DRAFT Comments to be submitted to the HL7 Policy Advisory Committee regarding the ONC Draft for Public Comment – "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs"

By: HL7 EHR Work Group - "Reducing Clinician Burden" Project

Dated: 7 January 2019

HL7 EHR WG - Reducing Clinician Burden Project

Since early 2018, the Health Level Seven (HL7) Electronic Health Record Work Group (EHR WG) has managed a "Reducing Clinician Burden" (RCB) Project. This ongoing effort was established to develop a common understanding of impactful burdens that should be addressed, in the form of EHR system functions and conformance criteria, in the next major release of ISO/HL7 10781 Electronic Health Record System Functional Model (Release 3).

The RCB Project has identified an extensive list of clinician burden topics compiled from many reference sources, including trade publications, professional society journals, articles, studies and personal experience. The intent is not to boil the ocean but rather to understand the extent of the burden. See Appendix A for the full list of burden topics identified by the RCB Project Team.

Also to be considered in conjunction with these comments are two documents, one as a companion and another for reference:

- 1) Known Clinician Burdens compared with ONC Strategies (DRAFT) Companion Document
- 2) RCB Analysis Worksheet, including Burden Topics, Raw Input from Reference Sources and Crosswalk to ONC Strategies and Recommendations (DRAFT) - Reference Document

Data Quality Burden (as an example)

"One primary burden of EHR/HIT systems and 'interoperability solutions' at present is simply that, in many scenarios, their representations aren't trusted. Any 'resource' that can't be trusted is necessarily a burden." - Finding of HL7 EHR WG "Reducing Clinician Burden" Project

The Surveys Say

- 3 out of 4 physicians believe that EHRs increase practice costs, outweighing any efficiency savings Deloitte Survey of US Physicians, 2016
- 7 out of 10 physicians think that EHRs reduce their productivity Deloitte
- 4 in 10 primary care physicians (40%) believe there are more challenges with EHRs than benefits Stanford Medicine/Harris Poll, 2018
- 7 out of 10 physicians (71%) agree that EHRs greatly contribute to physician burnout Stanford/Harris
- 6 out of 10 physicians (59%) think EHRs need a complete overhaul Stanford/Harris
- Only 8% say the primary value of their EHR is clinically related Stanford/Harris

"We're from the Government and We're Here to Help"

The ONC Draft Strategy brings to mind Ronald Reagan's oxymoronic statement. Clinicians have long believed that government is the single greatest source/cause of the problem/burden, either directly (e.g., payment policy, documentation requirements, mandatory measures and reporting) or indirectly (e.g., required EHR system functions specified by the EHR Incentive Program). Now clinicians struggle to believe that government has turned beneficent and has the genuine intent to be the source of any (even marginal) solution to reducing burden.

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21st Century Cures Act – "Interoperability"

Given that HL7's forte is health information exchange standards, it seems only appropriate to reference the 21st Century Cures Act's definition of "interoperability", as offered in this slide from ONC (presented at the HIMSS Annual Conference, March 2018)...

21st Century Cures Act: Interoperability Definition

- "(10) INTEROPERABILITY.—The term 'interoperability', with respect to health information technology, means such health information technology that—
 - "(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
 - "(B) allows for <u>complete</u> access, exchange, and use of <u>all</u> electronically accessible health information for authorized use under applicable State or Federal law; and
 - » "(C) does not constitute information blocking as defined in section 3022(a).".



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Our observation...

The 21st Century Cures Act, "Interoperability" Definition (as above but emphasizing subsection B): "The term interoperability," with respect to health information technology, means such health information technology that... allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law...".

It seems clear that the terms "complete" and "all" apply to health information technology and thus require that health information:

- SHALL be rendered for purposes of "interoperability" (including "access, exchange and use"); and
- SHALL be rendered as originated (captured) and as presented to the originating author, verifier and/or attester; and
- SHALL have the capability to be rendered as whole ("all" and "complete"): without alteration, reduction, omission, derivation or transformation; and
- SHALL thus be equivalent to the content of traditional health records captured manually (e.g., on paper) then reproduced or propagated via photocopier or fax machine as an identical rendition of the original.

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For HL7...

It's vitally important for HL7 to appreciate that clinician burden is endemic and is a shared responsibility. In other words, it's not only *what is HHS, CMS, ONC or someone else going to do about clinician burden?* It's also *what is HL7 going to do about clinician burden?*

HL7 has a range of standards that are known to carry weighty clinician burden.

For example, when a clinician receives a patient summary (whether CDA-based or FHIR-based), can its vital qualities and key content/context be immediately assessed?

Vital Data Qualities...

- Is it true and trustworthy? Accurate, authentic, assured?
- Is it action-able? Timely, current? Relevant, pertinent? Concise, succinct, to the point? Useful, usable?
- What is immediately known (evident or knowable) regarding its content?

Known and certain as to identity: patient, provider (individual or organization)

Known to show clear relationship between data and actions taken (i.e., actions taken to support individual health and to provide healthcare):

Who did what when, where and why

Known to retain clinical context and maintain vital inter-relationships with/between (as applicable):

• Problems, diagnoses, complaints, symptoms, encounters, allergies, medications, vaccinations, assessments, clinical decisions, orders, results, diagnostic procedures, interventions, observations, treatments/therapies, protocols, care plans and status

Known as to source and provenance ("source of truth"), with traceability to point of origination: human, device, software

Known as to accountable human authorship (if applicable) with role and credentials

Known as to time orientation (date/time of occurrence, chronology, sequence), and in terms of:

- What has happened: past, retrospective
- What is now in progress: present, concurrent
- What is anticipated, planned: future, prospective

Known to be verified (or not) with evidence of verification, verifier(s), date(s)/time(s) and method(s)

Known to be updated (or not) with evidence of prior state(s), effective date(s)/time(s)

Known to be unaltered (maintaining fidelity to original/source content)

or *Known* to be altered/transformed from source content/representation

Known to be complete

or Known to be partial/pending

or *Known* to be a snippet/fragment with other essential details elsewhere

Known to be comparable (correlate-able, trend-able) to like data, having same/similar context

Known to be consistent in terms of data definition and with corresponding data:

Element name(s), data type(s), range, input/display/storage format, unit(s) and scale of measure

Known to be sourced as structured (coded) content or not

Known, if coded, to include:

• Coding convention – vocabulary/terminology set or value set – and version

Known as to method and purpose of capture

Known as to how external data is integrated with health data/records in the local EHR

Known as to how external data is integrated with other health/data records from other sources

It is crucial for HL7 to be at the forefront of burden reduction by careful evaluation of its standards catalogue, to account for successful interoperability of complete health data/records including vital qualities (as above), and to focus on how and where to serve the immediate needs of front-line clinicians and their practices – and also patients – by honing and optimizing the full range of HL7 specifications.

Specific Comments

ONC DRAFT Strategy, Page 4, Paragraph 1: "This report, as required by the 21st Century Cures Act, addresses specific sources of clinician burden that will require coordinated action on the part of a variety of stakeholders across the health care system, including federal, state, local, territorial, and tribal government entities, commercial payers, clinical societies, electronic health record (EHR) developers, various health care provider institutions, and other service providers."

A. Embrace and Be Broadly Inclusive. These stakeholders are important but the list should also include accreditation bodies (of healthcare organizations), EHR/HIT standards development organizations (SDOs), public health agencies, pharmaceutical companies and medical device manufacturers.

ONC DRAFT Strategy, Page 4, Paragraph 2: "As part of its definition of interoperability, the 21st Century Cures Act describes 'the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user.' This definition reflects a key insight: that interoperability will not be achieved for users until their experience with electronic health information and technology has been made seamless and effortless, and, as a result, truly interoperable. The Department of Health and Human Services (HHS), including the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS), are committed to a vision for interoperable health information exchange that centers on the experience of clinicians and patients."

B. Definition of Interoperability. [See discussion regarding "all" and "complete" on Page 2 above.] We believe there is a key shortcoming in the 21st Century Cures Act description/definition of interoperability. First, it is derived from a definition often attributed to IEEE. The IEEE definition started as "exchange/use" (in 1990), and was later updated to include "without user intervention" (in 2014). Second, this definition was never scoped nor intended to describe interoperability of health data/records nor interoperation of EHR/HIT systems.

A key deficiency of this interoperability definition is that it leaves out the **vital source of truth** (point of health data/record collection), to which everything downstream (or subsequent) – sending, receiving, finding, integrating, using, all "without special effort" – must be anchored.

If you fail to account for the full lifespan and lifecycle of health data/records (collect, share and use) you have no basis to assess (the success or lack of) interoperability because you have no source of truth or starting/anchor point (point of collection) upon which to compare any manifestation of health data/records downstream, whether at the point of exchange or ultimately at each point of use. Further you have no way to determine if the health data/records you wish to exchange and/or use are valid in the first place.

This should be noted.

ONC DRAFT Strategy, Page 4, Paragraph 4: "In its roles as a payer and regulator, we believe there are many steps HHS can take to reduce burden by reassessing and revising different regulatory and operational aspects of federal programs, and with effective leadership on the key challenges of health IT-related burden."

C. Guidance and Advocacy but not Regulation. We too "believe there are many steps HHS can take to reduce burden" including taking positions of guidance and advocacy to advise and encourage (but not regulate) the many non-federal stakeholders cited previously. This should be stated.

ONC DRAFT Strategy, Page 4, Paragraph 5: "Since the passage of the 21st Century Cures Act, HHS and other federal partners have worked diligently to begin implementing the Act's many important provisions around interoperability, such as proposing a framework for trusted exchange among health information networks and improving the effectiveness of ONC's Health IT Certification Program."

D. Is TEFCA Viable? In February 2018, a variety of organizations submitted comments on ONC's proposed Trusted Exchange Framework and Common Agreement (TEFCA). While we understand that ONC's TEFCA is a requirement of the 21st Century Cures Act, we don't believe that it offered a viable path forward for widespread exchange nor interoperability of health data/records (as discussed in submitted comments). This

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concern is only amplified by what is offered in this ONC-proposed DRAFT "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs", released on 28 November 2018.

ONC DRAFT Strategy, Page 6, Paragraphs 1-2: "We envision a time when clinicians will use the medical record not as an encounter-based document to support billing, but rather as a tool to fulfill its original intention: supporting the best possible care for the patient... We see a future where those best suited to define the required content of a clinical note for billing or quality reporting purposes—the clinical specialty societies, professional boards, and clinicians themselves—do so, rather than the federal government. Like quality reporting, we see an environment where public health syndromic data is also made available to public health authorities at the local, state, and federal levels, without direct and separate actions by the clinician, during the day-to-day care of their patients."

E. Applause... We share this vision and applaud ONC's efforts toward fulfillment of the EHRs "original intention [in] supporting the [safest and] best possible care for the patient."

ONC DRAFT Strategy, Page 6, Paragraph 3: "We recognize and are deeply grateful to all of the extremely hard-working clinicians in this country, who work long hours and deal with increasingly complex administrative requirements, all while maintaining their singular desire to provide the best care for their patients... We are excited to put forward the HHS strategy and recommendations to help clinicians get back to what they do best—the healing arts..."

Page 7, Paragraph 7: "We believe that providers should be able to focus on delivering care to patients instead of spending far too much time on burdensome and often mindless administrative tasks. Providers particularly identify burdens associated with the use of health IT such as EHR system design, regulatory and administrative burdens associated with the use of EHRs during care delivery, required reporting activities, and documentation of claims for payment."

F. Get Out of the Way. While we agree with this salutation to "all of the extremely hard-working clinicians in this country", we believe that much of their hard work is siphoned away to support "increasingly complex administrative requirements", exhausting their energy/capacities and leaving little left to be focused on "their singular desire to provide the best care for their patients."

In the entirety of the ONC DRAFT Strategy, these statements come closest to acknowledging the HHS role in effective domination of the clinician community to fulfill mandates and engage activities that are of little/no value to the care and safety of patients or to support their clinical practice. How much better it would be to make that acknowledgement formally, offer an apology and reposition HHS's primary mission to support the patient and the front-line clinician, not by more regulation, not by more guidance, not by promised benevolence by-and-by, but by taking an enlightened decision to simply remove the burdens and get out of the way.

ONC DRAFT Strategy, Page 9, Paragraphs 4-5: "Section 13103 [of the 21st Century Cures Act] also requires HHS to prioritize EHR-related burden that may arise related to reporting clinical data for administrative purposes. The statute considers other areas of the health care enterprise, which may include EHR-related burden specifically public health and clinical research. Besides these enumerated areas, section 13103 permits the secretary to determine other areas for prioritization as appropriate... Section 13103 requires HHS to address actions that improve the clinical documentation experience, patient care, and are deemed appropriate by the secretary's recommendations. The statute notes that these actions may be taken by the secretary and by other entities."

G. Burdens Beyond. Work by the Health Level Seven (HL7) Electronic Health Record Work Group (EHR WG) has identified >30 clinician burden topic areas. The EHR WG "Reducing Clinician Burden" Project has been active since early 2018 and has captured input from trade publications, professional society journals, articles, studies and personal experience. (See Appendix A for the complete list.) A number of these topics are missing in this proposed ONC Strategy but must be included if HHS is prepared to consider the full extent/impact of clinician burden.

Again noting that "other entities" may include non-federal stakeholders including those previously cited.

ONC DRAFT Strategy, Pages 13-14, 1st Paragraph under Strategies and Recommendations: "The report lays out a series of strategies and recommendations that HHS is considering taking to mitigate EHR-related burden for health care providers. In order to ensure strategies are both high impact and feasible, HHS is focused on strategies which meet the following criteria:

- "Strategies should be achievable within the near to medium term, roughly 3–5 year window.
- "HHS should be able to either implement these strategies through existing or easily expanded authority, or should have significant ability to influence the implementation of these strategies.
- "Strategies should include actions that improve the clinical documentation experience and improve patient care."
- H. Burden Reduction Must Be Immediate, Forceful and Unrelenting. A "roughly 3-5 year window" is not acceptable to clinicians who must face the burden in daily practice. How many more clinicians (1000s?) will give up and burn out, never to return to front-line clinical practice?

The burden is clear, the response is protracted and appears to be a grudging submission to fulfill a legislative mandate that itself is over two years old. Almost none of what is proposed will occur in this political cycle and may be encumbered, if not unraveled, by "new" wisdom thereafter.

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Another Perspective on Burden...

Key Point

The draft strategy aims to reduce the 'burden' related to the use of primarily EHRs. This, however, only addresses the symptoms. The root cause is the lack of a useful and usable system that supports overall individual care in a complex, diverse health care economy. In the absence of such a system, the administrative functions have filled this 'system of care vacuum' leading to the problems identified. The way to relieve the burden is to ensure we have the systems for individual care that meet the needs of contemporary medicine and practice. Until then the problems identified will persist and the approaches proposed in the draft strategy will be at best damage limitation.

Aims of the Strategy and the Problems Identified

The draft "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs" is a response to a federal statute that:

"requires HHS to articulate a plan of action to reduce regulatory and administrative burden relating to the use of health IT and EHRs".

The strategy admits at the outset that:

"... technology has yet [to] make the practice of medicine easier for physicians and other health care professionals."

It cites the now substantial evidence supporting this assertion and in particular the serious problems with the use of electronic health records (EHRs) in direct patient care. Rather than improving individual care, EHRs are having an adverse effect by:

- interfering directly in the clinician-patient relationship with attention going on 'managing the system' rather than the patient;
- aggregating large volumes of 'data' but paradoxically making it ever harder for clinicians to know about and understand the overall health and care of their patients;
- generating essentially corrupted documentation (the so-called 'note bloat') that undermines the record as a faithful account of the health and care of an individual;
- having low utility and a poor user experience;
- making excessive time and cognitive demands on clinicians contributing to 'burn-out'.

In short EHRs have proved to be neither useful nor usable for their stated purpose of improving individual patient care. An EHR has low intrinsic utility to a clinician. Hence, at the outset, clinicians simply did not care that much about a system that was neither useful nor usable for care. Thus EHRs became, and remain, systems looking for a purpose. The 'administrative' demands became that purpose. Those demands were able to 'push through' and essentially usurp the functionality of the systems, resulting in the serious problems the report identifies.

Interoperable EHRs are the wrong model

EHRs are fundamentally ill-suited to the demands of contemporary health care. They are rooted in specialties and institutions. They are more akin to records of the workings of those institutions than records of the overall care of an individual. They have proliferated across those organizations and thus added to the fragmentation of individual care. They fail to address the major information challenge facing clinicians: individuals with multiple, complex health and social needs, receiving care from numerous providers across diverse organizations. 'Interoperability' is promoted as the answer to the proliferation of EHRs across institutions. This by itself has not and will not work. Interoperability is merely a technical capability. It is not a model for how individual care can be managed. This is the reason why all Health Information Exchanges (HIE) have failed to realize their intended benefits.

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EHRs, 'interoperability', and health IT in general have tried to automate the already failing existing practices rather than devising new ways of managing and assuring care. This has led to a 'system of care vacuum' that the regulatory approach has filled. The models for administering and regulating a Care Economy have morphed into the basis for managing the health and care of individuals. This is not only a burden but is a distortion of the whole purpose of care.

Damage limitation is not an answer

The draft strategy seeks to address this administrative burden as manifested through EHRs. However, when the document goes on to consider how to tackle that burden, it confines itself to what can best be described as mitigation. It appears to accept that the fundamentals of the approach embodied in multiple EHRs for each individual and interoperability cannot be changed. Thus the task becomes essentially one of 'damage limitation'. We contend that this will not work. The intrusion of the 'administrative burden' is as much a consequence of the lack of a 'system' for supporting individual care as it is due to the inappropriate formulation of regulation. We lack a credible 'system' for managing individual care that is fit for what we now expect from contemporary medicine.

We need an infrastructure for individual care

Of course, all efforts should be made to rationalize the current regulations to avoid unnecessary complexities, contradictions, duplication, and so forth. This work can proceed now and is not reliant on the EHRs and other IT systems. It requires taking a view across the whole Care Economy to understand the interactions between the various sources of regulation. This is however only stop-gap.

Much of the burden arises from the lack of a single, coherent account of an individual's health and care that is available when and where needed. Hence clinicians have to repeat everything about an individual in order to meet the demands of for example pre-authorization. Or scattered data have to be assembled by bespoke processes to satisfy performance metrics.

Substantive progress can only be made when the vacuum is filled with a system for individual care that is suited to contemporary needs. Such an infrastructure is qualitatively different from the existing systems that run institutional functions in hospitals, labs, offices, etc. The foundation of the new individual-centric infrastructure is an individual health record (IHR) that is unique to an individual. It does not replace the institutional systems but works with them. The IHR is the 'system to run the individual'. It provides the locus of integration for an individual's overall health and care. By deploying a clinically useful, usable, and used infrastructure for individual care, much of the burden will ease or even disappear.

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Comments based on Initiatives[I], Strategies[S] and Recommendations[R]

In review of Pages 45-67 of the ONC Draft for Public Comment "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs", we developed the following comments (left column below). Green highlights identify that many aspects of burden reduction are based on future HHS/CMS/ONC strategies and/or rely primarily on actions of organizations outside the federal government.

Recommendation Summary	Comments	
I1. Clinical Documentation		
I1.S1 Reduce regulatory burden around documentation requirements for patient visits.		
I1.S1.R1 Continue to reduce overall regulatory burden around documentation of patient encounters.		
 Reduces clinician burden associated with E/M coding requirements for patient encounters Single minimum for all encounters, with add-ons for different kinds and lengths Recommends other payers follow suit S1.R2 Leverage data already present in the EHR to reduce 		
 Reduces clinician burden by allowing certain patient encounter data already captured to be utilized without reentry Instead allows review, update and sign-off by billing practitioner Notes potential for new "review and verification process" Notes potential for new "audit functionality" for payer reassurance 	 Still requires extra staff ("the billing practitioner") to review, update and sign off Is vague regarding details of a new "review and verification process" Is vague regarding details of a new "audit functionality" Why not work immediately on review, verification, audit and interoperability functions sufficient to "reassure payers"? 	
I1.S1.R3 Obtain ongoing stakeholder input about updates to documentation requirements.		
 Reduces clinician burden by establishing a process and/or "representative task force" to capture input for further documentation guideline modifications Suggests HHS will work with "key participants" including "government, industry, heath care providers, payers, EHR developers, standards developers" 	 Suggests directional intent but realization (of burden reduction) will occur at some point in the future 	
I1.S1.R4 Waive documentation requirements as may be necessary for purposes of testing or		
administering APMs.		
 Reduces clinician burden by waiving some CMS documentation requirements (e.g., medical review) for certain APM participants 	 Suggests directional intent but realization (of burden reduction) will occur at some point in the future 	
I1.S2 Continue to partner with clinical stakeholders to encourage adoption of best practices related to		
documentation requirements.		
I1.S2.R1 Partner with clinical stakeholders to promote clinical		
 Reduces clinician burden by development of clinical documentation "best practices" Establishes collaboration between HHS and clinical professional societies 	 Foresees endorsement and implementation of best documentation practices at some point in the future 	
I1.S2.R2 Advance best practices for reducing documentation	n burden through learning curricula included in	
CMS Technical Assistance and models.		
 Reduces clinician burden by incorporating documentation best practices into CMS Technical Assistance and learning programs Promotes use of learning materials into state and private sector partner programs 	Describes a long-term strategy which will have little/no immediate impact on burden reduction	
I1.S3 Leverage health IT to standardize data and processes authorization processes.	around ordering services and related prior	

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Recommendation Summary Comments I1.S3.R1 Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization. + Reduces clinician burden by evaluating best practices Describes a possible strategy that is and "optimizing electronic workflows around prior likely to have little/no immediate impact authorization" on burden reduction + Seeks to "leverage existing data" to "reduce the total volume of prior authorization requests that clinicians must submit" I1.S3.R2 Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, and payers. Likely to have little/no immediate impact + Reduces clinician burden "through adoption of standardized templates [and] data elements" to justify on burden reduction medical necessity for orders and prior authorizations + Seeks to establish "real-time standards-based electronic transactions between providers, suppliers, and payers" + Suggests HHS "should continue to partner with the clinicians, payers, medical product manufacturers, and health IT developers" I1.S3.R3 Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes. + Reduces clinician burden by standardizing Suggests HHS may consider future documentation and exchange "for ordering and prior incentives but has no immediate impact authorization" on burden reduction [Unclear how this is the same or different than the previous recommendation (I1.S3.R2)] I1.S3.R4 Work with payers and other intermediary entities to support pilots for standardized electronic ordering of services. + Reduces clinician burden by establishing pilots for new Describes long term strategy that is likely "templates and suggested clinical data elements" to to have little immediate impact on burden promote wider adoption reduction + Suggests HHS collaboration with "health IT developers, the medical product industry, regulatory agencies and payers", along with "third-party exchange organizations" I1.S3.R5 Coordinate efforts to advance new standard approaches supporting prior authorization. + Reduces clinician burden by developing a "prior- Awaits development, maturity and authorization ecosystem through multi-stakeholder consensus adoption of new standards and protocols + Suggests HHS collaboration with "clinicians, health Likely to have little/no immediate impact information technology vendors and payers", along with the "[HL7] Da Vinci project and [the ONC] FHIR Task Force" and NCVHS 12. Health IT Usability and the User Experience I2.S1 Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools. 12.S1.R1 Better align EHR system design with real-world clinical workflow. + Reduces clinician burden by aligning EHR system design Encourages industry to act, but foresees and configuration with individual clinician workflow no federal role + Suggests HIT developers work with clinical organizations Should include clinical professional societies and SDOs in developing best practices

12.S1.R2 Improve clinical decision support usability.

Recommendation Summary Comments + Reduces clinician burden by improving and augmenting Encourages industry to act, but foresees CDS "beyond alerts to include predictive care no CMS/ONC role suggestions to help make decisions at the point of care" Should include clinical professional + Suggests building on National Academy of Medicine societies and SDOs in developing best CDS framework practices and implementation strategies + Suggests working with AHRQ to develop and promulgate best CDS practices + Suggests rapid incorporation of standards-based, computable, evidence-based care guidelines into clinical practice via interoperable CDS 12.S1.R3 Improve clinical documentation functionality. + Reduces clinician burden by promoting "methods to Encourages industry to act, but foresees capture both the structured and unstructured data", such no federal role as speech recognition - Should include SDOs + Suggests institutional policies "regarding copy-and-paste functionality... that balances efficiency with safety" + Suggests using "logging functionality... [to] help identify the time clinicians [spend] interacting with the EHR" + Suggests working with HIT and speech recognition developers 12.S1.R4 Improve presentation of clinical data within EHRs. Encourages industry to act, but foresees + Reduces clinician burden by optimizing and improving information display "in a context-driven and contextno federal role dependent manner" Should include SDOs + Suggests extracting and indexing data contained in scanned documents + Suggests exploring new "ways to facilitate presenting a patient's data in a longitudinal manner" 12.S2 Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction. 12.S2.R1 Harmonize user actions for basic clinical operations across EHRs. + Reduces clinician burden by developing "a shared Encourages industry to act, but foresees understanding of common interface and workflow design no federal role elements for common clinical tasks", across EHR - Should include SDOs systems + Reduces "the need to remember a series of divergent workflows for the same basic task" + Decreases clinician cognitive load and risks to patient + Suggests clinicians and clinical professional societies work with HIT developers 12.S2.R2 Promote and improve user interface design standards specific to health care delivery. + Reduces clinician burden by focusing "on user interfaces Encourages industry to act, but foresees to support the clinician's cognitive thought process in minimal federal role terms of complex pattern recognition" Should include SDOs + Suggests creating a "shared repository of EHR usability practices" for EHR developers + Suggests highlighting "results of these developer efforts... [in] the ONC Certified Health IT Product List" for prospective EHR customers + Suggests "a shift from check-box interface elements to intelligent features that extract needed data from routine clinical workflows" 12.S2.R3 Improve internal consistency within health IT products.

Recommendation Summary	Comments
+ Reduces clinician burden by ensuring "all aspects of the	 Encourages industry to act, but foresees
[HIT] system share a common user interface and style	no federal role
,	Should include SDOs
guide" 12.S2.R4 Promote proper integration of the physical environm	
+ Reduces clinician burden by optimizing "integration of	Encourages industry to act, but foresees
EHRs with the physical environment" to ensure "both	no federal role
efficient clinical team interaction and clinician-patient	Should include SDOs
interaction"	- Griodia iricidae OBO3
+ Suggests health care institutions "keep in mind EHR	
usage and clinical team interaction" in facility design	
+ Suggests EHR developers "support this priority with	
implementation guidance and software support"	
	ntained in health IT to reduce burden
I2.S3 Promote harmonization surrounding clinical content contained in health IT to reduce burden. I2.S3.R1 Standardize medication information within health IT.	
+ Reduces clinician burden by displaying "prescription drug	 Encourages industry to act, but foresees
information in a standardized format"	minimal federal role
Suggests following best practices and guidance from "the	Should include SDOs
NCPDP, the Institute for Safe Medication Practices	
(ISMP) and the FDA", also ONC's SAFER Guide	
I2.S3.R2 Standardize order entry content within health IT.	
+ Reduces clinician burden by refining descriptions for lab,	- Encourages industry to act, but foresees
imaging and other diagnostic orders to ensure they are	minimal federal role
clear and concise	Should include SNOMED International
+ Suggests collaboration between the CMS Division of	and other SDOs
Laboratory Improvement and Quality (CLIA regulator),	and other obos
the American College of Pathology and the Regenstrief	
Institute (LOINC administrator)	
I2.S3.R3 Standardize results display conventions within heal	th IT.
+ Reduces clinician burden by establishing "a common	 Encourages industry to act, but foresees
format for displaying results"	no federal role
+ Suggests "standardizing the display of test results [to]	 Should include SDOs
allow critical information to be reported first"	
+ Suggests "developers arrive at a standard for	
chronological display abnormal display and reference	
range inclusion"	
12.S4 Improve health IT usability by promoting the importance of implementation decisions for clinician	
efficiency, satisfaction, and lowered burden.	
I2.S4.R1 Increase end user engagement and training.	
+ Reduces clinician burden by ensuring their involvement	 Encourages industry to act, but foresees
"from the very beginning of the acquisition process to	minimal federal role
ensure that the product purchased by an organization will	 Should include SDOs
meet the needs of its end users and their desired	
workflows"	
+ Recommends clinicians be "actively involved with	
ongoing optimization of the EHR system, including	
workflow refinements, CDS tool review, and	
documentation and template optimization"	
+ Suggests "health care institutions ensure that all end	
users receive initial and ongoing EHR training with easily	
accessible and ongoing technical support, along with	
systems to promote competency"	
+ Suggests "leveraging EHR metadata [and] audit logs to	
develop insight into workflow and usage patterns"	

Recommendation Summary Comments + Suggests "institutions... ensure that adequate clinical staff are assigned to... [EHR] upgrade planning [and] change requests" 12.S4.R2 Promote understanding of budget requirements for success. + Reduces clinician burden by establishing a formal Encourages industry to act, but foresees "budget model that incorporates ongoing technical minimal federal role support for [EHR] end users, ongoing training of clinical staff, and required technical resources to support upgrades, system maintenance, troubleshooting, system backup, and disaster recovery functionality" + Suggests EHR developers assist healthcare institutions in planning/developing their budget model 12.S4.R3 Optimize system log-on for end users to reduce burden. + Reduces clinician burden by establishing secure but Encourages industry to act, but foresees short and straightforward modes of user authentication to no federal role access systems and information Should include SDOs + Suggests consideration of methods beyond user name/password, such as token-based and biometric 12.S4.R4 Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden. + Reduces clinician burden by advancing interoperability to Describes health information exchange enable "secure exchange of electronic health but not data quality nor how exchanged information... without special effort of the part of the user" data may be assessed for accuracy and + Suggests using the "framework for trusted exchange reliability, traceability to source, and thus among health information networks" [presumably trusted by the end user TEFCAl and "improving the effectiveness of the ONC's See "Vital Data Qualities" table above Health IT Certification Program" 13. EHR Reporting 13.S1 Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians. 13.S1.R1 Simplify the scoring model for the Promoting Interoperability performance category. + Reduces clinician burden by overhauling the scoring Describes long term strategy that is likely methodology for MIPS and the Promoting Interoperability to have little immediate impact on burden Program for eligible hospitals and Critical Access reduction Hospitals - Should include SDOs + Suggests that CMS will work with "clinicians and hospitals... to develop program requirements that reduce burden while improving quality of care" + Suggests that "in future rulemaking, CMS will evaluate the use of measure combinations that would give clinicians a recommended set of related eCQMs, Promoting Interoperability health IT measures, and Improvement Activities that are tied by a common thread and can be used by clinicians to maximize their participation in the program" I3.S1.R2 Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians. + Reduces clinician burden by incentivizing and rewarding Suggests directional intent but actual "innovative uses of health IT and advancements in incentives will occur at some point in the interoperability that improve care for patients" future

I3.S1.R3 Reduce burden of health IT measurement by continuing to improve current health IT measures and developing new health IT measures that focus on interoperability, relevance of measure to clinical practice and patient improvement, and electronic data collection that aligns with clinical workflow.

Recommendation Summary Comments + Reduces clinician burden by tuning HIT measures to be Describes long term strategy that is likely more closely aligned with and "relative to the value they to have little immediate impact on burden provide" reduction + Offers to provide value by 1) "being evidenced-based Should include SDOs and relevant to clinical care and... specialty"; 2) "promoting higher-value functionality"; and 3) "aligning measurement with clinical workflow" + Suggests CMS will work actively with stakeholders including clinicians and patients as part of this strategy 13.S1.R4 To the extent permitted by law, continue to provide states with federal Medicaid funding for health IT systems and to promote interoperability among Medicaid health care providers. + Reduces clinician burden by supporting "state initiatives Describes long term strategy that is likely that promote interoperability within and beyond the to have little immediate impact on burden Medicaid enterprise" reduction + Suggests that CMS will "work with states to integrate health IT into larger Medicaid Enterprise systems" + Suggests that "state Medicaid Enterprise systems should leverage or build upon existing federal investments including projects supported by Medicaid Promoting Interoperability Program funding" I3.S1.R5 Revise program feedback reports to better support clinician needs and improve care. + Reduces clinician burden by revising feedback reports to Describes long term strategy that may have little immediate impact on burden capture more useful and impactful information, improve report formats, streamline submission and update reduction processes 13.S2 Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs. 13.S2.R1 Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting. + Reduces clinician burden by improving data accuracy Describes need to improve data integrity but fails to note its negative impact on integrity of the clinical process and most importantly, its risk to patient safety See "Vital Data Qualities" table above 13.S2.R2 Adopt additional data standards to makes access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals. + Reduces clinician burden by improving access to, and Describes the use of FHIR, but overlooks integration, extraction and analysis of, data across HIT its key strength, where application design systems implements FHIR as the native data + Suggests broader adoption, of HL7 FHIR APIs to "allow construct and thus data is sourced/ for the development of electronic resources to facilitate captured, stored, exchanged, extracted, requests for data without requiring a clinician or health analyzed and accessed/used... data care provider to individually address potential variations never requires transformation... data in each individual request" retains its context and relationships to + Promotes use of the US Core Data for Interoperability other data (USCDI) which specifies "a common set of data classes required for interoperable exchange" 13.S2.R3 Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products. + Reduces clinician burden by making HHS administrative

Suggests directional intent but realization

(of burden reduction) will likely occur at

some point in the future

systems accessible via APIs

Suggests HHS "implement an API approach that

supports bidirectional data integration, which would allow

Recommendation Summary Comments health IT to seamlessly integrate with these systems and regularly update information related to physicians" 13.S3 Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden 13.S3.R1 Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures. + Reduces clinician burden by introducing "a 'test year' into Suggests directional intent but realization programs for new eCQMs wherein reporting on these (of burden reduction) will likely occur at eCQMs is optional", following this approach HHS could some point in the future use "measure data to refine new eCQMs as needed, but not as part of public reporting or performance evaluation" 13.S3.R2 Continue to evaluate the current landscape and future directions of electronic quality measurement and provide a roadmap toward increased electronic reporting through the eCQM Strategy Project. + Reduces clinician burden by "revis[ing] existing eCQMs Describes CMS/ONC work in progress and develop[ing] new eCQMs that will allow physicians that may take some time for realization and hospitals to increasingly transition to electronic (of burden reduction) measurement and reporting" + Implements CMS's new eCQM Strategy Project "to reduce eCQM development and implementation burdens through adding workflow considerations in the development process while reducing development time, obtaining more stakeholder feedback for the new eCQMs under development, and adding increased stakeholder transparency to these processes" + Suggests CMS and ONC "work together to refine and develop eCQMs so that quality measurement aligns with clinical workflow" 13.S3.R3 Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives. + Reduces clinician burden by "developing eCQMs that Suggests directional intent but realization align with clinical workflow and do not contribute extra or (of burden reduction) will likely occur at unnecessary steps to the use of health IT in patient care" some point in the future + Suggests "mining health IT databases for clinician performance trends could yield more robust and detailed quality measurement and improvement strategies" + Suggests exploring opportunities using "artificial intelligence and machine learning... to assess quality performance and improvement in wholly new ways that can yield more detailed feedback" 14. Public Health Reporting 14.S1 Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow. I4.S1.R1 Federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Privacy and Security Rules, to improve timely access to medication histories in PDMPs. States should also leverage funding sources, including but not limited to 100 percent federal Medicaid financing under the SUPPORT for Patients and Communities Act, to facilitate EHR integration with PDMPs

DRAFT Comments to be submitted to the HL7 Policy Advisory Committee regarding the ONC Draft for Public Comment – "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs"

By: HL7 EHR Work Group - "Reducing Clinician Burden" Project

+ Reduces clinician burden by integrating PDMP

+ Suggests "federal funding agencies... coordinate a shared strategy for all PDMPs to adopt common

care... [and] electronic prescribing"

prescription histories "into the routine workflow of patient

Dated: 7 January 2019

using existing standards.

Suggests directional intent but realization

(of burden reduction) will likely occur at

some point in the future

Recommendation Summary Comments standards over time to support PDMP and health IT integration" I4.S1.R2 HHS should increase adoption of electronic prescribing of controlled substances with access to medication history to better inform appropriate prescribing of controlled substances. + Reduces clinician burden by engaging prescription Describes long term strategy that may management (including controlled substances) "in a have little immediate impact on burden single workflow, reduc[ing] the time clinicians spend on reduction medication reconciliation, automat[ing] CDS such as drug-drug interactions, and facilitate[ing] the tracking of prescription fulfillment" + Suggests implementation of DEA-required "multifactor authentication [permitting] biometrics and modern approaches to authentication that can be more easily integrated into provider workflows" 14.S2 Inventory reporting requirements for federal health care and public health programs that rely on EHR data to reduce collection and reporting burden on clinicians. Focus on harmonizing requirements across federally funded programs that impact a critical mass of health care providers. I4.S2.R1 HHS should convene key stakeholders, including state public health departments and community health centers, to inventory reporting requirements from federally funded public health programs that rely on EHR data. Based on that inventory, relevant federal agencies should work together to identify common data reported to relevant state health departments and federal program-specific reporting platforms. + Reduces clinician burden by "identifying common and Describes long term strategy that is likely disparate data reporting requirements across [multiple to have little/no immediate impact on federal] programs, aligning similar reporting requirements burden reduction with data collected in normal workflows, and harmonizing Should include SDOs reporting requirements" + Suggests collaboration between HHS, CDC, SAMHSA, FDA, HRSA and USDA 14.S2.R2 HHS should continue to work to harmonize reporting requirements across federally funded programs requiring the same or similar EHR data from health care providers to streamline the reporting process across state and federal agencies using common standards. + Reduces clinician burden by harmonization of "common Suggests directional intent but realization data elements and transport standards across reporting (of burden reduction) will likely occur at requirements" of multiple HHS agencies some point in the future + Suggests adopting "a common standards-based [Unclear how this is the same or different approach to reporting EHR-captured data" than the previous recommendation (I4.S2.R1)] Should include SDOs I4.S2.R3 HHS should provide guidance about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorder health information in order to better facilitate electronic exchange of health information for patient care. + Reduces clinician burden by updating HIPAA rules Describes long term strategy that is likely "which govern privacy and security of patient health to have little/no immediate impact on information" to "facilitate HHS's goal of promoting burden reduction electronic exchange of health information for better care Should include SDOs coordination" + Suggests "development of technical standards for applying security labels and meta-data" (for data seamentation)

+ Suggests HHS "coordinate across federal agencies"

Appendix A - "Reducing Clinician Burden" Topics, compiled by the HL7 EHR Work Group

- 1) Generally
- 2) Patient Safety (and Clinical Integrity)
- 3) Administrative tasks
- 4) Data entry requirements
- 5) Data entry scribes and proxies
- 6) Clinical documentation: quality and usability
- 7) Prior authorization, coverage verification, eligibility tasks
- 8) Provider/patient face to face interaction
- 9) Provider/patient communication
- 10) Care coordination, team-based care
- 11) Clinical work flow
- 12) Disease management, care and treatment plans
- 13) Clinical decision support, medical logic, artificial intelligence
- 14) Alerts, reminders, notifications, inbox management
- 15) Information overload
- 16) Transitions of care
- 17) Health information exchange, claimed "interoperability"
- 18) Medical/personal device integration
- 19) Orders for equipment and supplies
- 20) Support for payment, claims and reimbursement
- 21) Support for cost review
- 22) Support for measures: administrative, operations, quality, performance, productivity, cost, utilization
- 23) Support for public and population health
- 24) Legal aspects and risks
- 25) User training, user proficiency
- 26) Common function, information and process models
- 27) Software development and improvement priorities, end-user feedback
- 28) Product transparency
- 29) Product modularity
- 30) Lock-in, data liquidity, switching costs
- 31) Financial burden
- 32) Security
- 33) Professional credentialing
- 34.1) Identity matching
- 34.2) Identity and credential management
- 35) Data quality and integrity
- 36) Process integrity
- 37.1) Problem list
- 37.2) Medication list
- 37.3) Allergy list
- 37.4) Immunization list
- 37.5) Surgery, intervention and procedure list

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