PHILIPS

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Office of the National Coordinator

Department of Health and Human Services

Philips comment

Trusted Exchange Framework and Common Agreement Draft 2

Dr. Rucker and staff,

As first detailed in our Feb. 20, 2018 comment to ONC on TEFCA 1, Philips continues to support the collaborative creation of a national exchange network that is patient-centric, free from unnecessary per-interface data management agreements and variable fee structures, and builds upon existing health information exchanges currently connecting the great majority of hospitals, health systems and attendant clinical data sources.

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We support TEFCA's goal of encouraging health plans and payers to participate in this framework to broaden patient, provider and payer access to and exchange of complete, mobile and readable patient views impacting connected care, analytics and outcomes.

To these ends - shall we say endpoints - we are structuring our comment to first reiterate summations of comment submitted to the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, and the CMS Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers (Proposed Rule).

Given the alignment aspects of these three federal initiatives both in language and timing, TEFCA cannot be considered in a vacuum, and we note that the data blocking proposed rule included RFIs specific to TEFCA.

Following these summations, we transition our comment to specific aspects of TEFCA 2 as proposed:

- Comment on 13 of 15 request for comments within Appendix 3: QHIN Technical Framework

- Exchange Modalities/MRTCs
- Standards
    - Transport protocols and data format standards
    - QHIN requirements, participant structure and exchange standards

Required TEFCA participation and exception language tied to TEFCA participation

As detailed in our May 31, 2019 comment to the data blocking proposed regulation born of the 21st Century Cures Act, with successful and collaborative networks and use case development in place through the CommonWell Health Alliance, Carequality and the eHealth Exchange, for example, participation in TEFCA as a voluntary program is already poised by vendors and HIEs leading and participating in these networks, which have in turn expressed enthusiasm for TEFCA and taking on QHIN and RCE roles. And in February of this year, for example, CommonWell announced its Connector's program, allowing any interoperability service provider to join/connect to its network minus previously established membership and onboarding processes. This is being done in the spirit of TEFCA's vision and goals. And as you are likely aware, CommonWell and the eHealth Exchange already provide a directed query gateway between its networks.

The current structure of the national exchange networks and increasingly streamlined onboarding will also serve MA plans and other CMS participation entities as described in the CMS Interoperability and Patient Access proposed rule to join established HIEs by the Jan. 1, 2020 date as currently proposed.

Upon TEFCA's original proposal, there was anticipation that voluntary participation would bring about some level of safe harbor from the now-proposed data blocking regulation. And while we believe that such a blanket or safe harbor approach is too broad, we recommend that ONC develop data blocking exception language, along with the seven exceptions now proposed, that would further facilitate voluntary participation in TEFCA, and that ONC not require vendors to participate in TEFCA, any more than it would be anticipated that payers and other entities would be required to participate.

Along with the RFI on whether vendors should be required to participate in TEFCA, companion language in the data blocking proposed rule again posits whether actions necessary to comply with the common agreement should constitute a narrow exception to blocking. Again, we support this approach but disagree that it could come about in "future rulemaking." We recommend this language be included in the final iteration of TEFCA's

structure and in the Cures Act/data blocking final rule to establish clear guidance and encouragement to stakeholders considering the merits of joining TEFCA's governance.

TEFCA is the broad connective tissue and visionary market approach that can succeed through a public-private collaboration and not as another requirement or regulatory burden.

Achieving this, though, will require some fine-tuning of TEFCA 2 as we describe below.

The scope and definition of electronic health information (EHI)

Given the obvious connection between the broad scope and definition of EHI within the data blocking proposed rule and its inclusion as the data to be exchanged within TEFCA in regards to "individual access," the "technical and legal requirements for sharing EHI" and for "exchange purposes" as written in TEFCA 2, it is clear that a more succinct or minimum data set needs to be set forth in the data blocking proposed rule that would translate to the TEFCA exchange of EHI.

We propose here that ONC consider the newly proposed USCDI as a minimum data set for exchange within TEFCA, and that it be supplemented by data types matched to use cases as further defined by TEFCA's RCE and QHINS with public stakeholder input and that of ONC.

We anticipate that the scope of EHI as currently proposed in the data blocking regulation will be subject to change upon a data blocking final rule, and that ultimately it will be reconciled within TEFCA exchange language.

Rather than refer or encourage ONC to review our complete comment on EHI, we have included it here at the close of our TEFCA 2 comment as Appendix A.

Payer participation, CMS' proposed rule and TEFCA

Finally in regards to alignment between TEFCA and related interoperability initiatives, in addition to the above comment on payer and health plan onboarding onto HIEs, we also believe that payers participating with CMS that advance data exchange capabilities as detailed in the CMS proposed rule will serve as an incentive for more providers to join HIEs and therefore participate in TEFCA, so that they can expeditiously communicate with the health plans regarding administrative and clinical issues.

For example, it is our understanding that one of the most significant administrative burdens for healthcare providers is the submission of prior authorization requests and supporting clinical data, and if providers are able to communicate electronically with health plans in processing PA requests, this has the potential to drive widespread participation of health providers in HIEs, without the need for regulatory mandates. We also believe the impact of the CMS proposed rule will crossover to private plans now presented with onboarding and participant levels to consider within TEFCA, buoyed by a voluntary approach and one that includes exception language tied to participation.

TEFCA 2 comment/categories

QHIN Technical Framework request for comments (Appendix 3)

There are a number of IHE Technical Framework specifications identified in support of the modality functions. These specifications offer several options depending on use cases supported – they are not a one size fits all. Further analysis is required to identify which actors, roles and transactions will need to be required for the TEFCA use cases. Without this level of specificity, the various systems may choose to implement their specific subset of the

technical framework which will lead to incompatibility between systems and prevent interoperability.

- **ONC Request for Comment #1**: While it may be helpful to have alternative standards to support a specific capability, having multiple options increases the complexity of potential solution and creates unnecessary risk. ONC should strive to select a single standard best suited for the use case needs. For vendors, having multiple standards/alternatives for the same capability increases the cost of development and adds unnecessary complexity. This should be minimized wherever possible. In the event that there is an emerging standard that could be considered, it may be prudent to expedite the development of the standard and hold off on requiring a specific standard until the target standard is available. It is also important to ensure the maturity level of the selected standards are sufficiently high as to eliminate unnecessary re-work by vendors to account for standards that are not ready for prime time.
- **ONC Request for Comment #2 and #3**: ONC should gain consensus on the minimal set of data elements and their coded values required for the SAML assertions.

- **ONC Request for Comment #4**: ONC should fully specify any allowed variations to completely and unambiguously specify the scenarios that would be required, and as within all areas of standards, should be done through a minimum set of use cases and scenarios allowed. This should include, for example, guidance on using ATNA, XUA and BPPC in combination, as well as when seeking consistency within boundary cases that must be supported, and the error conditions detected and raised as exceptions. Without this level of specificity, there will inevitably be cases where queries for data will fail and participants will not be able to get data and yet will not know why the queries were not successful.
- **ONC Request for Comment #5 and #6**: yes, the QTF should fully specify if discrete data queries are to be supported and what specific data elements (including format and value sets) should be supported. This should be aligned with the requirements imposed by the data blocking rule. Specific to request #6, we believe ONC should examine IHE's current profile development around mXDE and QEDm. As RESTful approaches gain attention, maturity and adoption within the industry, these emerging profiles are undergoing IHE review and should therefore result in market-ready consideration.
- **ONC Request for Comment #7**: The minimal data elements for XCPD are insufficient for matching across domains particularly as these domains get larger. If a query is sent directly to a specific data holder (e.g. a specific practice), the likelihood of two people with the same basic demographics (name, DOB,

gender) is low. As these entities come together, the likelihood of collision increase. When a collision occurs, the responding system either responds with nothing or there needs to be a second workflow (usually a list of records from which the user chooses) to choose the desired patient. We believe achieving the quadruple aim will require more non-user initiated computer to computer data requests which will mean there will be many transactions that do not have the benefit of the fuzzy logic a human operator can bring to the transaction. Given this, and absent a central source of truth for patient identification, it seems necessary for patient discovery to include a greater amount of demographics and for there to be a standardized scoring methodology for entities to use when responding across domains (e.g. QHIN to QHIN). We feel it would be helpful to require these performance standards within QHINs as well for exchange between their local participants, participant members and users and not limited to QHIN to QHIN exchange. As to desired data elements to reach a sustainable approach, we have experienced the matching of mobile phone numbers and address to at least two patient records/documents to be a positive approach, though it can be limiting in some categories of patient demographic areas such as pediatrics.

- **ONC Request for Comment #8**: Patient identity is a challenge for all participants in healthcare, and its resolution is paramount toward the mutual and critical goal of patient safety. Our experience in other countries with centralized ID systems indicates patient matching across domains is significantly easier and more accurate when this is available. This in turn leads to a higher amount of trusted exchange. Patient matching is the first step in the exchange process and without it we will all be unable to move data. The more data moves, the easier it will be to drive towards standards especially for data types not known or not contemplated today. While more attempted usage may

initially lead to nodes finding errors within payloads from other source nodes, we can only fix what we can observe. E-mail is an example of this usage pattern today. As new payloads are added (attachments, meeting invites, etc.) the high amount of usage across many settings and user types drives to an edge standard fairly rapidly so that various vendors systems can pass the minimum required elements between each other while still being able to differentiate their products for their customers.

- As for the increased security by keeping this data federated, there is some merit in that. But, it might also be more secure for consumers/patients if we further separate the clinical records from the identification record and keep ID centralized with the clinical data federated. This is a concept in line with the protections designed into HIPAA and observed in the design of other systems such as genomics datasets where the exposure of the linkage between a person's ID and the largely immutable genomics data could be catastrophic. A well secured, centralized patient ID lookup tool with no clinical data in it could help QHINs and other entities keep further separation between their clinical and identification data pools while improving their ability to effectively exchange data. That said, full separation with no patient demographics table at all within QHINs and just a hashed ID, would probably be too extreme of a change. This would necessitate the central entity being able to handle all patient level search functions which would dramatically alter

the TEFCA framework. We therefore believe the development of an NPI would fall outside the scope of TEFCA/QTF, but we welcome the opportunity to participate in next level discussions on how to work towards a standardized, nationally available approach to ID resolution that balances the safety, security and privacy rights of all patients while enabling the quadruple aim amid ongoing Congressional consideration. In the absence of an NPI, approaches to reconcile the challenges should include examining SHIEC's Patient-Centered Data Homes Initiative, for example.

- **ONC Request for Comment #9: Reference our comments to Request for Comment #7**. We do believe a minimum performance standard is necessary. We also believe a maximum should be considered or we risk patient identification becoming a data exchange blocker which is antithetical to the goals of TEFCA. It may be appropriate to consider different minimums and maximums by user or usage type. For example, a HIPAA covered entity and a general patient user may need to be treated differently irrespective of the data elements being returned. A CE and its business associates are bound by regulations and contract provisions to treat patient data with a certain level of care including informing individuals and the public if something went wrong. A patient/consumer who is accidentally provided the data of another individual is not subject to these regulations and associated sanctions and as such their query's matching logic may need to be at a higher level.

- **ONC Request for Comment #10**: The QTF should specify the functional and non-functional requirements for the record location services. This can be done by specifying the interfaces and quality and performance characteristics which should be demonstrated by the QHIN.

- **ONC Request for Comment #11**: The QTF should specify the functional and non-functional requirements for the directory services. This can be done by specifying the interfaces and quality and performance characteristics which should be demonstrated by the QHIN. Also, the governance of provider directories should be use-case driven as to what information attributes it includes and needs to be maintained to balance technical capabilities and with patient services and provider identity. This information should be included in the directories and available via the directory services to all members and QHINs.
- **ONC Request for Comment #12/#13**: We suggest that the QTF should define the minimal requirements to capture a patient's consent for the purpose of allowing access to his/her data. As long as we do not require this consent to be made available (via Query/Retrieve) to other QHINs the actual consent format (BPPC, APPC) is not the most important factor. What we believe to be of importance is to define the minimal set of consent policies a QHIN (or its participants) should implement (e.g. opt-in, opt-out, access in trauma situations). To come to a scalable consent solution ONC may consider separating the consent discussion into two parts. One part specifies the consent a "EHI custodian (or medical record keeper)" is required to have before releasing EHI in response to an incoming query request. The other part specifies a consent the requestor (or query initiator) need to pass with the query request to provide evidence that (s)he is making this request with consent from the patient. The second consent can be derived from a legal basis (e.g. a doctor who can proof to have a

legitimate treatment relationship may use an implied consent). The bare minimum ONC or the QTF should do is to mandate the use of an opt-in or an opt-out consent basis. Based on our experience globally we believe IHE's BPPC profile is sufficient for a minimal consent implementation.

- **ONC Request for Comment #14**: The QTF should identify the specific events (activities and transactions) that should be logged to the audit repository. For each event, the data recorded should be identified, including all provenance information.
- **ONC Request for Comment #15**: The QTF should specify the full set of error messages for all potential interactions between QHINs. These should be specified in a consistent format, and we further recommend that should additional error messages be needed, the development should align with existing profiles as described in TEFCA 2. ONC should very clearly elaborate if there becomes any intention to expand the full set of specifications outside of TEFCA 2 language/examples to ensure stakeholder input and consistent system behavior.

Exchange modalities/MRTCs

Philips currently supports query/retrieve and push models to our customers, provides outbound exchange and external access to data, as well as convergence among FHIR and HL7 formats to provide an API-driven connected care ecosystem.

For the purposes of TEFCA QHIN exchange modalities, we support Targeted Query, Broadcast Query and Message Delivery as included in TEFCA 2. In our comment to TEFCA 1 we recommended both push and population-level transfer. While we are pleased that Message Delivery/push remains, we encourage ONC to match the maturity of population-level transfer with its inclusion as a TEFCA exchange modality both in the future and to match TEFCA 2's current stated principle 6 of population-level data exchange, and finally that in keeping with our comment on EHI, exchange modalities be tied to use case.

Standards

Transport protocols and data format standards

As defined in Table 1 of TEFCA 2, Philips supports the use of the prescribed transport protocols. Philips supports both IHE and HL7 transport protocols

and maintains membership within interoperability standards organizations including HL7, IHE, DICOM, IEEE and the Personal Connected Health Alliance.

We understand that a range of transport protocols can be beneficial and are currently utilized within the industry.

But, where ONC has historically failed to shore up a major barrier to the efficient exchange of clinical data, TEFCA 2 also fails to address.

Philips operates thousands of interfaces with vendors, labs and health systems to aggregate and exchange actionable data, yet must normalize approximately half of it into a common, readable format toward beneficial clinical usage and the creation of longitudinal records.

We strongly recommend that ONC, through the TEFCA process, or if it better fits statutory abilities, through the data blocking proposed rule, prescribe enforceable data format standards to cease or minimize the historic use of proprietary code formats that cause disparate systems to fail to exchange readable data. For example, we have experienced more than 100 different coding formats for A1c. Through its annual standards advisory ONC has offered lists of data formats that has resulted in little more than an exercise rather than a tangible movement toward data format standards. The agency

can also seek to further align with existing organizations (IHE/PCHAlliance) toward prescribing enforceable standards.

As noted throughout our comment, success within TEFCA means taking the opportunity to conduct a holistic examination of limiting unnecessary standards variations not tied to exacting use cases. This includes aspects as recommended in Request for Comment #1, for example.

QHIN requirements, participant structure and exchange standards

Overall, Philips supports a hierarchy structure as published encompassing QHIN, member-participant, participant and user levels.

We seek clarity on what the financial implications would be matched to each, specifically around membership within a QHIN and operational flow-throughs, all in anticipation of stakeholder considerations, and recommend the RCE take this matter up toward clear messaging specifically to health systems and payers.

We continue to believe as noted in our comment to TEFCA 1 that a limited set of QHINs each with broad participation among a diverse set of stakeholders could fulfill TEFCA's participation goals. In this regard we

disagree with the elimination of record locator service/connectivity broker capability requirements for QHINS, which we supported in Philips' TEFCA 1 comment. We believe lowering the bar for QHIN functions will encourage the pursuit of QHIN status by entities not fully equipped to scale national exchange within the modalities proposed. Elsewhere in this comment we also speak to forces that could lead to QHIN attrition.

Also, in regard to TEFCA's structuring (QHIN, participant, participant-member, user) and the exchange of EHI, here again the relationship between efficient exchange and standards should be examined.

Elsewhere in the proposal, concerning the excerpted sections below, the normalization of local data should be addressed as well in the context of the excerpt on page 25, and concerning the reference within page 53, #2, is there a mediation process if EHI is not available, either through offline or foundational connectivity issues, and on what entity would correction fall?

Page 25:

HINs should, to the extent possible, ensure that the data exchanged within their own network and with other HINs meets minimum quality standards by using testing and onboarding programs to verify minimum quality levels.

Page 53:

(b) If the Participant stores or maintains EHI, the Participant shall also respond by providing all of the EHI it receives in the then applicable USCDI to the extent that all of the following conditions are satisfied:

1. The EHI is appropriate for and relevant to the applicable Exchange Purpose;

2. The EHI is available;

3. The Disclosure of EHI is permitted under and meets all required conditions of Applicable Law; and

4. The Disclosure is in accordance with any applicable Minimum Necessary Requirements as noted in Section 7.19 below.

While we believe ONC is correct to encourage QHINs to provide services outside of the scope of TEFCA's three exchange modalities to meet local needs, we also believe it is important that within the context of these three exchange modalities there is standardization of the minimum data set and methods by which QHINs connect to participants, participant members and users. As such, we encourage defining and requiring a standard model of exchange that all QHINs must be able to support locally. QHINs should be free to make their own decisions on alternate methods, but should always have the standard "vanilla" version available as a consistent starting point.

Without standardization at this level, we believe the stated goal of a single "on-ramp" to nationwide connectivity will be much less likely to be achieved. Connecting systems to an HIE is still difficult to this day and it could be much easier with a common, reference standard. This need for a standard is more acute if one assumes, as we do, that vendor products will often need to connect to more than one QHIN to meet customer needs. Furthermore, even if QHIN to QHIN network interconnects function perfectly, data must be in a format compatible to the local connections behind the two QHINs for data to be exchanged between the true holders and users of EHI.

We also believe this standardization is critical to the maintenance of a healthy marketplace of available QHINs and in addition can help create new opportunities for innovation currently hampered by the lack of access to EHI. It is unlikely that all QHINs will exist forever and some may fail to meet their customers' expectations necessitating a change in QHIN by a participant, participant member or user. Having a local on-ramp standard will make it easier to reconnect to a new QHIN and help avoid long periods where data holders are offline from the network.

In closing, among our business units we hold membership in the CommonWell Health Alliance, and certification and onboarding to the

eHealth Exchange (Sequoia Project), two market-leading and market-ready organizations we have confidence in toward taking up leadership roles within TEFCA

Overall, we believe that the success of TEFCA will hinge on its alignment with the data blocking proposed regulation and CMS interoperability expansion among its plan entities as detailed in our comment above, along with an expedited establishment of RCE/QHIN leadership to collaborate further with ONC and industry stakeholders.

Thank you for reviewing our comment, and as we have in the past, Philips is prepared to communicate further with ONC and be an asset on issues and provisions within this important healthcare initiative.

Greg Fulton

Philips PHM Policy Lead

c.c. Andries Hamster, Christopher Melo, Paul Wilder, Jason Gwizdala/Philips

Appendix A

Electronic Health Information and Export Data functionality

Arguably the most important aspects of the proposed rule are a thorough undertaking and understanding of the scope of EHI and its export, whether per-patient upon changing providers or upon a records request, or upon providers or a health system migration to another platform, and how these aspects mirror ONC implementation of Congressional intent.

While the definition of EHI is broad and supportable in our view, we would recommend some additions and request points of clarity:

- Philips recommends that consent directives, privacy requests, medical treatment research participation, if any, and advanced care/directives, if any, also be included within the definition of EHI.
- We would also recommend final rule language that EHI be both machine readable and human readable within the existing language around computable.
- As to the granularity of EHI, we request clarity on the definition of EHI as relates to information or data blocking. While we understand that not just data that is routinely presented to the patient/provider/payer in terms of results or clinical notes constitutes EHI, and that observational data produced by analytics or risk scoring is included, stakeholders need a more thorough understanding of the depth of EHI. For example, would a final procedure report or diagnostic imaging exam or discharge summary for an encounter suffice, or all continuous monitoring data, all the images from each diagnostic imaging exam (e.g. slices for a CT study or all loops for an ultrasound) fall within the definition?
- Similarly, within the proposed rule definition of EHI it is stated: “EHI may be provided, directly from an individual, or from technology that the individual has elected to use, to

an actor covered by the information blocking provisions." We surmise this includes patient wearables or remote patient monitoring data from cuffs and scales? Would this data type also be limited to milestone or actionable data as recorded within an EHR or clinical notes, or continuous raw data? Overall, what would the scope of patient-generated health data (PGHD) be? (We also note that in its 2019 IPPS final rule, CMS eliminated PGHD as a quality measure. Philips commented in support of maintaining the measure as PGHD, in the form of patient-reported outcomes surveys and burgeoning social determinants of health surveys, which bring value to the patient record. Eliminating PGHD as an incentive for health or hospital systems could discourage actors from valuing these data types.)

- We also see implications around "directly from an individual" in terms of the proposed rule noting that FHIR API data exchange upon a patient request through the application of the patient's choice would require read only capabilities, which could also preclude beneficial uses of PGHD. We understand that read only at the outset of this regulation may be a competent course in a complex and unprecedented regulatory process, but would recommend that write capabilities be considered for future functionality and rulemaking.
- Finally, in terms of clarity, we note the inclusion of "clinical information management systems" within the narrative language of the proposed rule, and would seek either a clear definition or its exclusion from rule language amid more clear language that does exist around the four categories of actors, EHRs, analytics platforms and observational data, etc. Additionally, in terms of the aforementioned four main actors cited within the proposed rule: vendors, HIEs, HINs and providers, ONC should assess whether its definitions here would benefit from detailed language of what is not considered an HIE or HIN. Where, for example, would public health interface engines, clearinghouses, clinical research platforms and middleware fall in or out of the categories of HIEs or HINs?

- In the Information Blocking section, ONC states, "We propose that EHI does not include health information that is de-identified consistent with the requirements of 45 CFR 164.514(b)." If the intent, by the stated definition of EHI, is to have "all the EHI that the health IT system produces and electronically manages for a patient or group of patients … (including) any data that may be stored in separate data warehouses that the system has access to, can produce, and electronically manages," we suggest that ONC provide further clarity on why de-identified patient data and its uses be excluded. Ultimately we would support a single, complete definition of EHI.

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In terms of the certification criteria data export, we recommend ONC assess a definition of what would constitute a minimum data export set, in line with the above comments, and would recommend a process or pathway to validate the completeness of the exported data to help forestall an interpretive reaction to data blocking by all stakeholders including and beyond the

four categories of cited actors, such as patient advocacy groups and of course patients themselves.

Upon reading the proposed rule, we detect an element of the blurring of the lines between what is the intent of the EHI export using the standard API and the information blocking requirement for providing all EHI, and suggest clarity on any perceived or defined differences.

Additionally, final rule language should speak to fulfilling EHI export if or when a request is limited in the data being sought, and whether EHI can be requested on a patient's behalf by a law firm or insurance company. What is the mechanism to honor or adjudicate such requests? Where would provider to provider requests fall as to a limited request or minimum data set? We further believe these implications will impact data blocking exceptions, specifically in the categories of harm and/or a request initially determined to be infeasible.

Given the whistleblower and data blocking complaint processes being put forth, and recent Justice Department settlements with two EHR vendors, including a $30 million award to a whistleblower in one case, stakeholders don't know what to expect upon the data blocking final regulation.

In terms of export standards, generally we do not find fault with current language allowing vendors to use their own export standards, but we caution that proprietary and legacy vendor exchange and data formats have hampered interoperability historically. Again, the Philips PHM platform that aggregates data from disparate EHRs within a health system typically normalizes approximately 50 percent of the data before being utilized for clinical usage. There are more than 100 data code formats for A1c, for example. We do therefore support proposed rule language that vendor formats and data dictionaries be included in requirements around data export. We also note from the proposed rule that HL7 FHIR itself can be a data export standard, but doubt that it would support all of the data types described as EHI.