above are specific to enabling FHIR-based data exchange. They are not comprehensive to support other use cases, such as patient understanding of provider participation in payer networks. To move forward successfully, we implore CMS: (1) to be crisp on the *primary* problem the nationwide provider directory is solving, and (2) ensure that its planned approach to resolve the problem is both scalable and reasonably self-sustaining.

Conclusion

Zus Health appreciates the opportunity to participate in this RFI process. We look forward to working with CMS and ASTP/ONC to help advance the health technology ecosystem to address provide burden and improve patient care. Please contact Amy Bagge-Smith, at abagge-smith@zushealth.com with any questions or requests for supplemental information.

Sincerely,

DocuSigned by:
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Jonathan Bush
Chief Executive Officer, Zus Health