PHILIPS

May 31, 2019

Donald W. Rucker, MD

National Coordinator for Health IT

Office of the National Coordinator

Department of Health and Human Services

Philips comment

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dr. Rucker and staff,

The Philips commitment to interoperability is historic and broad. Our business units range from imaging and diagnostics to remote care (telehealth and remote patient monitoring), population health management analytics, patient reported outcomes, interoperability services within HIEs and on to consumer products, all within the healthcare spectrum and all part of a vision of connected care.

Our Health Suite Digital Platform (HSDP) 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.

Among our business units we hold membership in the CommonWell Health Alliance, certification and onboarding to the eHealth Exchange, and provide both automated push and query and retrieve exchange protocols. Philips also maintains membership within interoperability standards organizations including HL7, IHE, DICOM, IEEE and the Personal Connected Health Alliance.

Our PHM platform business operates thousands of interfaces with vendors, labs and health systems to aggregate 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 understand that the elements leading stakeholders to a data blocking regulation are also historic and broad, a combination of unintended consequences of meaningful use, the persistent use of legacy and proprietary data formats not compatible with recognized standards toward efficient interoperability, and fear or the stated backdrop of fear around privacy and security hampering exchange and business models, along with other factors.

We met with your office and staff during the formation period of the initial TEFCA proposal and submitted comments, and we are pleased to provide comment to this proposed rule. We continue to be available as an asset to the agency within our shared goal of pristine interoperability with the patient as the focus.

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.

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.

HL7 FHIR Resources, Versions and Use Cases (RFI and narrative)

Philips appreciates the care – and the conundrum – ONC is respectively using to examine and is facing, in regard to trying to incorporate HL7 FHIR standards within certification criteria, the ARCH specifications/USCDI and the Cures priority of patient access through the HL7 FHIR API.

Industry stakeholders are well aware of the ever-evolving HL7 FHIR release options and maturity models, often tied to use cases and implementation

guides as developed by individual agencies and organizations now being brought together through regulation.

Philips too is developing and supporting the HL7 FHIR API for internal and external processes toward release version compatibility and advancement, and we too see HL7 FHIR benefiting interoperability and data management and as one of many gateways for patient empowerment.

We note that HL7 FHIR Release 2 is currently proposed, and likely seen as the simplest path forward for 3rd party applications and patient access to health records. But, given ONC's proposed timelines of API/USCDI and EHI export at 24 months, and testing even beyond, we believe it would muddy the waters to seek reconciliation among the four release options ONC has put forth: Release 2 only; Release 2 and 3 (either for certification); Release 3 and 4 (either for certification); or just Release 4.

If, though, upon the conclusion of this comment period, ONC follows a path of specifying multiple versions, provision also must be made for normative conversions – both backward and forward – between the versions they specify for all resources (including contained and referenced resources) and datatypes, and also provide for validation tools for testing conformance to the HL7 FHIR versions designated.

Philips recommends that ONC require just the most recent release and not a combination approach as the HL7 FHIR standard continues to mature. Further, given the timeframes to implementation, we believe there is no compelling reason to tie certification to a single, named version at this point in the rulemaking. We agree with the approach to enable support for the Standards Advancement Process to allow for more advanced versions of standards and implementation specifications to be approved for use under the Program in a timelier and flexible manner. This will promote the use of more mature elements of standards, and is especially relevant for HL7 FHIR which is evolving and maturing at this time. As many of the HL7 FHIR resources are at a non-normative maturity status, it will be important to move quickly to these resources when they become normative, rather than awaiting regulatory updates.

As ONC notes throughout the proposed rule:

- Standard API/patients and population is tied to HL7 FHIR DSTU Release 2
- ONC's consent management implementation guide to HL7 FHIR STU Release 3
- SAMHSA has developed a use case related to DS4P within HL7 FHIR STU Release 3. (Elsewhere in this comment, within Health IT for Pediatric Setting, we support the new/replacement HL7 FHIR and HL7 C-CDA DS4P criteria for privacy data segmentation.)
- The development and management of implantable devices speaks to one important aspect of Philips' healthcare mission. We note here that HL7 FHIR Release 4 includes a Device resource, with a UDI carrier, but its maturity level remains low. We support the inclusion of UDI data within the USCDI, and we also support ONC's proposal to require UDI for HL7 FHIR and for HL7 CDA (HL7 Version 3 Cross Paradigm Implementation Guide: Medical Devices and Unique Device

Identification (UDI) Patterns, Release 1), in part because if the data is already captured it can be mapped into the data elements of the FHIR resource or the CDA template, and in part due to the alignment with ARCH version 1.

- And finally, as ONC notes within the proposed rule, *ONC could approve a new version of the FHIR standard 'Release 5' in the future…(and)…leave the scope of the ARCH the same or update (necessarily) the implementation specifications for the FHIR profile and FHIR server requirements accordingly to align with the new FHIR versions. As an alternative example, ONC could leave the FHIR standard version the same and approve a new version of the ARCH to include more FHIR resources.*

There are no easy answers, but we can assure you that based on direct discussions with our health system customers, they are only beginning to understand that as the prescribed API Data Provider they are considered to be the actor that supplies access to and deploys the API technology, and are subject to complaints of data blocking.

Health systems are already being told by EHR vendors that "other" external third-party applications that could tie into their systems carry privacy and security concerns, and that they should only allow access to their current vendor API technology, pricing, contracting, etc., which we believe counters the spirit and language of Cures based on no special effort and the application of the patient's choice, as well as proposed rule language around

relationship fees. Also, very few health systems yet understand the option is available to host their own HL7 FHIR servers.

During the Senate HELP Committee's March 26 hearing on the proposed rule, Sen. Tammy Baldwin raised the issue of vendor "gaming" of the processes based on fears around data security.

This is not to cast blame at ONC but to underscore that all stakeholder conversations about the HL7 FHIR API going forward and into regulation would be unduly complicated by discussions around the fine points of release versions and functionality. We recommend ONC put forth rulemaking with a broadened stakeholder lens, and we agree that education is the responsibility of the entire industry.

Philips recommends ONC explore nomenclature around a Patient API in the greater marketplace, and a Certification API or a Standards API within industry focus that could still take on the normative reconciliation needs described above while sending a message to all stakeholders that HL7 FHIR is the manageable exchange process it is being promoted as.

Health IT for Pediatric Setting

Philips includes multiple pediatric hospitals and health systems among its customer base. We support the proposed rule's provisions for pediatric care, including the addition of pediatric vital signs within the USCDI and the promotion of the set of 10 pediatric functionality elements within the certification program, initially on a voluntary basis. We further recommend that over time pediatric provisions be formalized within the current certification program and not as a separate program, and that this future aligns with the 2015 Children's EHR format. We are also following the recommendations process of ONC's Health Information Technology Advisory Committee (HITAC) to expand pediatric data types within the program and support its goals.

We believe for the preventive and risk-based aspects of population health management and value-based contracting and care to progress, care management, quality, value, sustainability and outcomes tracking should be established for the lifetime of the patient. While federal quality or value-based care programs currently focus on older and/or chronically ill patients, mirrored by private or multi-payer models, pediatric care remains primarily in a fee-for-service structure. We know that progressive pediatric systems we serve are voluntarily entering into value programs and we are supporting the functionality needed to do so. An increased movement toward pediatric data and data exchange within ONC programs such as certification and

standards will benefit this movement and, we believe, lead to more formal value structures from CMS/CMMI within pediatric care.

Also as part of the proposed rule impacting pediatric care, we support the advent of new/replacement DS4P CCDA and FHIR functionality versions toward document, section and entry level privacy tagging to lessen the manual burden on pediatric providers and staff, all toward improved data segmentation.

We would, though, seek clarity in the final rule as to timelines. We would generally agree with proposed timelines that health IT for pediatric setting provisions would become effective upon the date of the final rule, as shown in ONC's webinar and presentation materials, along with that of data blocking. We would seek clarity on the API interface with the USCDI showing a rolling implementation ending year three, all as to how FHIR and/or FHIR versions to be described in the final rule would impact the noted pediatric provisions overall. We are also commenting on a recommendation for FHIR version(s) to be issued overall (3rd party apps, DS4P etc.) within the final rule elsewhere in this comment.

RFI – Required vendor participation in the Trusted Exchange Framework and Common Agreement (TEFCA)

As noted in our February, 2018 comment on the original TEFCA proposal, we support the vision and structure of TEFCA, specifically the process whereby the majority of the data exchange service level agreement, implementation and oversight details would be facilitated by the private sector, which is well placed to do so.

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 already participating in these networks, which have 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 easily join/connect to its network sans the normal 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" 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 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 next iteration of TEFCA's structure.

There are two tracks to consider here. One is the regulatory-driven approach to provide patients with access to their medical records and the standards to do so. The other is the ongoing clinical necessity of data exchange among health systems matching TEFCA's original goals, which should contribute to the improvement of provider workflows and efficiencies. Also of course in consideration is the CMS interoperability proposed rule that bridges the regulatory language and furthers participation requirements. TEFCA's approach is, and should be, market driven to advance and fine-tune interface agreements, population-based exchange and other use cases health systems can assess as clinically driven needs to enter a pristine national exchange governance.

As noted above, Philips met with ONC staff and was invited to participate in roundtable discussions leading to the drafting of TEFCA's original proposal. There we put forth several interoperability barriers to consider and forward-thinking aspects of interoperability speaking to population health management and value-based care models that appeared in the proposal and that should remain in the process, such as population-based queries and bulk transfers. If EHI in its broad definition within the data blocking proposed rule can be exported – whether per-patient or during a health IT system migration - then population-based or bulk exchange should be equally capable.

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.

Patient Matching RFI

In the continued absence of a national patient identifier (NPI) – and we urge ONC to continue to work with Congress toward establishing an NPI – we recommend ONC work with the existing national exchange networks and use case organizations such as the CommonWell Health Alliance, eHealth Exchange and Carequality, to assess what is being done right now for patient matching toward expansion into a more singular and governed network as envisioned by ONC through its TEFCA initiative.

CommonWell, for example, utilizes what it calls advanced auto-linking as part of its master patient index and record locator service, based on patient demographics. Currently covering the majority of the nation's hospitals and health systems, these networks are linked through collaborative directed query.

As noted elsewhere in this comment, the Philips PHM platform aggregates data from disparate EHRs and systems toward the normalization of data formats. Within that process we utilize algorithms to track and reconcile collisions toward patient matching, a process that we would be happy to have further communications with ONC.

USCDI

Like device development and management, imaging is another core aspect of the Philips healthcare mission. As proposed, we support the inclusion of imaging narrative within the USCDI.

We also recommend that ONC help lead the movement to structured data formats for imaging and imaging related information, which would lead to cross-vendor data usage toward enhanced algorithm solutions and data analytics in this space. Doing so again would mean standards maturity for both structure and semantic content, and could preclude the historic interoperability barriers on other data types based on proprietary and legacy data formats.

Also, we recommend ONC and other agencies explore the future candidacy of social determinants of health data into the USCDI, done within the

process as described in the initial TEFCA draft, specifically as to whether patients have or warrant a referral to social services, and whether a social determinants screening in on file or is recommended. As CMS, through Medicare Advantage plans, has begun assessing provider reimbursements for SDOH clinical engagement, data points around this important factor in prevention and population health are becoming actionable parts of the patient record.

Also within considerations around the USCDI, Philips notes that the CMS proposed rule seeks comment on whether a set or subset of IMPACT Act-related post-acute care data elements be included in the USCDI. We believe post-acute care is a vital aspect of population health management, readmissions reduction and healthcare system sustainability, and as noted above, an area that would benefit from expanded interoperable health IT and attendant reimbursements and incentives to spur adoption.

We understand that CMS is engaged in an evaluation process of the Standardized Patient Assessment Data Elements (SPADEs) for post-acute care settings and received stakeholder feedback through February of this year. We also understand that further analysis of reporting and other aspects of these data elements is underway through September of this year.

Philips recommends that given these existing timelines, CMS should finalize the current examination process, and then establish agreed-upon data elements to take on candidate status within the next iteration of the USCDI.

Elsewhere in the proposed rule, we note that CMS is proposing a requirement that MA Plans, Medicaid and CHIP Managed Care entities (MCOs, PIHPs, PAHPs), and QHP issuers in FFEs should coordinate care between plans by exchanging, at a minimum, the data elements in the United States Core Data for Interoperability (USCDI) standard at enrollee request at specified times.

Given this aspect of new provisions around the USCDI as itself is described in the ONC proposed rule, we further believe CMS should complete its evaluation of SPADE data elements toward USCDI candidacy status to ensure that all stakeholders are given the proper time and assessments to comply with a host of new interoperability functions as described in both rules.

As to whether MA plans, etc. should be required to exchange the USCDI with each other, patients and providers, we support the provision overall, and recommend the timeline to do so mirror that of the API/USCDI rolling implementation timeline as described in the ONC proposed rule.

Provider Disincentives RFI

In reaction to this RFI, we would recommend ONC work with CMS on any future disincentives connected to data blocking. CMS, through its 2019 IPPS final rule's Promoting Interoperability language, and through its more recent Interoperability and Patient Access proposed rule, is leveraging payment adjustments and conditions of participation increasingly tied to interoperability functions for hospitals, providers and health plans.

Also through the QPP/MACRA program and other quality or value-based care models, incentives and disincentives for providers is established and in review. The physician compare website and plans for a hospital compare site are fall within an overall disincentives category.

For providers and clinicians who may be outside of the scope of CMS and tied to the broad list of provider types included in the data blocking proposed rule, ONC should also explore any related procedures or language included in existing state-level licensure provisions.

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 proposed rule

PHILIPS

Greg Fulton

Philips Policy Lead