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Donald Rucker, MD
U.S. Department of Health and Human Services
Office of the National Coordinator for Health IT
Attn: Trusted Exchange Framework and Common Agreement
Switzer Building
330 C St SW
Washington, DC 20201

Dear Dr. Rucker,

We appreciate the opportunity to submit comments on the Trusted Exchange Framework, Minimum Required Terms and Conditions, and QHIN Technical Framework. We appreciate ONC's responsiveness to industry comments on the first draft of the Trusted Exchange Framework and Common Agreement (TEFCA), and we offer the following comments on patient matching, record location services, and privacy and security requirements.

About Verato

Verato enables healthcare organizations to manage, match, and link their patient and member data with unprecedented ease, accuracy, scale, and performance—and at the lowest cost. Verato's cloud-based patient matching technology uses the next generation of matching architecture, called Referential Matching, and is HITRUST-certified. Verato's clients include some of the largest providers (Intermountain, Northwell, Texas Health, Advent Health, UPMC), payers (UnitedHealth) and Health Information Exchanges (Healthix, CRISP, Manifest MedEx) in the country and we help them to achieve the highest match rates in the industry. Verato can serve as an Enterprise Master Patient Index (eMPI) for an organization, or our technology can work alongside existing eMPIs or EHRs, helping them resolve their duplicate records.

Minimum Required Terms and Conditions

Patient Demographic Data for Matching

ONC proposed in Section 3 that QHINs would need to evaluate their data management practices using the PDDQ Framework annually. Patient matching in US healthcare depends on the proper operation of every individual matching engine in the "network." Today, our poor state of interoperability is caused by wide variation in data quality and matching quality that starts at every end-node (hospital, payer, pharmacy, clinic, test facility) and extends to every HIE/HIN. While TEFCA does not address the quality at the end-nodes or participating HIEs, it can at least influence the quality of data and matching at the QHINs through PDDQ. We support the inclusion of this requirement in the Minimum Required Terms and Conditions (MRTCs). Below, we provide additional ways we believe ONC can help to improve patient matching.

Sharing Data Outside of the US

In Section 2, ONC included a restriction on using, disclosing, or hosting data outside of the US, which we have included below.

2.2.11 No EHI Outside the United States. With respect to activities that are subject to these terms and conditions and the Common Agreement, no QHIN shall Use or Disclose any EHI outside the United States except as required by Applicable Law or as provided below.

(i) QHINs shall not Use or Disclose any EHI to any person or entity outside the United States (or allow any third party acting on its behalf to take such action) except to the extent that an Individual User requires his or her EHI to be Used or Disclosed outside of the United States.

(ii) QHINs may only utilize cloud-based services that are physically located within the United States. All EHI provided to a cloud services provider shall be stored physically within the United States and shall not be transferred to or located in any other countries or jurisdictions.

We understand that this limitation is intended to protect our national security and ensure that foreign governments do not gain access to the health information of US citizens. We agree with the requirement that EHI be “physically stored” within the US and encourage ONC to finalize that portion of the clause. However, we are concerned with the requirement that data not be “used or disclosed” outside of the US, particularly since these terms are defined quite broadly.

Utilizing offshore resources has become a very common and accepted practice in healthcare today for specific activities like medical coding because it is so manually-intensive. It seems quite likely that some QHINs or their technology suppliers might use offshore resources to perform other manually-intensive activities like detailed quality reviews of match results – which could be done more thoroughly with offshore resources while still keeping interoperability costs low.

We believe that ONC can achieve strong protections AND enable QHINs to deliver interoperability at low cost if it defined the requirements for offshore operation in a highly prescriptive manner as follows:

“Any offshore personnel or entities must be subject to all of the same security training and screening as on-shore employees. Further, all offshore infrastructure must adhere to the same safeguards and certifications as on-shore operations (including HIPAA and HITRUST). Further, it must be made technically impossible for any EHI data to be transferred out of the US to laptops, stored on drives, or otherwise outputted in digital form.”

The use of remotely-controlled laptops (located in the US) operated from “dumb terminals” (i.e. located offshore) that are inhibited from any local storage or digital output along with VPNs makes this kind of tightly controlled operation perfectly feasible today. We think this modification offers better security than most on-shore operations and is a proper safeguard for US EHI. We believe that the blunt prohibition of any offshore activity ultimately does not serve the US’ need for highest quality/reasonable cost interoperability.

QHIN Technical Framework

Patient Identity Resolution

In the QHIN Technical Framework, ONC included a requirement that *A QHIN MUST be capable of accurately resolving requests to match patient demographic information with patient identities under its domain*. We agree with this overall requirement for QHINs. In fact, it is the cornerstone of the QHINs' role in national interoperability. We ask ONC to consider how the RCE should ensure that QHINs meet such a requirement. Is there a certain percentage of records that must be accurately matched? What happens if a QHIN is not accurately matching records and who will monitor this? In our letter to ONC on its proposed information blocking rule, we suggested that ONC work with CMS to institute a patient matching benchmarking program for health IT developers that would evolve to also test end-user implementations of patient matching. Those recommendations are reiterated below. We believe the only way to ensure that QHINs meet this patient matching requirement is to require the use of a patient matching technology that meets match rate baselines and, ultimately, to test the match performance as implemented at each QHIN.

ONC Request for Comment #7: The IHE XCPD profile only requires a minimal set of demographic information (i.e., name and birth date/time). Should QHINs use a broader set of specified patient demographic elements to resolve patient identity? What elements should comprise such a set?

Verato Response

The US Core Data for Interoperability (USCDI) contains a set of demographics that can be used for matching. Since the USCDI is the data set named in the MRTCs, we recommend that QHINs be required to exchange all of the demographic data elements included in the USCDI. On a national scale, Name + Birthdate is far too narrow of a range of attributes to uniquely identify a person. With its largest customers, Verato has seen how solutions that work on modest regional scale break down completely at larger national scale. As ONC adds demographic data elements, such as email address to the USCDI, they should become required data elements for QHINs to exchange.

However, we would caution that adding more demographic information is still not a guarantee of proper patient matching at super-regional or national scale. The statistics and region-specific tuning upon which probabilistic matching is based will struggle or fail at super-regional scale. The QHINs will need to use patient matching technology that has proven its performance at super-regional scale, which should be amply demonstrated by meeting the match rate baselines established by the patient matching benchmarking program.

ONC Request for Comment #8: There are many possible approaches to Patient Identity Resolution, each with its own benefits and risks. For example, a centralized index of patient identity information may be more efficient for resolving patient identities across disparate communities, but also poses a greater risk to privacy if the system is compromised. Federated approaches may be less susceptible to external threats like cyberattacks, but harder to scale across many communities. Recognizing that new technologies and business entities with robust identity matching solutions may disrupt traditional approaches, should the QTF specify a single standardized approach to Patient Identity Resolution across QHINs?

Verato Response

A centralized index of patient identity information may be efficient for resolving patient identities; however, we agree that it introduces unique cybersecurity concerns. Since the Common Agreement is intended to be a nationwide agreement, a centralized index of patient identities would amount to a single central database of identities for the entire country. As we have seen with major breaches in the last five years, such databases are a major target.

Another problem with a single centralized database is the inherent problem of compounding errors – where traditional EMPI matching degrades as the number of sources increases because the injection of just one error for a given identity will affect every future match of that person. In a federated solution, that error injection would be isolated just to one QHIN’s super region. Verato would suggest that an even better solution would be Referential matching because it further limits the compounding of errors since every new identity is compared against an “answer key” reference database, thereby limiting the propagation of errored identities.

Fortunately, there is now a new technique available within Referential Matching that allows a federated QHIN approach to matching, but also provides the efficiency of a centralized EMPI. Because Verato’s referential matching uses a reference database of identities to serve as an “answer key” for all patient matching, every identity stored within a Verato MPI is inherently mapped to its corresponding reference identity in the Verato reference database. If all QHINs were to independently use the Verato MPI product, then each of their respective patients would be inherently pre-mapped to each other by virtue of their connection to the corresponding reference identities. This cross-matching happens automatically and internally to Verato and can be “turned on” and exposed for any cooperating Verato customers, such as a group of cooperating QHINs. In this model, a QHIN could determine all of the shared patients at other cooperating QHINs by simply checking the cross-reference.

In other words, under the Common Agreement, every QHIN would have instant visibility into where all of its patients exist at all other QHINs. In fact, participant-level enumerators (e.g. MRNs) at every hospital could also be stored as private attributes within the QHINs EMPIs, so that in queries to the Participant’s EHR, further matching would not be required. This would ultimately deliver the matching efficiency of a centralized EMPI, with matching accuracy that does not degrade with scale, and allow for independent federation of QHINs with isolated cybersecurity.

While the solution described above would work very well as a single vendor solution, it is not technically infeasible for two referential matching vendors to collaborate and harmonize their offerings to offer this architecture as a multi-vendor solution.

We do not believe that the Technical Framework should specify a single standardized approach, rather, it should specify patient matching baselines QHIN must meet as well as the behavior of QHINs when multiple potential matches are found. For example, if more than one match is found, should a QHIN return all results and allow the requestor to select the correct record? Or, if multiple potential records are found, should the QHIN return nothing? The Additional Required Terms and Conditions or the Technical Framework should specify these policies.

ONC Request for Comment #9: Different communities tolerate different degrees of risk with respect to accurately matching patient identities. Should QHINs meet a minimum performance standard (e.g., a minimum acceptable matching accuracy rate) over a specified time period? Likewise, different algorithmic techniques for matching patient identities use different approaches and must be tuned to the applicable patient population and continuously refined over time. Should QHINs measure and report on the performance of the algorithm(s) they rely on (e.g., by calculating precision, recall, etc.)?

Verato Response

In our comment letter on ONC's proposed information blocking regulation, we offered a recommendation on how ONC could create a patient matching benchmarking program for health IT developers and ultimately for testing implementations of such technology. We reiterate those comments here. We believe that the benchmarking program could easily be used to test QHINs' patient matching capabilities and ensure that they meet a minimum baseline target.

Create a Test Data Set

The Support for Patients and Communities Act included a 100 percent funding match from CMS for qualified state PDMPs. This funding is being used by many states to connect their PDMPs across state lines and share data. This funding provides a unique opportunity to create a test data set that could be used for product benchmarking. PDMP demographic data has all of the qualities needed for a good patient matching test (highly variable misspellings, out-of-date data, varying capture mechanisms, broad geographic reach, not synthetically-created). There is an opportunity for states to contribute PDMP demographic data only (no clinical data) to a data set that could then be refined by an appropriate testing body (possibly one or two of the current ONC Accredited Testing Laboratories). Refining could occur in multiple ways, but ultimately the testing body would have what would amount to a test key so that the testing body would know what the expected outcomes should be (i.e. what matches should be made by the matching technologies).

Benchmarking and Reporting

Under the Cures Act, ONC is required to establish an EHR Reporting Program. ONC has not yet established such a program but intends to do so in future rulemaking. The reporting program provides an excellent opportunity to begin benchmarking matching technologies. Once the test dataset is created, ONC can require that, as part of the reporting program, certified health IT developers who match patient data (e.g. developers who are certified to criteria that facilitate exchange such as APIs) must test their products against the test dataset and report the results to ONC. The results of such tests would show how well products natively perform and create echelons or tiers of benchmark performance that will inform the entire industry of what it should expect. We believe that some health IT developers will perform in the upper echelons, while others would land in the lower end on the spectrum. We also expect that the best-of-breed matching vendors, while not certified health IT developers, would voluntarily test their products' performance. This benchmarking would bring a new level of transparency to matching tools, and we anticipate that ONC could use that data to set initial baseline targets and associated timelines for certified health IT developers who are in the lower echelons to improve their products to meet the baselines. Over time that baseline can be raised to drive all products into the upper end of the upper echelon.

Testing Implementations (Future State)

Most sophisticated matching tools do not perform very well out-of-the box. They must be highly tuned to exploit characteristics of the population, data sources, and data collection methods that are often very unique to each implementation at a health system or payer. This tuning is very complex and more of an art than a science. Consequently, a healthcare organization could be using the top of the line, gold standard matching product that exceeds the ONC baseline but still fail to achieve good matching results. Benchmarking the vendor technology described above is the first step towards improving patient matching across the nation. The next essential step is ensuring that the real-world implementations of those tools are meeting appropriate baselines too. We understand that there are inherent challenges with testing individual implementations, but we strongly encourage ONC to conduct a study that recommends a feasible approach to testing real-world patient matching implementations. In the world of interoperability where every hospital and payer are charged with making coordinated matching decisions for shared patients, they carry a fundamental responsibility to do it well. Without standards, measurement, and rules this federated interoperable environment will never work well enough. Basic patient safety and wellness are at stake. If ONC does not pick up this responsibility, then we ask who will?

Record Location

The QHIN Technical Framework includes a requirement that “*A QHIN MUST be capable of accurately identifying the location of all appropriate patient EHI prior to responding to a QHIN Query.*”

We agree with this requirement, since the primary responsibility of a QHIN is to be a conductor of data between separate parties. If a QHIN cannot identify where all data is located, it will not be able to respond to queries on behalf of its participants. However, ONC stopped short of requiring a record location service (RLS). We are concerned that excluding an explicit requirement for an RLS could lead some QHINs to attempt to provide their services in a completely federated manner. This will not be scalable and could ultimately slow down response times for all QHINs, which could lead to provider and user unhappiness with the networks. In order to scale the TEFCA, we believe that RLS must be a requirement for every QHIN.

ONC Request for Comment #10: Recognizing there are different ways to implement Record Location services, should the QTF specify a single standardized approach across QHINs?

Verato Response

As detailed in our above responses, we are extremely concerned about the accuracy of patient matching within a QHIN. Hundreds or thousands of contributing health organizations – all with different levels of patient matching performance – are attempting to match patient records with each other. An organization with low patient matching performance will inject its errors into the broader network and those errors will compound across matching within the QHIN. Ultimately, it will be the responsibility of the QHIN to accommodate for and resolve these errors across the network. And, accurate patient matching between QHINs is exponentially more challenging because it assumes that each QHIN has resolved all errors for their contributing organizations.

Verato has first-hand experience with this dynamic of matching at scale within and across networks. The largest Health Information Exchanges (HIEs) in the country use Verato for the most accurate patient matching at scale. In an analysis conducted across three HIEs, compared to their standard query methods, Referential Matching was able to identify 7.5x more patient record locations between any two HIEs and over 27x more patient records across all three HIEs.

We believe that the QTF should specify the requirement for an RLS and its technical specifications. The Carequality Document Query Implementation Guide contains such technical specifications for implementors to optionally use an RLS to facilitate their queries. We recommend that the QHIN Technical Framework utilize similar specifications for RLS, rather than reinventing the wheel.

Conclusion

Nationwide interoperability has the potential to transform our healthcare system, and we strongly support and applaud the agency's goals in developing a framework that would facilitate the flow of patient health information. However, patient matching within a large network, not to mention across large networks, poses a significant challenge that needs to be addressed. Patient safety is at risk. We encourage ONC to carefully consider feedback from the industry and ensure that appropriate time is provided before these policies are finalized and enacted. We are happy to answer any questions ONC has about our comments. I can be reached at mark.larow@verato.com.

Thank you,

A handwritten signature in black ink, appearing to read "Mark LaRow". The signature is fluid and cursive, with the first name "Mark" and last name "LaRow" clearly distinguishable.

Mark LaRow

CEO, Verato