

Altera Digital Health Response: Health Technology Ecosystem

Focus	Question	Questions
PATIENTS AND CAREGIVERS		
Patients & Caregivers (PC)	PC-8	c. What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?
Patients & Caregivers (PC)	PC-10	b. What changes would you suggest?

Patients & Caregivers (PC)	PC-10	c. What use cases could have a significant impact if implemented through TEFCA?
Patients & Caregivers (PC)	PC-10	d. What standards are you aware of that are currently working well to advance access and existing exchange purposes?
Patients & Caregivers (PC)	PC-10	g. Are there adequate alternatives outside of TEFCA for achieving widespread patient access to their health information?
Patients & Caregivers (PC)	PC-14	a. What are the challenges today in getting patients/caregivers to sign up and use digital identity credentials?
Patients & Caregivers (PC)	PC-14	b. What could be the benefits to patients/caregivers if digital identity credentials were more widely used?
Patients & Caregivers (PC)	PC-14	c. What are the potential downsides?
Patients & Caregivers (PC)	PC-14	d. How would encouraging the use of CSPs improve access to health information?
PROVIDER		

Provider (PR)	PR-5	Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each, describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:
Provider (PR)	PR-5	b. Standardized API for Patient and Population Services
Provider (PR)	PR-5	g. Bulk FHIR – Do you support Group ID-based access filtering for population-specific queries?
Provider (PR)	PR-5	h. SMART on FHIR – Do you support both EHR-launched and standalone app access? What does the process for application deployment entail?
Provider (PR)	PR-5	i. CDS Hooks (for clinical decision support integrations)
Provider (PR)	PR-9	How might CMS encourage providers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins that need to be tracked for each provider relationship?
Provider (PR)	PR-9	b. How might CMS balance patient privacy with convenience and access to digital health products and services that may lead to significant improvements in health?
Provider (PR)	PR-10	a. What are the challenges and benefits for providers?

Provider (PR)	PR-12	Should ASTP/ONC consider removing or revising any of the information blocking exceptions or conditions within the exceptions (45 CFR part 171, subparts B through D) to further the access, exchange, and use of electronic health information (EHI) and to promote market competition?
PAYER		
Payer (PA)	PA-1	What policy or technical limitations do you see in TEFCA? What changes would you suggest to address those limitations? To what degree do you expect these limitations to hinder participation in TEFCA?

Payer (PA)	PA-2	How can CMS encourage payers to accelerate the implementation and utilization of APIs for patients, providers, and other payers, similar to the Blue Button 2.0 and Data at the Point of Care APIs released by CMS?
Payer (PA)	PA-3	How can CMS encourage payers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins?
Payer (PA)	PA-4	What would be the value to payers of a nationwide provider directory that included FHIR end points and used digital identity credentials?
Payer (PA)	PA-5	What are ways payers can help with simplifying clinical quality data responsibilities of providers?
Payer (PA)	PA-5	<p>a. How interested are payers and providers in EHR technology advances that enable bulk extraction of clinical quality data from EHRs to payers to allow them to do the calculations instead of the provider-side technology?</p>

Payer (PA)	PA-5	<p>b. In what ways can the interoperability and quality reporting responsibilities of providers to both CMS and other payers be consolidated so investments can be dually purposed? Are there technologies payers might leverage that would support access to real time quality data for healthcare providers to inform clinical care in addition to simplifying reporting processes?</p>
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TECHNOLOGY VENDORS

Technology Vendors (TD)	TD-1	<p>What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?</p>
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Technology Vendors (TD)	TD-2	<p>a. What additional data would be most valuable if made available through CMS APIs?</p>
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Technology Vendors (TD)	TD-2	b. What data sources are most valuable alongside the data available through the Blue Button 2.0 API?
Technology Vendors (TD)	TD-2	c. What obstacles prevent accessing these data sources today?
Technology Vendors (TD)	TD-2	d. What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?
Technology Vendors (TD)	TD-3	Regarding digital identity implementation:
Technology Vendors (TD)	TD-3	a. What are the challenges and benefits?

Technology Vendors (TD)	TD-3	b. How would requiring digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 CSPs) impact cybersecurity and data exchange?
Technology Vendors (TD)	TD-4	How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?

Technology Vendors (TD)	TD-5	How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers? Who should publish such a directory, and should users bear a cost?
Technology Vendors (TD)	TD-6	What unique interoperability functions does TEFCA perform?
Technology Vendors (TD)	TD-7	To what degree has USCDI improved interoperability and exchange and what are its limitations?
Technology Vendors (TD)	TD-7	a. Does it contain the full extent of data elements you need?

Technology Vendors (TD)	TD-7	b. If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?
Technology Vendors (TD)	TD-7	c. If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?
Technology Vendors (TD)	TD-7	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?

Technology Vendors (TD)	TD-8	What are the most effective certification criteria and standards under the ONC Health IT Certification Program?
Technology Vendors (TD)	TD-9	a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?
Technology Vendors (TD)	TD-9	b. What would be the drawbacks?
Technology Vendors (TD)	TD-9	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)?

Technology Vendors (TD)	TD-9	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?
Technology Vendors (TD)	TD-9	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?

Technology Vendors (TD)	TD-10	For EHR and other developers subject to the ONC Health IT Certification Program, what further steps should ASTP/ONC consider to implement the 21st Century Cures Act's API condition of certification (42 U.S.C. 300jj-11(c)(5)(D)(iv)) that requires a developer's APIs to allow health information to be accessed, exchanged, and used without special effort, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws?
Technology Vendors (TD)	TD-11	a. Should this capability be revised to specify standardized API requirements for EHI export?

Technology Vendors (TD)	TD-11	b. Are there specific workflow aspects that could be improved?
Technology Vendors (TD)	TD-11	c. Should CMS consider policy changes to support this capability's use?
Technology Vendors (TD)	TD-12	Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?
Technology Vendors (TD)	TD-13	What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?

Technology Vendors (TD)	TD-13	a. What are the primary obstacles to this?
Technology Vendors (TD)	TD-13	b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?
Technology Vendors (TD)	TD-14	a. How many endpoints is your network connected to for patient data sharing? What types, categories, geographies of endpoints do you cover? Are they searchable by National Provider Identifier (NPI) or organizational ID?
Technology Vendors (TD)	TD-14	b. How are these connections established (for example, FHIR (g)(10) endpoints, TEFCA/Integrating the Health Enterprise (IHE) XCA, or proprietary APIs)?
Technology Vendors (TD)	TD-14	c. Do you interconnect with other networks? Under what frameworks (for example, TEFCA, private agreements)?

Technology Vendors (TD)	TD-15	a. How would increased use of bulk FHIR improve use cases and data flow?
	TD-15	b. What are the potential disadvantages of their use?
Technology Vendors (TD)	TD-16	What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?
Technology Vendors (TD)	TD-16	a. Do current rules encourage scalable network participation?

Technology Vendors (TD)	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?
Technology Vendors (TD)	TD-18	a. Could you, as a technology vendor, provide examples for the types of practices you have experienced that may constitute information blocking. Please include both situations of non-responsiveness as well as situations that may cause a failure or unusable response?
Technology Vendors (TD)	TD-18	b. What additional policies could ASTP/ONC and CMS implement to further discourage healthcare providers from engaging in information blocking practices?
Technology Vendors (TD)	TD-18	c. Are there specific categories of healthcare actors covered under the definition of information blocking in section 3022(a)(1) of the Public Health Service Act (PHSA) that lack information blocking disincentives?
VALUE-BASED CARE ORGS		

Value-Based Care Orgs (VB)	VB-3	What are essential health IT capabilities for value-based care arrangements?
Value-Based Care Orgs (VB)	VB-3	a. Examples (not comprehensive) may include: care planning, patient event notification, data extraction/normalization, quality performance measurement, access to claims data, attribution and patient ID matching, remote device interoperability, or other patient empowerment tools.
Value-Based Care Orgs (VB)	VB-7	How can technology requirements for APMs, established through CEHRT or other pathways, reduce complexity while preserving necessary flexibility?
Value-Based Care Orgs (VB)	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?
Value-Based Care Orgs (VB)	VB-9	What technology requirements should be different for APM organizations when comparing to non-APM organizations (for example, quality reporting, and interoperability)?

Value-Based Care Orgs (VB)	VB-10	In the Calendar Year (CY) 2024 Physician Fee Schedule final rule (88 FR 79413), CMS established that CEHRT requirements for Advanced APMs beyond those in the “Base EHR” definition should be flexible based on what is applicable to the APM that year based on the area of clinical practice. What certification criteria should CMS identify under this flexibility for specific Advanced APMs, or for Advanced APMs in general? Are there specific flexibilities or alternatives to consider for smaller or resource-constrained (such as rural) providers in meeting CEHRT requirements without compromising quality of care or availability of performance data?
Value-Based Care Orgs (VB)	VB-12	What technology standardization would preserve program-specific flexibility while promoting innovation in APM technology implementation?
Value-Based Care Orgs (VB)	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?

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There is real opportunity associated with the inclusion of patient-sourced data from devices such as home-based technologies: scales, blood pressure devices, glucometers, personal health trackers, etc. Any of those can transmit data to in turn populate an EHR.

Further, as described previously, the exchange of radiologic / PACS data is a big hole currently in health care. While providers generally have good access to images from within their own organization, those images are not readily accessible by patients or by other providers seeing the patients. Radiologic apps should be invited to the table for this conversation, but the industry will still need to address issues with size limits in common exchange methodologies. The TEFCA RCE should also be tasked with determining how to map the image exchange use case with the technical infrastructure being built by the QHINs. As that comes together, EHRs can then work within the expanded infrastructure to appropriately support the transmission and reception of exchanged images.

We also point out the long-standing challenge of integrating data from diverse sources and specifically that stemming from the lack of a universal standard for provider attribution. There are a number of use cases that demand the consolidation of data from multiple systems (e.g., EHRs, claims, apps), but it's critical that providers be appropriately credited for positive outcomes or held accountable for wasteful care. That requires solving the provider attribution challenge, so we encourage prioritizing that.

We suggest that TEFCA should be the framework for exchange that is promoted by the government through public policy levers with the goal of ultimately creating what feels to all connected stakeholders like one source for comprehensive health-related data even where there are separate networks and data sources behind the scene. TEFCA is still in early stages of adoption with many providers not yet connected, either because their vendor is still working to connect to QHINs or the providers themselves are still waiting for further motivation to connect, but it is clear that additional incentives for participation could have a positive impact on moving that forward even more quickly.

Patients having data in multiple patient portals is a well-recognized issue. Patient-facing 3rd party apps are not yet at the point of being able to effectively aggregate and display data from multiple sources, including patient portals, at least not without significant manual work by the patient or caregiver, so this should be an area where TEFCA is explored to evaluate what role it can play in addressing that challenge.

Lastly, CMS has authority to set requirements, incentives and penalties for most critical stakeholders in the healthcare ecosystem - payers, labs, diagnostic care centers and providers alike. The lack of standards-based exchanged required of most of them is a measurable barrier to cost-effective and easily consumable exchange, and TEFCA is one way in which they could be required to exchange data that would address those challenges.

CMS blue button technology for a patient, Payer APIs, EHR vendor APIs for patient and provider use, state and regional public health reporting, and quality measure reporting are all areas of opportunity.

TEFCA uses both CCDA and FHIR standards today. CCDA has been in use for a decade so has matured over time. The initial certification deployment of FHIR was delivered by vendors by 12/31/2023, so the industry is still in the early stages and watching the use cases expand in real-time as the USCDI versions and standards move forward, FHIR will be enhanced and expanded to a more mature state.

That said, while FHIR holds tremendous promise, it is not the appropriate standard for all data exchange use cases. XDR and XDM, for example, have been working well for years and don't need to be replaced. It's important that requirements not force re-work that adds no additional clinical or efficiency value and would add unnecessary cost to the system.

There is no other nationwide alternative to TEFCA that allows the level of connectivity and data exchange that is necessary to improve healthcare outcomes. Further, numerous stakeholders from across the ecosystem have bought into the promise of TEFCA and made investments in their own technology to connect to a QHIN, from software developers to many provider, public health agencies to the VA, and there is no option that would present the same coast-to-coast, agency-to-agency opportunity

The need to make improvements in digital identity management is clear, as the issue of patient matching is critical to smoothing the health information exchange process. However, in mapping the path forward, it is important to recognize that the digital identity credentialing process could be challenging for some patients with limited technology, including those with limited income or healthcare financial support. Other barriers could include a lack of access to video conference calling, and for those who would need to mail documents, it could mean a time delay when setting up accounts or a risk that some patients have difficulty getting to a post office.

If efforts specific to digital identity credentialing, we suggest that a non-proprietary credentialing process be allowed to increase the options and organizations able to provide support.

It is also unclear what the source of funding for this initiative will be, particularly for the patient access side. The only reasonable approach to this is for public funding to underpin this effort; asking either providers or patients to pay for it is infeasible.

There would clearly be an economy of scale with one account to be used by patients and providers across multiple platforms. There should be a quick and obvious decrease in the burden borne by patients in trying to access their healthcare information across multiple platforms.

Please see other related comments

As education is rolled out and they come to better understand the benefits that will come from widespread patient credentialing, as well as the role played by CSPs, such an approach would likely engender improved trust among patients.

All of the API options listed below, beyond (b) Standardized API for Patient and Population Services, were proposed in the HTI-2 proposed rule. We indicated our support in moving forward with them in our comments responding to the HTI-2 proposal.

Yes, we support this standard via the 170.315 (g)(10) ONC certification criterion, which includes individual patient queries and responses, along with FHIR Bulk export queries and responses using group ID.

Yes (see above)

Yes (see above)

Altera has one EHR solution that supports CDS Hooks today. Our other solutions have addressed this use case using other technologic approaches. Our intention is to comply with any finalized regulation that may be released addressing requirements specific to CDS Hooks.

The readiness and willingness of providers to accept digital identity credentials would certainly at least in part depend on the options supported by the technology they use. Providers generally already employ their own standalone solutions that perform some type of identity verification, and they would need to understand some dramatic improvement in functionality to believe the hassle of changing solutions would be worthwhile. This is another place that CMS can use its power of incentives to drive desirable behaviors.

While a federal privacy law would provide important baseline protections, CMS can help balance privacy with access by promoting robust data security practices, requiring transparency in data use, and enforcing interoperability standards that empower patients without compromising their data.

Hard to tie a digital identity credential to significant improvements in health directly. Use MFA like Google Authenticator. Let patients setup whatever option they'd like with it's a phone number, email or application.

Clearly, it is more efficient to have access to one log in that can be used across multiple applications. The result would be very favorable after both providers and patients go through any initial challenge inherent in setting up the verified identity.

We support the maintenance of key information blocking Exceptions, particularly the Manner and Infeasibility Exceptions/ They are structured so as to balance the need for broad access to EHI with secure implementation. They also support an approach in which stakeholders are supported in exchanging data efficiently without having to accept only expensive, proprietary methods. Conversely, narrowing these Exceptions could extend barriers to interoperability and hinder innovation for smaller developers and providers. We do, however, urge ONC to prioritize stability in the information blocking regulations and use clear sub-regulatory guidance to make necessary adjustments, rather than finalizing the burdensome "requestor preference" proposal from HTI-2. We also suggest that more flexible, context-aware approach to the Infeasibility timeline would help the industry make better use of the Exception.

On the other hand, a scenario that is not addressed by the Information Blocking exceptions is arising more and more frequently across the industry. The scenario is one in which a healthcare provider organization declines to pay the developer of their EHR/other health IT software for contracted licenses/services while continuing to use the software; they do this while claiming that termination of the contract for non-payment would be information blocking. Contract law and guidance from the ASTP/ONC both indicate that health IT vendors can legally terminate the contract and cease providing access to the data in the database as long as they make available the entirety of the customer's database - all EHI - in machine readable format. However, provider organizations in numerous cases have refused to accept those terms, insisting that to do this would be information blocking, even as they refuse to meet their payment obligations. We ask that ASTP/ONC revise the Licensing or Fees Exception - or add a new Exception - to address this critical trend and make clear that health IT vendors have no obligation to continue providing unending access to patient data when they are not being paid contractually agreed upon Fees for their software and associated services. Unfortunately, some provider organizations are misusing the Information Blocking law, and ASTP/ONC should make adjustments as necessary.

There is currently no true incentive for payers to participate, but that may change as the payment use case for TEFCA is more widely implemented. Embracing TEFCA would mean embracing standards-based exchange in a way that would be a fundamental upending of their approach to date.

We cannot reiterate strongly enough the criticality of standardization across all entities that interface for Treatment, Payment and Operations purposes, including payers. Because of the ONC certification program, health IT vendors and providers are much farther along than payers in adopting standards-based exchange methods, including APIs, so they have significant work to do.

For example, CMS has finalized the mandatory use of FHIR R4 for Electronic Prior Authorization for items and services. However payers are not required to follow the implementation guides that are the standards part of the ePA workflow precisely because CMS deemed that to do so would be too burdensome for payers. As a result, however, there is going to be an avoidable chasm between the technologies that EHR developers are being asked to deploy versus those that will be at the other end of the ePA exchange process, which is going to result in implementation challenges, unnecessary costs to the system, and the high likelihood of redevelopment at some point when payers are ultimately required to use standardized exchange methods.

CMS should consider requiring payers who receive Medicare/Medicaid reimbursements to support digital identity credentials for patients.

A directory of connectivity information, including endpoints, is a necessity. TEFCA is managing a directory of participants and sub-participants, and that functionality could possibly serve as a directory for endpoints. The participants included should be providers, payers, CMS, facilities, etc. Please note that a directory of this type must be in place in order prior to implementing the Electronic Prior Authorization process for items and services, which calls into question the 2027 deadline for ePA use by providers.

Payers - both government and commercial - should adopt a consistent set of standards for quality measure specifications, value sets, data requirements, and calculation logic. Such coordination would address the burdensome variability and unnecessary complexity that providers must currently navigate in reporting quality data to various payers, including within CMS programs, which would be helpful to both clinicians and health IT developers.

The value of bulk extraction of clinical quality data depends on there continuing to be very timely feedback shared with the submitting providers. Providers are very used to receiving insights into their performance from dashboards, and that has to continue to get them to embrace payer-side calculations. That data enables meaningful course correction by the providers during the reporting period, which is critical given that the submitted data drives at least part of their payments.

Providers will also need to be 100% confident in the accuracy of the calculations before the approach can be successfully rolled out industry-wide. Because we are looking at a time of transition, we strongly encourage CMS to permit providers choose to grant calculation authority to CMS or to continue to perform the calculations themselves using a calculator of their choice until such a time when CMS has demonstrated that their calculator methodology and technology works effectively and can be trusted to be accurate.

Altera supports the move to Digital Quality Measures for all quality reporting for all programs as long as there is an alignment of the quality measure specifications, implementation guides, value sets, and calculation methods across CMS and other payers. This would enable providers and health IT developers to leverage the same infrastructure and workflows across programs and could reduce the number of redundant quality measures of different types. However, for this to work, there needs to be a planned technologic strategy and timeline clearly defined and achievable. We recommend that CMS implement a phased, consensus-driven approach to start with pilots that are restricted to a small number of core quality measures. This would allow stakeholders to test real-world workflows, evaluate interoperability standards, and iterate before anything was scaled more broadly.

Once implemented, real time outcomes need to be available to inpatient and ambulatory providers to improve patient care.

Developers will both meet market demand and comply with any regulatory requirements that are released. If our clients are convinced of the need for the adoption of additional products, we will work to meet that demand (and most technologies that meet a need for Medicare patients will also be useful more broadly for other constituencies, which is a positive).

However, there is going to be a need for education of providers so they understand any suggested adoption of new tools. Even where software developers make new technologies available, the providers don't always see the value of expending resources or disrupting workflows. Incentives may be necessary to encourage providers to move forward with implementing these technologies, particularly where the benefits of the connectivity benefit others but not providers directly.

CMS should also consider how to streamline and make more transparent regulatory requirements, which would also lower barriers to entry for new digital health products targeting beneficiaries and caregivers.

Also, it's important to recognize that there is currently a strong focus on the use of FHIR bulk exports to address use cases for providers and other healthcare entities, but it does not play a role in patients getting access to their own data. That has to be addressed through other approaches, as mentioned elsewhere in our response.

Implementation of Electronic Prior Authorization for Items and Services and Quality Measurement reporting via APIs would be very helpful to providers, especially if feedback is made available in real time. That said, CMS can increase developer engagement by making provider directory data available via API.

Additionally, as noted elsewhere in our response, CMS must be sure to enable real-time access to cost data back to participating providers. Developers could build more effective tools if CMS made available timely, patient-specific cost data to support both provider performance and price transparency for patients.

Attribution inconsistencies currently impede accurate performance measurement and data usability. Improved attribution methods would improve both developer functionality and provider trust in CMS data. In assessing how to encourage access of these data sources, CMS should allow flexibility in how solutions are implemented by providers and avoid overly prescriptive or burdensome requirements regarding either presentation or utilization. Room for industry innovation in how different systems ingest the data from APIs and how it's presented in the workflows must be protected in the regulation.

Altera is supportive of expanding the use of APIs, but we caution that implementation of those APIs must be standards-based for every anticipated use case. Exchange via consensus-based standards is necessary for any of these projects to be cost effective and safe. It is not feasible for EHR vendors to spend development resources on non-standards-based use cases that in turn requires customization for usefulness.

There also needs some type of incentive for adoption of API-based functionality by hospitals and providers because if the market does not want to use what vendors are developing, then the requirement is a waste of resources at a time where we are already challenged to satisfy numerous Federal and state regulations.

We also note that it is very challenging for EHR vendors to complete Real World Testing for functionality that our clients have been uninterested in implementing due a perceived lack of value to them. A recent example that proved very difficult to find clients to test with in 2024 was the use of the FHIR bulk export.

Lastly, we reiterate the importance of real-time quality feedback loops. Our EHRs and related technologies include dashboards that allow providers to monitor their quality measure success throughout the reporting period, which allows them to adjust as necessary to improve their scores. It is critical that providers retain the ability to track and interpret their performance in near real time even as CMS rolls our new approaches to quality measure reporting, such as FHIR bulk export.

At a high level, we request clarification regarding the intended scope of digital identity requirements and who the credentials are intended for (e.g., patients, caregivers, providers, proxies). Further, how do CMS and ASTP/ONC expect them to be used across different workflows and systems?

Digital identity credentials can improve security and trust, and they can support consistent identity verification across disparate systems for the benefit of greater interoperability and patient safety. It can also offer an improved access to patient data by allowing users to provide their own identity. However, implementing digital identity at scale would involve significant workflow and integration complexity even beyond the points already made about the challenges of convincing patients to participate. It requires cross-organizational trust, as well as coordination regarding how third-party apps and healthcare entities verify and accept credentials. Without clear governance, implementation standards, and designated use cases, widespread adoption remains difficult.

Another very important challenge to highlight is that of the difficulty of coordinating across inconsistent state government and agency standards. We strongly encourage CMS and ASTP/ONC to work closely across federal and states to identify and collaborate on use cases that will offer the most effective outcome.

Requiring digital identity credentials would positively impact cybersecurity and data exchange. One model to consider as options are reviewed would be the standardized digital ID model implemented across Europe. A number of health IT vendors do business in Europe and already have those standards available within their products, so it could be a more rapid approach to consider.

CMS could work with ASTP/ONC to establish a certification program specifically for standards-based API functionality and to include requirements not just for CEHRT but also connections made by payers, public health agencies, and other ancillary providers.

We also strongly urge both CMS and ASTP/ONC to avoid requiring standards within regulatory requirements before they have been sufficiently tested in real-world environments and gone through the full standards development and approval process. Developers have proven themselves to be willing to adopt standards as demanded by the market (for use cases that the market agrees will be useful), but premature adoption in regulations without demonstrated operational readiness or for functionality that the market will be uninterested in implementing / using unnecessarily increases burden.

We also recommend that ASTP/ONC make available a new information blocking exception specific to scenarios when third parties request connections through proprietary APIs rather than following standards-based approaches, thus asking us to complete Development to satisfy the request. That would not preclude vendors from declining to do the work based on availability of resources but would alleviate the burden from vendors to always do work stemming from requests for proprietary/custom solutions. We do not feel the Manner Exception is specific enough to address this issue or the frequency with which the industry is having to apply it or move to the Infeasibility Exception within the unreasonable timeframe allowed.

We believe that CMS should host and publish the list and work within the government appropriations process to determine how to cover the cost. We do not support shifting any of the cost burden to users. Maintaining a functional, national directory should be considered core infrastructure and supported through federal investment or aligned with existing regulatory programs.

To ensure accuracy and sustainability, the directory should be maintained by entities with an interest in its completeness and accuracy, such as those facilitating exchange (e.g., TEFCA participants) or those involved in provider credentialing and licensing (e.g., state licensing boards). Such a directory should not be limited to FHIR endpoints only, but rather any relevant endpoint or addresses used for standards-based exchange, e.g., DirectTrust addresses. We also suggest that there should be a directory for payers, as well, since that is also an obstacle currently.

Note that providers very frequently require contracts before making their endpoints accessible by 3rd party vendors. This is a consideration that should not be underestimated as a factor in any plan for moving forward with this change.

In the current environment, TEFCA is unique in its potential to standardize and scale nationwide health data exchange by tackling three challenges that have bedeviled the industry for decades: outlining clear governance requirements, defining use cases not efficiently addressed elsewhere, and holistically evaluating technical requirements across the defined use cases with a view of the whole environment, as opposed to a more siloed approach that has been taken to date. The inclusion of robust record locator services is also an important value add that reduces the burden of managing proprietary or non-standard connections

TEFCA could more specifically offer a significant improvement for Public Health connectivity, facilitating the flow of detailed, time-sensitive information more robustly than approaches that require individual contributions from HIE separately or even direct transmission from individual providers. Generally, HIEs serve defined geographic regions or within states, and they only connect with each other on a limited basis outside of the structures of TEFCA. Further, there are pockets of the country that are not served by an HIE at all. Because maintaining and connecting to multiple siloed HIEs can be costly, If TEFCA can truly deliver on scalable, standards-based exchange, it could reduce duplicative infrastructure investments. These are all areas in which TEFCA can help address insufficiencies with real-time access to data.

USCDI as a relatively new standard has measurably improved the consistency and usability of health information at the point of care and in the process of exchanging patient data. There are still some issues to be addressed (inconsistency with HL7 standards in some places and the frequency with which USCDI versions come out, which should instead be every two years), but it's clear it has been a step in the right direction.

It does not contain the full extent of data elements needed for all interoperability use cases. We suggest gradually broadening scope to provide a more complete, standardized basis for all EHI.

We do note that the two paths for USCDI development - USCDI and USCDI+ - can be confusing for developers and users of the technology. This could be addressed by refocusing on a unified standard, with use-case-specific annotations to identify critical elements for different programs.

With every annual update we get close to the inclusion of all required and /or useful healthcare data. The primary limitation of USCDI is not the format itself, but the lack of clarity re: USCDI's long-term purpose does create uncertainty. If the goal is to eventually standardize all EHI under a common framework, that intent should be articulated with a published deliberate strategy that outlines the intended phases. This predictability would be very helpful to the industry.

USCDI is a good starting point and much farther along than what the industry started with several years ago, but we do reiterate a point made by vendors for years, which is that any future expansion of the included data needs to be required with adequate time allowed for vendors to develop and deploy. This should take precedence over other projects that might also add real value to the healthcare system as a whole. As noted, too, additional datasets already in process through the USCDI+ model (eg. behavioral health, maternal health, public health, quality reporting, etc.) should also be consolidated into a single streamlined framework for USCDI that would support greater predictability.

We do not support a non-proprietary but less structured format and have experience with ONC certification program requirements not being standards based. The following are historical reasons for our stance.

The original 170.315 (g)(8) API certification criterion was not standards based. That resulted duplicative development once the FHIR and USCDI standards were named. Another current example is the 170.315(b)(10) EHI Export criterion which only addressed the extraction of data. It did not address the incorporation of that data into the target database. Health IT vendors cannot support every proprietary solution they may encounter. It also diverts resources from moving forward with new ONC certification program requirements and new entrepreneurial solutions are needed by our clients to reduce burden and improve efficiencies.

In addition, Health IT vendors are required to deliver non-standards based functionality related to patient requested restrictions in 170.315(e)(1) as part of the ONC HTI-1 requirements with a delivery timeframe of 12/31/2025. Requiring capture of a non-standards based patient request for restrictions functionality is not useful and will result in provider burden. The patient request of restrictions is one piece of an incredibly complex workflow related to the exchange of data. Honoring a patient request for restrictions without a standards based approach across the healthcare ecosystem will not be successful.

The FHIR Bulk Export requirement in 170.315(g)(10) is an example of when a new standard is introduced for use for the first time. The requirements for the standards did not address standardization of patient list capabilities for use in defining the population to export data. Examples that should be addressed in standardizing patient list capabilities include dynamic/static lists and filtering capabilities such as provider, practice, age, condition/diagnosis, procedure, etc. It did not include requirements for CDS Hooks or a subscription model. In the ONC HTI-2 proposed rule included both CDS Hooks and a subscription standard.

ePrescribing is an example of a good standards-based certification criteria, as are the Privacy and Security (P&S) criteria. The CCDA is another good example of a standard that has matured and been updated over the last decade and is working effectively across the ecosystem. HL7 FHIR-based API criteria have also been highly impactful, supporting significantly expanded data access and exchange and prompting and innovative app development system.

Public health connectivity has been supported through a scalable reporting infrastructure, especially for immunization and electronic laboratory reporting. The lack of reciprocal obligations on public health agencies (PHAs) to adhere to the same standards leads to fragmentation and unnecessary work to connect, however, which is an area presenting additional opportunities for improvement.

This is the next logical step and is fully supported by Altera. Redefining certification to emphasize API-enabled capabilities, especially HL7 FHIR-based APIs, would be very useful to modernizing interoperability. HL7 FHIR-based APIs enable flexible and efficient data sharing - more so than IHE Document Exchange APIs. However, we do point out that there are non-API approaches that remain valuable and very effectively serve a purpose, such as functionality-based privacy and security, and do not need to be replaced through any evolution to FHIR-based APIs.

It is also critical that CMS continue to understand and reflect in regulatory program requirements the timeframe that is required for EHR and other health IT developers to complete the work, deploy and implement updated standards and enhanced workflows as they are changed.

As in any other endeavor of this magnitude, time and cost are potential drawbacks. There would be little benefit in forcing migration away from infrastructure and standards-based exchange that is efficient without a clear increase in value in some way. Certification reforms must take into account cost, maturity, and implementation feasibility, not just the number of criteria.

Many forms of unstructured data, such as faxes, scanned documents and free-text content, are already supported in terms of exchange by HL7 FHIR-based APIs (the DocumentReference resource). It would still be useful to expand USCDI to more explicitly include these data types, however.

We also note that even free text data needs some type of associated coding for a recipient to know what it is. For example, code applied to a narrative paragraph, such as history of present illness, can ensure that a recipient understands what has been sent to them without having to open the file. For faxed records, however, functionality would be needed to add an identifier upon receipt. If it is a test result, for example, it should be labeled as a result with a result date. In any case, ASTP/ONC should consider where functionality exists but simply needs to be incorporated into certification vs. where the functionality would be new and thus take more time.

Responding to queries for API-based data should be an automated process, not manual, and it should include patient consent management. This is an example of where the entire ecosystem of the query and response via API should be standards-based in order to function successfully. TECCA could also serve an incredibly valuable role in this process.

Additionally, significant staff work and training are required for provider organizations to successfully incorporate API-based data requests into their workflows, and this is another example where provider adoption depends on meaningful incentives. CMS could clearly impact adoption for this through incentive alignment—for example, rewarding automated case reporting via eCR to replace manual submission burdens. Provider organizations could provide useful advice regarding how to best align API engagement with clinical workflows and resource constraints.

Moving forward with the CMS planned Digital Quality Measure (DQM) approach would be the right approach here. This should include centralized data aggregation at the patient level, but it must also include calculation of the DQM measures with a bi-directional flow of data back to them in real-time so providers can have immediate feedback. If CMS or another entity carries out centralized measure calculation, providers must still have near real-time visibility into those results within their EHR environment. In those situations, CMS should adopt a standardized API mechanism for pushing calculated results back into EHR dashboards to ensure continuity.

Further, standardization in the format for quality measures is critical because currently there are 6-8 different types of quality measures that have different specifications, as well as reporting format for the same measure concept. Moving all measure types to DQM measures with real-time feedback would significantly reduce burden across the entire healthcare ecosystem.

There is a difference in the use cases between a patient accessing their data and any other authorized person accessing their data. There seems to be a perception amongst some stakeholders that any third party vendor that wants to use the data should have access to the data, but that is not always the case. HIPAA compliance must be maintained in all cases related to which entities or people are allowed access to the data. Further, providers are not required to use any third party that a vendor may wish for them to use; this typically requires a contractual relationship between the two parties.

On the other hand, patients or authorized caregivers should always have access to their data through any third party application that can meet the standards for connecting to the EHR APIs. In our anecdotal experience from Real World Testing activities, some of these third party vendors do not support the full USCDI set of data, and some request custom development to support their application, which adds unnecessary cost to implement.

As predicted when the the 170.315(b)(10) EHI Export certification criterion was proposed, the functionality as deployed in the real-world has failed to achieve the desired benefits for providers and patients for many reasons. First, the criterion only addressed the extraction of data and not the receiving end (the incorporation of that data into the target database). Second, we have heard from providers on how this functionality is not useful to them. They do not understand the use case for the EHI Export or the FHIR Bulk Export and in which circumstances they would use either one. While both are well-intentioned, the need for provider education has always been historically underestimated by ASTP/ONC and CMS as they prompted the roll out of new functionality to the market.

As a Health IT vendor, we always support moving forward with standardized requirements as opposed to pushing the requirement of functionality before standards are sufficiently tested at scale. In our experience, delivering non-standards-based functionality frequently ends up being a short-term waste of resources for us, our clients and the entire healthcare ecosystem because the exchange goal behind the use case is usually not satisfied effectively and development work ultimately has to be redone once standards are actually finalized and ready. That said, one note of caution: in order for a standards-based approach to be used for this use case, it would require a significant expansion in the concepts of the USCDI and all the necessary development work that would need to take place before the overarching EHI Export project could be successfully completed. Alternatively, the EHI Export requirement could be re-scoped to not include all EHI but rather a reference guidance on how to support EHI Export using HL7 FHIR Bulk Data inclusive of an organized USCDI data set.

No, this is not an issue of workflow. We also reiterate that certification as required by the government should not prescribe workflows, user interfaces or internal steps that organizations should take. Certification should be solely about requiring that functionality exists in a product and works as intended.

Instead, workflow associated with any capability should be left to the developer to finetune in conjunction with the clients using their systems, given that new functionality always has to be considered in the larger context of the product architecture and configuration choices. Standardizing workflow details across vendors would create unnecessary rigidity and complexity without adding meaningful value.

EHI Export as a product capability is called upon rarely - only when a patient wanting a machine-readable copy of their data or when an organization or single provider wants to move their data to another EHR. Instead of mandating anything specific to EHI Export, CMS should instead support broader adoption of standards-based exchanges (e.g., HL7 FHIR and HL7 CDA) that already satisfy most interoperability needs. If existing standardized exchange mechanisms (such as FHIR or C-CDA) fulfill the vast majority of real-world needs more effectively, there is no benefit in requiring the use of EHI Export for its own sake. Additionally, USCDI and FHIR profiles can be used more in the future to fully support the "all EHI" use case as for exceptional cases requiring more comprehensive datasets.

CMS is right to consider non-CMS data sources and networks, but those should be endorsed only when they store and exchange data in a standards-based format that aligns with the ONC certification criteria. For example, in the Items and Services Electronic Prior Authorization rule from CMS, the implementation guides for the critical workflows were only recommended for payers but not mandatory, reflecting the fact that most payers to date have shied away from API adoption and never been held to a requirement to employ standards-based exchange mechanisms. This has added very real costs to the system as a whole and will continue to do so as more payer-oriented exchange use cases are priorities. This will also have a negative impact on ePA-related workflows for clinicians when the whole point of requiring ePA is to lessen provider burden. The payers - and some policy makers - seem comfortable expecting health IT vendors to do customized development for their clients in the absence of standardized APIs being made available across the payer ecosystem, but that is not widely feasible and will, again, add completely avoidable costs.

APIs that provide access to a patient's complete EHI could open the door to exciting opportunities for many healthcare stakeholders. Most critically, patients and caregivers would be supported in better engaging in their own care and moving their data exactly where they want to - including to other providers they are seeing who currently regularly do not have all data necessary (particularly images). Clearly the care coordination possibilities among various providers are endless, as complete longitudinal health records would become more accessible across systems. Researchers and public health agencies could also benefit, gaining access to richer, real-world data sets for analytics, population health management, and disease surveillance.

That said, any massively expanded capability to access entire patient datasets would need to be paired with impenetrable privacy protections and standardized data structures. Also, what about patient consent? And what data would other entities have a legal right to access who currently are not covered by the HIPAA statute? These are incredibly important questions that must be worked out.

Exchange of the entirety of a patient's record isn't valuable unless it's consumable on the receiving end. However, the consumability of that data relies not only on the exchange of standardized data but also a multitude of choices made by clients in terms of configuration and additional content specific to their clinician workflows. This frequently is done without coding on our part, such as nursing admission assessments, and as a result, there is a significant amount of data in an EHR database that is not coded and therefore more difficult to exchange efficiently.

USCDI defines a structured, consensus-driven subset of health data that is standardized, broadly applicable, and readily interoperable. Conversely, the full scope of EHI encompasses vast and often unstructured or proprietary data elements that vary widely across systems and use cases, so processing that more complex and less standardized data also requires more sophisticated tools, resources on both sides of the exchange, and safeguards. Inherently, the concept of exchanging all EHI is understood to likely introduce additional costs, workflow burdens, and risks of inaccurate interpretation of patient data. We recommend that ASTP/ONC focus on continued development and adoption of standards, including incrementally expanding USCDI, so as to provide continued progress even as flexible pathways to access additional EHI when justified as created.

Altera solutions certified to 170.315(g)(10) have published all patient facing for client databases where the functionality was implemented for promoting interoperability purposes, and we did implement the use of NPIs for providers and hospitals. Altera has clients in almost every state and some US territories.

Note that the ASTP/ONC guidance was flexible in how identifiers were implemented by health IT vendors, which may result in a lack of standardization in published endpoints. .

Connections were established in accordance with the standard provided in 170.315(g)(10). Connectivity to a QHIN will be starting in the near future.

Altera EHRs include non-FHIR based connectivity to state and regional HIEs and CareQuality, as well as an incredibly wide range of registries and state and regional public health agencies. While our clients also have access to FHIR-based connectivity, but most existing connections today are non-FHIR based because they date back to days before FHIR was even created.

The initial deployment of FHIR Bulk under the certification requirements is based on nascent standards. As the standards are updated and expanded, additional use cases will more easily be able to be supported because the foundation will be in place. In fact, the HTI-2 proposed rule included a significant expansion on the focus of the API functionality, including proposals related to subscriptions and CDS Hooks, as well as proposed new APIs specifically for Electronic Prior Authorization and Provider Access. It would also be helpful to have expanded guidance from both ASTP/ONC and CMS plus standards promulgation, once through the testing process, around the use cases for the FHIR Bulk patient list functionality.

The patient list should take into consideration all critical data, such as diagnosis or condition, patient age, physician, etc.. There should be standardization of how that functionality can be deployed so that vendors who want to connect don't have variability as information is exchanged. The patient list functionality also needs to be specified to support both static and dynamic output.

As stated elsewhere, we also emphasize that the promise of Bulk FHIR is very dependent on greater adoption than is currently in place, the maturity of purpose-built implementation guides, and access to robust testing tools. Even where EHRs are certified to support HL7 FHIR Bulk Data Access already, many providers and other stakeholders have been slow to adopt the new technology because they don't see a strong business case for doing so and believe the additional value to their clinical process will be minimally useful. CMS has an important role to play here in driving adoption and deep use of FHIR Bulk through either motivating incentives or through the power of Medicare Condition of Participation levers.

Due to the lack of utilization of the FHIR Bulk Export by our clients, we are not yet at the point of identifying disadvantages of their use.

The ultimate goal needs to be widespread use of a nationwide healthcare sharing network, such as TEFCA, by all relevant stakeholders. This type of model is self-perpetuating - as adoption grows, the value to users grows, which in turn draws in more participants to add even more value through greater availability of even more data. We strongly believe that once such a sharing network is up and running, it could easily replace many point-to-point models, such as connectivity from an EHR to numerous individual state immunization registries. In order to eliminate point-to-point connections, a full assessment will need to be completed, but that will be necessary before all data being shared over a network can be converted.

Additionally, there are many entities involved in these connections that are not currently required to comply with the ONC certification and interoperability/information blocking programs, so expanding requirements re: standards and free data exchange will be critical to involving those other important data stakeholders.

Current HHS rules do not fully encourage scalable network participation. In order for health IT vendors to commit resources to support scalable network participation, CMS/ONC needs to better incentivize other healthcare ecosystem stakeholders.

Use of a nationwide healthcare data sharing network could reduce costs in the long run. To be successful, however, all healthcare stakeholders will need to participate at scale, which is not happening rapidly at the moment because of a lack of incentives. Currently, there is frustration among many providers that they bear the cost and operational burden of purchasing new health IT or functionality for which they are not the primary beneficiary, and that is a consistent barrier to getting those organizations to implement and actively use new functionality that we make available. To remedy this, CMS and ASTP/ONC should co-develop a strategy to incite the use of expanded health IT functionality by the entire ecosystem. Incentives = Adoption.

Most Altera clients are connected with third-party vendors that are not covered under the interoperability and information blocking requirements. In our experience, they are not always responsive in collaborating to resolve connectivity issues.

Additionally, ambulatory providers who meet the MIPS exclusionary criteria are not required to have certified functionality in place and may not be able to send CCDAs to hospitals or respond to FHIR API queries.

The definition of healthcare provider under the 21st Century Cures act provision is extremely broad. However, disincentives are limited to hospitals and providers participating in the Promoting Interoperability program. To really drive change across all of health care, it would clearly be beneficial for both CMS and ONC/ASTP to request that Congress authorize creation of a disincentive structure beyond the narrow list currently in place today and expanded to all healthcare entities (including labs, pharmacies, payers and public health agencies) that play a critical role in exchange.

A “health care provider” is defined in the statute as: a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x-2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title , an ambulatory surgical center described in section 1395l(i) of this title, section 1395w-4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

Please see our response to TD-17 for healthcare provider types who face disincentives who face violating the information blocking regulations.

Successfully value-based care models require seamless care coordination, performance measurement, patient engagement, and data-driven decision-making. All of this requires standardization and consistency across CMS programs, particularly in quality measurement and reporting. Accelerating dQM development and adoption - and specifically focusing on the use of standardized data elements and formats (e.g., FHIR-based exchange of USCDI) - is crucial to ensuring that health IT provides accurate, near-real-time insights into quality performance that supports clients in adopting the desired behaviors.

In addition, because value-based payments typically go to organizations spanning multiple care settings using multiple EHR platforms, another complication stems from data normalization, mapping, and aggregation.

As a health IT vendor, we hear from our clients in value based care organizations that there are major challenges in data aggregation across multiple organizations for submission. This is frequently a barrier to those organizations that would otherwise be interested in participating in value-based programs.

APM requirements of participation should align more closely with real-world use cases, as well as implementation guides (IGs), testing tools, and reporting workflows that providers and developers find not only necessary but practical. Consistent value sets and reporting mechanisms across programs would significantly reduce participation burdens for provider organizations.

That said, it's important that use of these resources be encouraged without mandating rigid implementations to protect room for user-friendly approaches. Flexibility can be maintained by supporting modular, standards-based approaches that enable providers to choose the tools that best fit their workflows, as long as they conform to a consistent underlying technical framework.

This cited condition of participation is an example of the challenges that occur when there are no named standards and the entirety of the workflow is not addressed. There was no named standard for the transmission of these notifications, and the requirement only addressed the transmission of the notifications but was silent on how recipients were to incorporate those messages into their workflows. While most vendors used an emerging standard based on Direct Messaging, the outcome has been less than ideal and could be revisited to be more valuable.

We also reiterate that policies that create shared responsibility and accountability across the healthcare data ecosystem - not just for hospitals and physician practices using certified EHR technology - are essential to realizing the full value of digital tools in APMs.

The requirements should be the same because they all interact with each other. We see little benefit to requirements being different, and in fact, it causes market confusion and exacerbates the digital divide that is a risk to patients in less connected geographies.

Beyond the base EHR, certification criteria that would be beneficial would be related to Public Health Reporting. Missing is public health reporting functionality for immunization registries, electronic case reporting, syndromic surveillance, antibiotic use and resistance reporting, and electronic reportable labs. While this reporting may not be required by the ACO, there are likely state laws and regulations requiring it.

Robust testing infrastructure and real-world validation tools are essential. Ensuring these tools are accessible and relevant not just to EHR vendors but also to eligible hospitals (EHs), critical access hospitals (CAHs), physician practices, app developers, and other stakeholders would reduce implementation burden and accelerate adoption.

It would be helpful to have clarification of the definition of a 'provider' in the context of a nationwide provider directory. Does it include hospitals, care providers, payers, etc.? For example, it is unclear where payer endpoints will be located for the upcoming items and services ePA API. In one response to a prior rule, CMS indicated that providers could manually locate endpoints on payer websites, which is not viable. They should not be overlooked as useful directories are created.

