Comments on: DRAFT "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs"

Source: US Department of Health and Human Services
Office of National Coordinator for Health Information Technology (ONC)

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Thank you for the opportunity to comment on the ONC DRAFT "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs" (ONC Draft Strategy).

General Comments

We believe ONC's Strategy for Reducing Clinician Burden is both noteworthy and commendable but note the following...

1. 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

2. Systems of Individual Care

The ONC 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 ONC Draft Strategy will be at best damage limitation.

3. Aims of the Strategy and the Problems Identified

The ONC 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 ONC Draft 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 ONC Draft Strategy identifies.

4. 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, as referenced in the Draft Strategy, 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. (This is also a key shortcoming of the Trusted Exchange Framework/Common Agreement (TEFCA) as proposed by ONC last year.)

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.

5. 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.

6. Needed: 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.

7. 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. They have actively reviewed and analyzed the serious subject of clinician burden and burnout – particularly as it relates to the impact and use of EHR/HIT systems. The Team wants to ensure RCB is a foremost objective as they develop future (US and international) standards for EHR system functionality. This endeavor has led the Team to review >50 reference sources, including trade publications, professional society journals, articles, studies and personal experience. They have now identified >35 topic areas and detailed the burden associated with each (see Appendices A and C for an enumeration of burden topics).

The HL7 EHR WG RCB Project does not intend to boil the ocean but rather to understand the substance and extent of clinician burden.

Given our active involvement in leadership of the HL7 RCB Project Team effort, we have decided to include/ derive portions of our comments from their work (with permission and full attribution). This includes portions of our General Comments and the Appendices referenced below (and attached).

Appendix A: Clinician Burden Topics
Appendix B: Specific Comments on ONCs Initiatives, Strategies and Recommendations
Appendix C: Known Clinician Burdens compared with ONC Draft Strategy

HL7 EHR WG RCB Project materials including the latest project overview, analysis worksheet, focus group drafts, the RCB success story template, meeting notes, plus links to most all RCB reference sources are posted to the HL7 EHR Interop Wiki:
http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG#HL7_.22Reducing_Clinician_Burden.22_.28RCB.29_Project

8. Clinician Burden is a Progressing Crisis

As enumerated by the HL7 RCB Project Team, clinician burden is manifest in a host of interrelated topics and areas of concern. See Appendix A and Comment #1. In sum, clinician burden has reached crisis proportions. It is a crisis that impacts many clinicians all day, every day. It is a crisis they can neither ignore nor escape but also find hard to address. It impacts their time with patients, their time with colleagues in professional activities, their personal time – at home and with their families. It is constant and it impacts their lives in appreciable ways.

Many are seeking other assignments, outside of front-line care of patients. Many are burning out, unable to cope with the persistent stress and feelings of doom. Many are retiring early from a profession they otherwise love and from patient care and interaction that they otherwise enjoy and find rewarding.

9. Abandon Top Down Regulatory Mandates in Favor of Clinician/Market Driven Solutions

Let's recall what was in place prior to the advent of the HITECH Act and ONC (now CMS) promulgated EHR system certification programs:

- CCHIT was formed in 2004 through the efforts of AHIMA, HIMSS and NAHIT/AHA;
- CCHIT certified EHR systems from 2005 through 2011 under its own program;
- CCHIT functional certification criteria for EHR systems were created, vetted and approved by stakeholders with substantial clinician engagement and input;
- CCHIT certification criteria drew from US and international standards, such as ISO/HL7 10781 EHR System Functional Model (then Release 1/1.1, now Release 2), developed with multi-stakeholder input and approved by consensus ballot;
- CCHIT promoted a voluntary approach: EHR system certification was voluntary; adoption of certified EHR systems was voluntary.

The value of certified EHR systems was entirely market driven. Vendors decided whether there was market value in certifying their systems and carrying the CCHIT seal. Clinicians and provider organizations could evaluate whether CCHIT-certified EHR systems offered value in terms of their clinical practice needs and thus procurement decisions.

In 2009 under the HITECH Act, ONC decided to throw out all aspects of the prior (CCHIT-based) functional criteria, testing and certification process. This ushered in the Meaningful Use era where ONC decided what the government wanted in terms of EHR system functionality, including minimum data sets, patient summaries, quality and performance indicators and reporting, public health reporting, so-called interoperability...

Let's now recognize that the ONC/CMS programs have achieved a key objective in "incentivizing" adoption of EHR/HIT systems: >95% of hospitals have adopted such systems, while about 90% of eligible clinicians have done the same.

We believe it's time to abolish the federal ONC/CMS EHR/HIT Incentive Program(s) and return to a free market model where clinicians and other EHR system users are principle owners/drivers of EHR/HIT system functional and usability specification, conformance/certification criteria, inspection/testing and certification. Let the clinician community and free market decide which systems meet their criteria and clinical practice needs.

10. Office of Clinician Advocate

The clinician burden crisis is such that it demands full-time attention and immediate action. It is our recommendation that HHS form an Office of the Clinician Advocate to give clinicians an eminent champion and proponent to address burden and find effective and comprehensive solutions.

Comments on Data Quality Burden

The following Vital Data Qualities are derived from work of the HL7 EHR Work Group – "Reducing Clinician Burden" Project Team...

Vital Data Qualities (before and after exchange)
• **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/HIT system
***Known* as to how external data is integrated** with other health/data records from other sources

"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

11. Data Quality Burden

The ONC Draft Strategy says little about data quality yet we know that truth (accuracy/authenticity) and trust (assurance) are vital to clinician confidence in EHR/HIT record content and in using that content for clinical decision-making. We believe ONC should include the Vital Data Qualities (above) as an essential component of the objectives and strategies for reducing clinician burden.

12. Certain Rendering Superseded by Uncertain Rendering?

An earlier generation of health record transmission and reproduction relied on fax machines and photo copiers. While these technologies are now much maligned when compared to new whiz-bang "solutions" such as EHR/HIT systems and the touted elixir of "interoperability", there is one vital characteristic where they remain superior, if not infallible. Fidelity to source – what goes in (source artifact) is identical to what comes out (artifact produced by the fax transmission or copier function). If not, these devices would be immediately placed out of service and then repaired or replaced.

We are pleased to note that the ONC has recommended "industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting"

[I3.S2.R1], but don't believe data mapping resolves data accuracy burdens unless/until the basic requirement of fidelity to source is first addressed.

21st Century Cures Act Interoperability Definition: "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 complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State of Federal law; and (C) does not constitute information blocking..."

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."

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13. Subsection A – Definition of "Interoperability"

As noted above the ONC Draft Strategy quotes Subsection A of the 21st Century Cures Act Interoperability.

We believe there is a key shortcoming in the 21st Century Cures Act Subsection A definition of interoperability. Noting first that 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). Then noting that this definition was never scoped nor intended to describe interoperability of health data/records nor interoperation of EHR/HIT systems.

A key deficiency of the Subsection A 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 key shortcoming (gap) in definition makes it difficult to ensure, much less assess, the set of Vital Data Qualities for any unit of health data/record content. Thus is guaranteed that the burden of ensuring/assessing truth (accuracy/ authenticity) of, and trust (assurance) in, health data/record content cannot be overcome by the clinician in their daily clinical practice.

14. Subsection B – Definition of "Interoperability"

We believe Subsection B in the 21st Century Cures Act (above), is key to reducing burden as it provides "for complete access, exchange, and use of electronically accessible health information...". It is clear that the terms "complete" and "all" apply to health information technology and thus require that health information:

- SHALL be rendered *completely* for purposes of "interoperability" (including collection, "access, exchange and use"); and
- SHALL be rendered *completely* as originated (captured at the source) 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.

15. The Shortfall of Subsets and Extracts

Following on the previous comment, renderings of Consolidated Clinical Data Architecture (HL7 Standard C-CDA) patient summaries and renderings of US Core Data for Interoperability (USCDI), are promulgated as requirements in ONC and now CMS regulations yet are by definition, subsets/extracts of patient health information content. These renderings are neither *all* or *complete* and thus do not meet the interoperability stipulations of Subsection B.

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."

16. 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 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."

17. 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."

18. Saddled by Another Burden – TEFCA

In February 2018, we (CentriHealth/UnitedHealth Group) 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 (as proposed) it offered a viable path forward for widespread exchange nor interoperability of health data/records (as discussed in our submitted comments). This concern is only amplified by what is offered in this ONC Draft Strategy, and only increases our concern that TEFCA itself saddles an added burden on clinicians.

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."

19. Applause, but...

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."

The intention of the note is supporting the best quality care for the patient. Any content purely for billing, administrative, quality support, or any other purposes is therefore peripheral to the core purpose. The role of the clinical specialty societies, professional boards, and clinicians should be to define the core clinical content necessary for best longitudinal clinical care and communication of care management and clinical thinking among care team members. The role of policy makers and regulators should be to develop alternative mechanisms for recording and collecting data for reimbursement, public health, EHR usage reporting, and quality indicators which do not divert clinician time and attention from patient care and do not obscure more important clinical data in the record.

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."

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20. Stand Up, Stand Strong, Stand Aside

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 care, effective treatment 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 engage immediate and diligent efforts toward removing the burdens and ultimately, getting 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."

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21. Burdens Beyond

As noted in Comment #7, the Health Level Seven (EHR WG) RCB Project Team has identified >35 clinician burden topic areas. 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."

22. 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 slow awakening and response to fulfill a legislative mandate that itself is over two years old. Concerns have been raised that almost none of what is proposed (in the ONC Draft Strategy) will occur in this political cycle and may be encumbered, if not entirely unraveled, by "new" wisdom thereafter.

Comments on ONC Coverage of Clinician Burden Topics

- See Appendix A for an extensive list of known clinician burden topics.
- See Appendix C which uses the same list of known clinician burdens compared with ONC Draft Strategy.
- Appendices A&C are derived from work of the HL7 EHR WG RCB Project Team.

Comments on ONC's Proposed Initiatives, Strategies and Recommendations

- See Appendix B summaries of ONC's proposed initiatives, strategies and recommendations (left column) and specific comments (right column) including notations regarding extended timeframes (yellow highlights) and reliance on the actions of non-federal government organizations (pink highlights).
- Appendix B is also derived, supplemented and based on comments by the HL7 EHR WG RCB Project Team.

Appendix A – "Reducing Clinician Burden" Topics

Compiled by the HL7 EHR Work Group – "Reducing Clinician Burden" Project Team

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

Appendix B – Specific Comments on ONC Proposed Initiatives[I], Strategies[S] and Recommendations[R]

Derived, supplemented and based on comments developed by the HL7 EHR Work Group – "Reducing Clinician Burden" Project Team

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", a number of comments are offered (left column below). It is noted that many aspects of burden reduction are based on future HHS/CMS/ONC strategies (yellow highlights) and/or rely substantially on actions of organizations outside the federal government (pink highlights).

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	– Still in the future – will not be implemented in the CMS Physician Fee Schedule until 2021 – The current CMS proposal to link a decrease in documentation regulation to initiating a level payment for all office visits has been universally opposed by specialty societies and clinicians as being financially unfeasible, and, with MDM and time-based sub-codes to adjust for work actually done, just as complicated and burdensome as the current system. Also it applies only to outpatient E&M services covered by Medicare. This will not produce meaningful change in clinical practice and EHR functioning without equivalent changes for inpatient and ED services and commensurate requirements for private payers to adopt the system.
I1.S1.R2 Leverage data already present in the EHR to reduce re-documentation in the clinical note.	
+ Reduces clinician burden by allowing certain patient encounter data already captured to be utilized without re-entry + 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 – Make recommendations but take care not to increase burden with non-essential elements
I1.S1.R4 Waive documentation requirements as may be necessary for purposes of testing or administering APMs.	

Recommendation Summary	Comments
+ 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 – Is only for those able to participate in APMs which are too cumbersome and expensive for smaller practices.
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 documentation best practices.	
+ 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 – Again, make recommendations but take care not to increase burden with non-essential elements
I1.S2.R2 Advance best practices for reducing documentation 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 – Making resources available is not useful unless these "state and private sector partners" actually have incentives to develop "their own initiatives"
I1.S3 Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.	
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 and "optimizing electronic workflows around prior authorization" + Seeks to "leverage existing data" to "reduce the total volume of prior authorization requests that clinicians must submit"	– Describes a possible strategy that is likely to have little/no immediate impact on burden reduction – No hint of a plan for how it could be accomplished
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.	
+ Reduces clinician burden "through adoption of standardized templates [and] data elements" to justify 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"	– Likely to have little/no immediate impact on burden reduction – Will require a lot more than just "partnering" – Again, make recommendations but take care not to increase burden with non-essential elements
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 documentation and exchange "for ordering and prior authorization"	– Suggests HHS may consider future incentives but has no immediate impact 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.	

Recommendation Summary	Comments
+ Reduces clinician burden by establishing pilots for new "templates and suggested clinical data elements" to promote wider adoption + Suggests HHS collaboration with "health IT developers, the medical product industry, regulatory agencies and payers", along with "third-party exchange organizations"	– Describes long term strategy that is likely to have little immediate impact on burden reduction – Again, make recommendations but take care not to increase burden with non-essential elements
I1.S3.R5 Coordinate efforts to advance new standard approaches supporting prior authorization.	
+ Reduces clinician burden by developing a "prior-authorization ecosystem through multi-stakeholder groups" + Suggests HHS collaboration with "clinicians, health information technology vendors and payers", along with the "[HL7] Da Vinci project and [the ONC] FHIR Task Force" and NCVHS	– Awaits development, maturity and consensus adoption of new standards and protocols – Likely to have little/no immediate impact – Requires substantial work by partners outside the federal government
I2. 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.	
I2.S1.R1 Better align EHR system design with real-world clinical workflow.	
+ Reduces clinician burden by aligning EHR system design and configuration with individual clinician workflow + Suggests HIT developers work with clinical organizations	– Encourages industry to act, but foresees no federal role – Should include clinical professional societies and SDOs in developing best practices – Industry has been aware of this particular recommendation for the last 8-10 years, and it is unlikely to happen without new incentives or regulatory intervention. – "Part of alignment with the clinical workflow is flexibility for an end user to customize their individual electronic workflow." More than just part! Clinical workflow can be highly variable, complex, and nonlinear. Given the demonstrated variability between specialties, between individual clinicians, and even between patients for a given clinician, even the best user centered design will never produce a single ideal workflow which is "usable" by all practitioners of all specialties in all contexts. Systems must be highly flexible and customizable within very broad safety guardrails in order to fit clinicians' cognitive styles, reduce cognitive loads and support better care.
I2.S1.R2 Improve clinical decision support usability.	
+ Reduces clinician burden by improving and augmenting CDS "beyond alerts to include predictive care suggestions to help make decisions at the point of care" + Suggests building on National Academy of Medicine CDS framework + Suggests working with AHRQ to develop and promulgate best CDS practices	– Encourages industry to act, but foresees no CMS/ONC role – Should include clinical professional societies and SDOs in developing best practices and implementation strategies – "Predictive care suggestions" as opposed to just guideline reminders will require new AI capabilities not yet available – "Standards based, computable, evidence based guidelines" are not generally available,

Recommendation Summary	Comments
+ Suggests rapid incorporation of standards-based, computable, evidence-based care guidelines into clinical practice via interoperable CDS	and many current guidelines are vague, or contradictory, or impose too much cognitive load to implement in the context of workflow – Some of this whiz-bang CDS functionality will more likely get in the way (potentially causing delay and bafflement), rather than buttress good decision making practices
I2.S1.R3 Improve clinical documentation functionality.	
+ Reduces clinician burden by promoting "methods to capture both the structured and unstructured data", such as speech recognition + 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	– Encourages industry to act, but foresees no federal role – Should include SDOs – If the documentation regulations required for billing are appropriately reformed and specialty societies, professional boards, and clinicians define the core clinical information really needed for best clinical care, much of the copy/paste problem will resolve on its own – If EHR/HIT systems judiciously recognized input being "pasted" (e.g., input buffers filled with lots of characters in milliseconds) they could challenge the enterer as to why they are pasting and where the copied data comes from – could reduce note bloat
I2.S1.R4 Improve presentation of clinical data within EHRs.	
+ Reduces clinician burden by optimizing and improving information display "in a context-driven and context-dependent manner" + Suggests extracting and indexing data contained in scanned documents + Suggests exploring new "ways to facilitate presenting a patient's data in a longitudinal manner"	– Encourages industry to act, but foresees no federal role – Should include SDOs – "Then the end user is presented with a manageable amount of data and successfully guided to needed information in a context-driven and context-dependent manner." This presumes there is one best way to present information that will work for all clinician cognitive styles in all specialties in all contexts. No such ideal way exists, and the user must have tools to customize and optimize the fit. – Extracting and indexing data requires more than just OCR and even NLP. It will require elements of ML and AI to organize that data in such a way as to make it available in real time at the point of care. – How does this differ from I2.S1.R1?
I2.S2 Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.	
I2.S2.R1 Harmonize user actions for basic clinical operations across EHRs.	
+ Reduces clinician burden by developing "a shared understanding of common interface and workflow design elements for common clinical tasks", across EHR systems + Reduces "the need to remember a series of divergent workflows for the same basic task" + Decreases clinician cognitive load and risks to patient safety	– Encourages industry to act, but foresees no federal role – Should include SDOs – It seems unlikely that EHR developers in a competitive market-based system will voluntarily accept "common interface and workflow design elements for common clinical tasks", across EHR systems.

Recommendation Summary	Comments
+ Suggests clinicians and clinical professional societies work with HIT developers	
I2.S2.R2 Promote and improve user interface design standards specific to health care delivery.	
+ Reduces clinician burden by focusing "on user interfaces to support the clinician's cognitive thought process in terms of complex pattern recognition" + 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"	– Encourages industry to act, but foresees minimal federal role – Should include SDOs – Again, UCD is beneficial and necessary, but not sufficient. No practical panel of test users will ever be representative of the huge spectrum of cognitive processes and contexts across the user base. No single one-size-fits-all set of interface design standards will support every (or even most) clinicians' "thought processes in terms of complex pattern recognition."
I2.S2.R3 Improve internal consistency within health IT products.	
+ Reduces clinician burden by ensuring "all aspects of the [HIT] system share a common user interface and style guide"	– Encourages industry to act, but foresees no federal role – Should include SDOs – Again, this is contrary to EHR developers' underlying business model and is unlikely to happen voluntarily
I2.S2.R4 Promote proper integration of the physical environment with EHR use.	
+ Reduces clinician burden by optimizing "integration of EHRs with the physical environment" to ensure "both efficient clinical team interaction and clinician-patient interaction" + 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"	– Encourages industry to act, but foresees no federal role – Should include SDOs – A lot of this is low hanging fruit and has already been accomplished. Also, the recommendation is only helpful to a certain degree. The clinician still must devote attention to keyboarding data in the EHR even if he is gazing at the patient and this disrupts the interaction. (Or the clinician documents later raising problems with memory, accuracy, and work-life balance.)
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 information... in a standardized format" + Suggests following best practices and guidance from "the NCPDP, the Institute for Safe Medication Practices (ISMP) and the FDA", also ONC's SAFER Guide	– Encourages industry to act, but foresees minimal federal role – Should include SDOs – For all I2.S3 recommendations: this type of standardization would be beneficial and even necessary, and it should have been undertaken when the very first criteria for EHR certification were developed and written. At this point, expecting developers to undertake this voluntarily is completely unrealistic.
I2.S3.R2 Standardize order entry content within health IT.	
+ Reduces clinician burden by refining descriptions for lab, imaging and other diagnostic orders to ensure they are clear and concise + Suggests collaboration between the CMS Division of Laboratory Improvement and Quality (CLIA regulator),	– Encourages industry to act, but foresees minimal federal role – Should include SNOMED International and other SDOs

Recommendation Summary	Comments
the American College of Pathology and the Regenstrief Institute (LOINC administrator)	
I2.S3.R3 Standardize results display conventions within health IT.	
+ Reduces clinician burden by establishing "a common format for displaying results" + Suggests "standardizing the display of... test results [to] allow critical information to be reported first" + Suggests "developers... arrive at a standard for chronological display... abnormal display... and reference range inclusion"	– Encourages industry to act, but foresees no federal role – Should include SDOs
I2.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 "from the very beginning of the acquisition process to ensure that the product purchased by an organization will 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" + Suggests "institutions... ensure that adequate clinical staff are assigned to... [EHR] upgrade planning [and] change requests"	– Encourages industry to act, but foresees minimal federal role – Should include SDOs – Yes, end users should "own" the EHR. Yet with most organizations already locked in to hugely expensive EHR products, how likely is it that there will be opportunities to involve end users in acquisition? Increased end user involvement should not occur by cumbersome forced training to fit a predetermined model. There is NO one predetermined one best model. The EHR must have much more flexibility and customizability to accommodate different clinician needs and cognitive styles. End user opportunities to participate in configuration and optimization must avoid the endless delays currently seen in such processes.
I2.S4.R2 Promote understanding of budget requirements for success.	
+ Reduces clinician burden by establishing a formal "budget model that incorporates ongoing technical 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	– Encourages industry to act, but foresees minimal federal role
I2.S4.R3 Optimize system log-on for end users to reduce burden.	
+ Reduces clinician burden by establishing secure but short and straightforward modes of user authentication to access systems and information + Suggests consideration of methods beyond user name/password, such as token-based and biometric access	– Encourages industry to act, but foresees no federal role – Should include SDOs – How does this differ from current smart card tap and go or biometric systems already widely implemented?
I2.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 enable "secure exchange of electronic health information... without special effort of the part of the user"	– Describes health information exchange but not data quality nor how exchanged data may be assessed for accuracy and reliability, traceability to source, and thus trusted by the end user

Recommendation Summary	Comments
+ Suggests using the "framework for trusted exchange among health information networks" [presumably TEFCA] and "improving the effectiveness of the ONC's Health IT Certification Program"	– Should recognize/encompass the "Vital Data Qualities" enumerated above
I3. EHR Reporting	
I3.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.	
I3.S1.R1 Simplify the scoring model for the Promoting Interoperability performance category.	
+ Reduces clinician burden by overhauling the scoring methodology for MIPS and the Promoting Interoperability Program for eligible hospitals and Critical Access Hospitals + 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"	– Describes long term strategy that is likely to have little immediate impact on burden reduction – Should include SDOs
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 "innovative uses of health IT and advancements in interoperability that improve care for patients"	– Suggests directional intent but actual incentives will occur at some point in the future – What does this even mean? What is a "Health IT Improvement Activity?" How can clinicians achieve "innovative use of health IT and advances in interoperability" without new technical capabilities provided by their EHR vendors?
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.	
+ Reduces clinician burden by tuning HIT measures to be more closely aligned with and "relative to the value they provide" + Offers to provide value by 1) "being evidenced-based 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	– Describes long term strategy that is likely to have little immediate impact on burden reduction – Should include SDOs
I3.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 that promote interoperability within and beyond the Medicaid enterprise" + Suggests that CMS will "work with states to integrate health IT into larger Medicaid Enterprise systems"	– Describes long term strategy that is likely to have little immediate impact on burden reduction

Recommendation Summary	Comments
+ 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 capture more useful and impactful information, improve report formats, streamline submission and update processes	– Describes long term strategy that may have little immediate impact on burden reduction
I3.S2 Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.	
I3.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 improving data accuracy in terms of "administrative and financial burdens" but not impacts/burdens related to clinical care, interventions and decision making, and most importantly, patient safety – Should recognize/encompass the "Vital Data Qualities" enumerated above
I3.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 integration, extraction and analysis of, data across HIT systems + Suggests broader adoption, of HL7 FHIR APIs to "allow for the development of electronic resources to facilitate requests for data without requiring a clinician or health care provider to individually address potential variations in each individual request" + Promotes use of the US Core Data for Interoperability (USCDI) which specifies "a common set of data classes required for interoperable exchange"	– Describes the use of FHIR, but overlooks its key strength, where application design implements FHIR as the native data construct and thus data is sourced/ captured, stored, exchanged, extracted, analyzed and accessed/used... data never requires transformation... data retains its context and relationships to other data
I3.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 systems accessible via APIs + Suggests HHS "implement an API approach that supports bidirectional data integration, which would allow health IT to seamlessly integrate with these systems and regularly update information related to physicians"	– Suggests directional intent but realization (of burden reduction) will likely occur at some point in the future
I3.S3 Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden	
I3.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 programs for new eCQMs wherein reporting on these eCQMs is optional", following this approach HHS could use "measure data to refine new eCQMs as needed, but not as part of public reporting or performance evaluation"	– Suggests directional intent but realization (of burden reduction) will likely occur at some point in the future

Recommendation Summary	Comments
I3.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 and develop[ing] new eCQMs that will allow physicians and hospitals to increasingly transition to electronic 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"	– Describes CMS/ONC work in progress that may take some time for realization (of burden reduction)
I3.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 align with clinical workflow and do not contribute extra or unnecessary steps to the use of health IT in patient care" + 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"	– Suggests directional intent but realization (of burden reduction) will likely occur at some point in the future
I4. Public Health Reporting	
I4.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 using existing standards.	
+ Reduces clinician burden by integrating PDMP prescription histories "into the routine workflow of patient care... [and] electronic prescribing" + Suggests "federal funding agencies... coordinate a shared strategy for all PDMPs to adopt common standards over time to support PDMP and health IT integration"	– Suggests directional intent but realization (of burden reduction) will likely occur at some point in the future
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 management (including controlled substances) "in a single workflow, reduc[ing] the time clinicians spend on medication reconciliation, automat[ing] CDS such as drug-drug interactions, and facilitate[ing] the tracking of prescription fulfillment"	– Describes long term strategy that may have little immediate impact on burden reduction

Recommendation Summary	Comments
+ Suggests implementation of DEA-required "multifactor authentication [permitting] biometrics and modern approaches to authentication that can be more easily integrated into provider workflows"	
I4.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 disparate data reporting requirements across [multiple federal] programs, aligning similar reporting requirements with data collected in normal workflows, and harmonizing reporting requirements" + Suggests collaboration between HHS, CDC, SAMHSA, FDA, HRSA and USDA	– Describes long term strategy that is likely to have little/no immediate impact on burden reduction – Should include SDOs
I4.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 data elements and transport standards across reporting requirements" of multiple HHS agencies + Suggests adopting "a common standards-based approach to reporting EHR-captured data"	– Suggests directional intent but realization (of burden reduction) will likely occur at some point in the future – [Unclear how this is the same or different 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 "which govern privacy and security of patient health information" to "facilitate HHS's goal of promoting electronic exchange of health information for better care coordination" + Suggests "development of technical standards for applying security labels and meta-data" (for data segmentation) + Suggests HHS "coordinate across federal agencies"	– Describes long term strategy that is likely to have little/no immediate impact on burden reduction – Should include SDOs

Appendix C – Known Clinician Burdens compared with ONC Draft Strategy

Derived from work of the HL7 EHR Work Group – "Reducing Clinician Burden" Project Team

Columns below:

RCB Topic – "Reducing Clinician Burden" topic – [##] corresponds to topic identifier in Appendix A and the HL7 EHR WG RCB Analysis Worksheet
The clinician burden – describes what clinicians see as their challenge and the compulsory load they must carry
ONC – Is this burden addressed in the ONC DRAFT? If so, designated by Initiative[I], Strategy[S] and Recommendation[R]

	RCB Topic	The clinician burden...	ONC
Generally [1]			
	Mandates, Impositions, Overload	Faced with mandates and no control: • "No other industry... has been under a universal mandate to adopt a new technology before its effects are fully understood, and before the technology has reached a level of usability that is acceptable to its core users." – New England Journal of Medicine, Transitional Chaos or Enduring Harm? The EHR and the Disruption of Medicine, 22 Oct 2015 • "Many clinicians know what they want — but haven't been asked... Our biggest mistake lies not in adopting clunky systems but in dismissing the concerns of the people who must use them." – Ibid. • "Although the original intent behind the design of EHRs was to facilitate patient management and care, the technology largely has been co-opted for other purposes. Payers see the EHR as the source of billing documentation. Health care enterprises see it as a tool for enforcing compliance with organizational directives. The legal system sees the EHR as a statement of legal facts. Public health entities see it as a way to use clinicians to collect their data at drastically reduced costs. Measurement entities see the EHR as a way to automate the collection of measure data, reducing their reliance on chart abstraction. Governmental entities see it as a way to observe and enforce compliance with regulations. All these impositions on EHR systems have created distractions from their potential value in supporting care delivery... The ability of these systems to support care delivery will not improve unless physicians and others who deliver care insist that the functions needed by clinicians and their patients take priority over nonclinical requirements." – American College of Physicians, Putting Patients First by Reducing Administrative Tasks in Health Care, 2 May 2017	
	Practice Constraints	Faced with constraints on clinical practice: • Must spend more time dealing with constraints on how to do their jobs and less time simply doing them • Must conform their clinical practice to constraints of EHR/HIT system	
Patient Safety (and Clinical Integrity) [2]			
	Safe Use, Clinician Oversight	Confronted by challenges regarding selection, governance, safe use and proper engagement of EHR/HIT systems/software • Safe design and development of EHR/HIT software • Safe configuration and implementation of EHR/HIT systems: data capture, content, context, sequence; patient flow, work flow, information flow... • Often without rigorous testing • Often without clinician review, supervision and guidance	Partial I2.S4.R1
	Decision Support	Faced with concerns regarding validity of metrics, algorithms, units and methods of measure...	Partial I2.S1.R2 I2.S4.R1
	Integration, Overload	Concerns about system and data integration, information overload, missing or overlooked data resulting in missed or delayed diagnosis, improper dosing, incorrect treatment...	
	Usability, user interface	Concerns regarding system usability, poor or counter-intuitive user interfaces layout; confusing selection choices; obverse display order, mis-selected options, including selection of wrong patient...	Partial I2.S1.R1 I2.S2.R1-R3
	Alerts, reminders	Concerns regarding alert fatigue, missed or mis-configured alerts, reminders, notifications...	Partial I2.S1.R2
	User Competence	Faced by lack of experience and training	I2.S4.R1-R2

	RCB Topic	The clinician burden...	ONC
	Risk Reporting	Confronted with lack of mechanisms for users to report safety risks and assurance that they are addressed in a timely manner	Limited I2.S2.R1
Identity Matching [34.1]			
	Patient Identity, Identity Matching	Uncertain as to proper patient matching and true identity of records received from elsewhere • No national patient ID for healthcare • Mismatched ID attributes: common identifiers, name (first, middle, last, prefix, suffix), birthdate, birth sex, birthplace, mother's maiden name... • One record, two (or more) patients OR two (or more) records, one patient	**No**
Identity and Credential Management [34.2]			
	Identity Management	Uncertain as to if/how identity and identifiers are managed: • Persons: patients, individual and organizational providers • Places: locations, addresses, points of care/service (offices, patient rooms, exam and procedure rooms) • Medical devices, monitors, instruments • Stationary hardware, devices, networks, addresses • Mobile devices • Within and across organizations • Within and across municipalities, states, regions, nations	**No**
	Credential Management	Faced with uncertainty as to if/how professional credentials are managed, verified and renewed	**No**
Data Quality and Integrity [35]			
	Data Authenticity	Uncertainty as to data accuracy/authenticity if sourced elsewhere	**No**
	Data Provenance	Uncertainty as to data provenance if sourced elsewhere: who (author, credential(s), role), what (action taken), when (date/time, sequence), where (location), why (purpose of capture), how (method), under what conditions, units and method of measure	**No**
	Data Context	Uncertainty as to data context: clinical (purpose/rationale, conditions), administrative, operational	**No**
	Data Completeness	Uncertainty as to whether data is complete, partial or missing	**No**
	Data Verification	Uncertainty as to whether data has been verified, whether from manual or automated entry • If verified, by whom (clinician, credentials), when (date/time) and by what method?	**No**
	Data Update	Uncertainty as to whether data has been updated or corrected • Do new value(s) supersede the old? • If updated, by whom (clinician, credentials) and when (date/time)? • Are clinical decisions and care/treatment plans, based on previous data values, at risk?	**No**
	Data Distortion	Uncertainty as to whether data has been distorted, end-to-end from source to use and during system-to-system exchange • Was data transformed? From one code/value set to another? From one human language to another? • Was the original source content and context carried forward without alteration? • Were data structures and semantics preserved? • Was data naming and definition preserved? • Were errors, alterations or omissions introduced in the course of exchange?	Partial I3.S2.R1
	Data relationships	Concerns regarding missing or incorrect linkages between medications, allergies, problems, diagnoses, encounters, assessments, clinical decisions, diagnoses, orders, results, diagnostics, interventions, procedures, observations, therapies and care plans	**No**
Process Integrity [36]			
	Actions Taken	Uncertainty as to who did what, when, where and why	**No**

	RCB Topic	The clinician burden...	ONC
Administrative Tasks [3]			
	Governmental, Regulatory, Accreditation	Faced by time-intensive administrative tasks to support: • Federal government regulatory mandates: ACA, HIPAA, Stark, MACRA, MIPS, Medicare/Medicaid... • State government and regional regulatory mandates • Accreditation guidelines: JCAHO, NCQA, URAC, ISO 9000...	Partial I1.S1.R1-R4 I3.S1.R1-R5 I3.S2.R1-R3 I3.S3.R1-R3
Data Entry [4]			
	Unrelated to Immediate Care or Patient Needs	Faced by requirements to enter myriad data unrelated to the clinician's specialty or immediate reason for care/treatment, bloating the clinic note • Structured documentation tools often make it difficult to communicate the complex details of patients' care and nuanced clinical reasoning • Instead desire to create a concise narrative and be done	Partial I1.S1.R1-R4 I1.S2.R1-R2 I2.S1.R3 I2.S2.R1-R4 I2.S3.R2 I2.S4.R3
	Driven by External Factors	Confronted by hundreds of structured data items to comply with external drivers • External drivers include: billing and claim substantiation, measures for quality, value and performance programs, compliance (e.g., accreditation, consents, patient education), avoiding malpractice claims	
	Duplicative	Faced by need to re-enter data already captured in the patient record	
	Cumbersome	Contending with: • Cumbersome array of poorly designed data entry methods, a multiplicity of input screens, inefficient flows, navigation of deeply nested drop-down menus, long pull-down pick lists that are neither filtered nor contextualized, keyed entries, pointing devices... • Multiple disparate user interfaces across care settings, systems and apps, multiple sign-ons required... • Mismatched granularity of coded entry vs. intended (preferred) description, often code/value set offers choices too specific or too general	
	Patient Story	Confronted with lack of clear patient story and history: • Narrative is often lost due to poor syntax, note construction templates combined with structured data elements	**No**
Data Entry Scribes [5]			
	Proxies	Faced with added cost of data entry scribes • Often accompanied with excessive error rates and high turnover	**No**
Clinical Documentation – Quality and Usability [6]			
	Chart Review	Confronted by time-consuming, tedious, if not often incomprehensible, chart review task • Hard to find current, usable, action-able items among vast volumes of data (mind-numbing combat with note bloat) • Hard to discover if data has been updated with more current values • Hard to discover if data is accurate/authentic, has been verified, or is simply noise • Difficult to navigate blobs of external data that are discontinuous and disjoint from locally generated content • Difficult to distinguish excessive/duplicate notes carried (copied) forward without useful new information • Lack of available tools to efficiently incorporate complicated data into information, track multiple highly complex problems, and maintain/ensure continuity of medical decision making • Difficult to track patients care and treatment over time and space	Partial I1.S2.R1-R2 I2.S1.R3-R4 I2.S3.R1-R3
	List Review and Management	*See "Problem List", "Medication List", "Allergy List", "Immunization List" and "Surgery, Intervention and Procedure List" Sections*	*See Section(s) Indicated*
	Data Integrity	*See "Data Integrity" Section*	
	Process Integrity	*See "Process Integrity" Section*	
Prior Authorization, Coverage Verification, Eligibility Tasks [7]			

	RCB Topic	The clinician burden...	ONC
	Tedious, Time-Consuming Process	Contending with tedious and time-intensive tasks to verify and document coverage, coverage limits and authorization for particular tests, procedures, medications, supplies and referrals • Difficult to navigate rules and criteria • Often required to provide details, check boxes and fill out variant forms for each payor • Often requiring lengthy phone calls to achieve satisfactory resolution • Often requiring dedicated staff to follow each request to conclusion • Sometimes leading to delayed or interrupted treatment and even severe to life-threatening health outcomes • Sometimes requiring patients remain hospitalized while awaiting authorization for necessary services or supplies that otherwise would allow them to be discharged earlier, increasing costs and putting them at risk for added complications	Partial I1.S3.R1-R5
Provider/Patient Face-to-Face Interaction [8]			
	Engagement and Dialogue	Confronted with constant interference in, and impediment to, the clinician/patient relationship • Finding patients are put off by screen gaze instead of direct eye contact • Noticing interruptions in the flow of conversation, often with long periods of silence, amid perception of being distracted, disengaged, and less then patient-focused during the consultation • Finding that patients feel uncomfortable, reluctant to express concerns, ask questions, or talk while clinician is typing or looking at the screen, • Finding that less time spent interacting with the patient tends to lower the quality of care, patient satisfaction, and reimbursement because appointments are longer with fewer scheduled in a day	Limited I2.S2.R4
	Flow Management	Confronted with: • Counterproductive work, information and data entry flows that distract from patient engagement at the point of service/care	Partial I2.S2.R1-R4 I2.S2.R1-R4
Provider/Patient Communication [9]			
	Sharing and Interaction	Faced with challenges of communication: • Finding that patients have a limited view of their digital health information and often have difficulty communicating with their care team • Finding that patient portals are not easily navigated and shared, except to accomplish the most basic aspects of medication refills or to request an appointment	**No**
Care Coordination, Team-Based Care [10]			
	Interaction, Communication	Contending with limited/no team-oriented functionality: • Lack of efficient tools for immediate/continuous interaction with team members, particularly across organizations/systems • Face-to-face team interaction is most efficient but phone-based text/messaging often works better than EHR-facilitated communication	Limited I1.S2.R1 I2.S1.R1-R2 I2.S2.R4
	Assignment, Delegation	Faced with limited ability to: • Delegate, assign or distribute data entry or other tasks to team members • Share role or task responsibility or accountability	**No**
	Standards of Practice	Constrained by limitations, across services and specialties and across organizations: • Lack of uniform educational requirements, standards of care, and standards of conduct for clinical teams	**No**
	Enforced Clinical Roles	Dealing with limited functionality to: • Accommodate substantial differences in the HIT needs of different clinical roles (nurse vs physician), clinical situations (acute vs chronic care), clinical environments (intensive care unit vs ambulatory clinic) and institutions, stifling multi-user communication, coordination and collaboration • Capture the same essential data among multiple members of the care team, including key fields essential for care management, care gap analysis for prevention, and clinical care maintenance – often simply not available	**No**
	Isolation	Faced with limited ability to:	**No**

	RCB Topic	The clinician burden...	ONC
		• Know that patients have been (are being) seen by other clinicians • Gain awareness – often too late for meaningful engagement in the care process • Perform discrete tasks outside of isolated "sessions" which are not conducive to shared team engagement • Capture collaborative clinical notes with multiple clinician authors contributing	
	Reimbursement	Faced with reimbursement constraints: • Current payment system is not designed to offset the costs associated with forming, training, and sustaining clinical teams and do not empower all members of the clinical team to meaningfully participate	**No**
Clinical Work Flow [11]			
	Optimization	Faced with limited (or no) functionality to: • Optimize screen/data entry sequences to match work flow, sequence of care delivery and the way clinicians think • Tailor work flows to care setting, service, specialty or individual clinician practice patterns • Ensure pertinent patient information is gathered and available prior to each encounter • Improve balance between reading, writing, thinking, decision making and navigating • Support evolving nature of diagnostic and disease processes	Partial I2.S1.R1-R4 I2.S2.R1-R4 I2.S3.R1-R3 I2.S4.R3-R4
	Cognition	Dealing with: • Information clutter, non-essential screen splays, overtures and missives • Increased cognitive load, decreased situational awareness, often impairing a clinician's ability to comprehend and focus on patient's problem(s) • Recognition, impressions and complex thought patterns that are non-linear and do not fit a generic mold • Variety of disparate and disjoint systems/apps to review patient data from multiple sources	
	Shortcuts	Contending with: • Limitations on training or real-time hints which fail to describe how to unlock key usability functions and shortcuts	I2.S4.R1-R2
	List Review and Management	*See "Problem List", "Medication List", "Allergy List", "Immunization List" and "Surgery, Intervention and Procedure List" Sections*	*See Sections Indicated*
Disease Management, Care and Treatment Plans [12]			
	Guidelines, Rules	Coping with limited functionality to manage: • Guidelines and rules to enable/support care and treatment planning based on diagnosis or known best practices	**No**
Clinical Decision Support, Medical Logic, Artificial Intelligence [13]			
	Rule setting	Faced with limited (or no) functionality to: • Optimize clinical decision support rules based on care setting, service, specialty, clinician practice patterns	Partial I2.S1.R2 I2.S4.R1
Alerts, Reminders, Notifications, Inbox Management [14]			
	Interruptive	Contending with: • Frequent, often non-essential or unrelated, interruptions for clinical and administrative alerts, reminders and pop-up windows that may force hard stops in work flow, thought processes and patient interactions • Alerts and reminders that lack key identifying and contextual information, forcing a digression to a separate system or app • Lack of ability to instantly discern between important information needing immediate response/action versus that which is routine or entirely irrelevant • Alert fatigue	**No**
	Configuration	Constrained by: • Inability to designate/configure priorities for alerts, reminders and notifications: e.g., urgent (interrupt) vs. routine (review now or later)	**No**

	RCB Topic	The clinician burden...	ONC
		• Limitations in ability to automatically route specific message types to other members of the care team	
Information Overload [15]			
	Avalanche	Contending with: • Avalanche of data from external sources, mostly patient summaries • Patient summaries that are an arbitrary snapshot in time and even when taken together never represent a complete patient record or picture of the patient • Data that is stale or irrelevant • Hours spent searching for data that is expected, buried in the muddle or never found	**No**
	Targeted	Faced with limited functionality to ensure: • Smart data synthesis, highlighting data that is timely, concise, pertinent/relevant and action-able • Data targeted to patient problem/diagnosis or condition • Data targeted to receiving clinicians service, specialty, clinical practice patterns and/or preference(s)	**No**
	Data Integrity	*See "Data Integrity" Section*	*See Sections Indicated*
	Process Integrity	*See "Process Integrity" Section*	
Transitions of Care [16]			
	Disjunctions	Confronted with: • Disconnects in transitions from care setting to care setting, including missing information regarding problems, orders, medications and discharge instructions, follow up appointments • Lack of key information when referrals are ordered, including reason for referral • Lack of ready information exchange between referring and referred to clinician, including acceptance of referral and expected plan/schedule for follow up	**No**
Health Information Exchange – Claimed "interoperability" [17]			
	Record Fragments	Faced with time-consuming, tedious, if not often incomprehensible, review of incoming data from external sources • Noting that patient summaries are only record fragments, snapshots in time, subsets, never complete records • Information is seldom synthesized and offered as timely, concise, pertinent/relevant and action-able	**No**
	Lapses	Contending with: • Data known to have been captured elsewhere but is not yet available in local system/app • Situations where passing the baton often results in dropping the baton as it is realized that information was exchanged but not recognized as clinically significant until sometime after the fact, confounding efforts to recover lost time, inaction or inappropriate action	**No**
	Push and Pull	Coping with: • Data that should be pushed but isn't (e.g., incorrect push rules or other misconnect) • Data that is pulled but where the query may: 1) never return a response; 2) be mis-directed; 3) return an incomplete response; 4) return an avalanche response; 5) return a belated response (some hours, days or weeks later)	**No**
	Gaps, Disparities and the Unknown	Contending with affirmative (or negative) trust issues when inbound data is or has been: • Replete with gaps, disparate structures, content and/or representations that are not resolvable • Transformed in the course of exchange – introducing errors. alterations, omissions, mis-mapping, missing context... • Superseded/updated with more current values • Accurate/authentic – with evidence that it is unaltered from its source – or not • Reviewed, verified or attested by a clinician (in the source system/app) before exchange – or not	**No**
	Provenance	Faced with: • Data received without evidence of its source or provenance	**No**

	RCB Topic	The clinician burden...	ONC
	Sharing with the World	Contending with myriad requirements (and potential disjunctions) for sharing such as: • Needing to exchange data with thousands of variant health care systems/apps that patients want to use • Vast structural gaps in achieving true data liquidity and interoperability	
	Identity Matching	*See "Identity Matching" Section*	*See Sections Indicated*
	Data Integrity	*See "Data Integrity" Section*	
	Process Integrity	*See "Process Integrity" Section*	
Medical/Personal Device Integration [18]			
	Separate Worlds	Coping with: • Limited integration of device data in EHR • Detailed data, including trend patterns, that are often more complete and offered at higher resolution on device displays	**No**
Orders for Equipment and Supplies [19]			
	How We Get What Patients Need	Confronted with: • Limited functionality to support orders for equipment and supplies, particularly in the case of discharge order and/or where pre-authorization is required	Limited I1.S3.R1-R5 I2.S3.R2
Support for Payment, Claims and Reimbursement [20]			
	How We Get Paid	Faced by continuing constraints on clinical practice due to reimbursement justification and related documentation requirements – designed for billing and not taking care of patients – and finding that: • Some documentation requirements are a relic of fee-for-service and make little sense in new payment models • All payers, whether public or private, have their own approaches, rules, and requirements related to insurance eligibility verification; appropriate billing for services; prior authorizations for medications, procedures, and other services; appeals for lack of payment; reporting of quality and resource use measures, as well as feedback reports on those measures; referrals and treatment plans; alternative payment model (APM) participation and more • Tasks may differ from payer to payer; appear one month without notice, then reappear modified or changed the next • Very difficult for anyone to review a patient chart, weed through the billing related documentation, and find out quickly and efficiently what they actually need to know about a patient for care and treatment purposes	Not for commercial payers
	Evaluation and Management Codes	Confronted by coding/documentation requirements of US Evaluation and Management (E/M) guidelines for claims/payment • Consumes a significant amount of time and does not reflect optimal clinician workflow, impacting system usability • Constrains notes that target billing requirements, often using check boxes and radio buttons to facilitate calculation of coding points • Creates voluminous patient records and many extraneous notes of little or no clinical value, overrules clarity and concision, and does not result in documentation that readily conveys the essence of an encounter • Requires extra clinician and staff time – unreimbursed • Uses an outdated 1995/1997 framework built on a model of clinical care involving complaint or symptom-based face-to-face encounters between a patient and a clinician... since the 1990s, the nature of clinical work has evolved, including greater emphasis on patient-centered, collaborative models of care with clinical teams working together to manage chronic conditions... the intensity of this work, which often requires complex medical decision-making and care coordination, which is not well represented in the current E/M framework. • Documents parameters that are of marginal relevance to the encounter, but are required in order to receive the level of payment that their effort deserves	Partial I1.S3.R1-R5 I3.S1.R1-R5 I3.S2.R3 I3.S3.R1-R3
	Medicaid	Faced with complex Medicaid (and contractor) billing requirements that vary state by state...	
	MIPS/APMs	Faced with Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) and their requirements for quality, interoperability, performance improvement, cost management...	
Support for Cost Review, Comparison of Alternatives [21]			
	Economies	Dealing with limited functionality to:	**No**

	RCB Topic	The clinician burden...	ONC
		• Review costs and find comparable alternatives for care, treatment, equipment and supplies	
Support for Measures – Administration, Operations, Quality, Performance, Productivity, Cost, Utilization [22]			
	Scope, Alignment, Value	Contending with capture and reporting of measures which are: • Imposed by public and private payers; governments and policymakers; private certification, accreditation, and recognition organizations; vendors and suppliers; health care consumers; and other clinician practices and health care provider organizations • Not aligned: terms, definition, scope, method of capture/collection and reporting format for each measure • Not captured and stored as discrete and structured elements in health record • Of little value or consequence to immediate patient care and treatment or needs of clinical practice • Beyond the scope of practice and expertise of various specialties • Reported and tallied, by clinician and by organization, but are often so scant as to be clinically insignificant (thus of no value)	Partial I3.S1.R1-R5 I3.S2.R1-R3 I3.S3.R1-R3
Support for Public and Population Health [23]			
		Faced with myriad public health reporting requirements: • Lack of good tools to capture, maintain and report public health data in proper form, at the proper time, to multiple agencies	Partial I4.S1.R1-R2 I4.S2.R1-R3
Legal Aspects and Risks [24]			
	Record Quality and Reliability	Awareness that: • Legal world is routinely demonstrating EHR-sourced records are inauthentic and vary from fundamental requirements for data quality • Concerns regarding direct costs of impeachment of records in legal and regulatory processes • Increasing recognition by payers that EHR-sourced records don't meet their record specification requirements • Internal to clinical organizations, extensive rework costs are absorbed by the provider organization (including clinician time) to "correct" defective documentation	**No**
	Risks, Liability	Contending with: • External data that is typically not integrated with internal data and is not semantically interoperable, such that most internal communications and decisions are informed by an incomplete subset of the data actually available in the organization's system • Serious concerns regarding risks to the safety/quality of care/treatment decisions as well as potential liability on the part of clinicians/organizations for data that is received but not fully reviewed and assessed as to timeliness, relevance and action-ability	**No**
User Training, User Proficiency [25]			
	Development of Skills, Literacy	Faced by: • Insufficiency of training for system/app use • Development of skills and system literacy with a confirmed level of proficiency • Lack of reimbursement for time in training	I2.S4.R1-R2
Common Function, Information and Process Models [26]			
	Endemic Variance	Faced with myriad disparities: • Disjoint system and app functionality • Variant user interfaces based on divergent design choices and usability heuristics • Lack of common data naming, definition, structure, data types, code/value sets, classification schemes, terminology and vocabularies	**No**
Software Development and Improvement Priorities, End-User Feedback [27]			

	RCB Topic	The clinician burden...	ONC
	Clinician Input	Contending with: • Software development priorities primarily based on external and other non-clinical factors (e.g., Meaningful Use, MIPS) not clinical care and treatment, or even patient safety, needs • Limited ability to incorporate clinician (or other end user) input into product design • Software feedback mechanisms which are constrained, hidden or non-existent and even if engaged seldom result in any direct response, much less corrective/remedial action • Vendors and IT staff who often lack clinical knowledge, understanding or expertise and where communication is a dead-end endeavor	Partial I2.S4.R1
	Software Updates	Confronted by software updates: • System/app "fixes" that are ugly appendages to already poorly designed user interfaces • System updates which often incur extended down-time, where work-arounds and manual systems must be deployed • System updates which may not be fully tested before deployment	**No**
	User Centered Design?	Faced with usability issues: • Systems that have been certified for User Center Design yet still exhibit poor usability behaviors	Partial I2.S1.R1-R4 I2.S2.R1-R4
Product Transparency [28]			
	Development	Faced with no/limited disclosure regarding software development lifecycle • How software products (EHR/HIT systems) are designed, developed, packaged, tested, implemented and supported, from inception on • How product requirements are established, vetted and revised over time	**No**
	Implementation	Faced with no/limited disclosure regarding software functionality when implemented • How data is managed and how data flows from source through retention to use • How data is managed during exchange including transformation • How clinical decision support is engaged, how rules are managed, how alerts and other actions are triggered • How clinical workflows are managed, how rules and alternate flows are engaged	Partial I2.S1.R1-R4 I2.S2.R1-R3 I2.S3.R1-R3
Product Modularity [29]			
	Unique Needs	Confronted by unique needs and otherwise limited functionality • Lack of common trust and record infrastructure (including current EHR products) to support system/app modules (or "plug-ins"), selected based on functionality (e.g., supporting specific clinical practice(s), population needs, analytics), usability, user interface, cost and other beneficial and proven characteristics	**No**
Lock-In, Data Liquidity and Switching Costs [30]			
	Transfer of Essential Records	Faced with a heavy penalty if considering another system • Lack of protection against EHR data 'lock in' which contributes to increased dissatisfaction and expense • Significant costs which may be imposed to obtain a usable copy of their data that can be imported into a new EHR system • Costs involved in moving large quantities of data from one system to another	**No**
Financial Burden [31]			
	Market and Vendor Constraints	Contending with market and vendor constraints • The economic model of competition (versus collaboration) and maximizing profit (versus healthcare for the common good) has led to resistance and the preservation of market share for current IT vendors • Concerns over EHR sustainability and high cost of available solutions are a substantial deterrent and limitation to their use • Ever-increasing costs of health IT products and services, including new module(s) needed to perform a specific function • Additional fees for every interface to another system or service, as well as ongoing fees for moving data • EHR vendors who develop and sell systems/apps have a competitive incentive to keep their software proprietary	**No**

	RCB Topic	The clinician burden...	ONC
Security [32]			
	Data Protection	Faced with requirements for system security and data protection • Risks and liability for data breaches • Costs to acquire and maintain security measures and expertise	**No**
Professional Credentialing [33]			
	Knowledge and Application	Must contend with ongoing requirements to maintain professional credentials • Ever-changing body of medical knowledge and application in practice • Lack of good tools to support learning and renewal	**No**
Problem List [37.1]			
	Problem List Management	Uncertainty as to problem list management • Hard to distinguish between formally diagnosed problems, signs, symptoms and other problems • Hard to determine active vs inactive problems • Hard to determine problem timeframe: onset, treatment, resolution • Hard to determine who last reconciled problem list (clinician, credentials), when (date/time) and where • Hard to determine which problems may be missing	**No**
Medication List [37.2]			
	Medication List Management	Uncertainty as to medication list management • Hard to distinguish between prescribed meds and over-the-counter meds • Hard to determine which meds are currently taken • Hard to determine who last reconciled medication list (clinician, credentials), when (date/time) and where • Hard to determine which medications are missing	**No**
Allergy List [37.3]			
	Allergy List Management, including Medication Allergies	Uncertainty as to allergy list management • Hard to distinguish between allergies and sensitivities • Hard to determine which allergies are currently active • Hard to determine which allergies have been treated, the method and disposition of treatment • Hard to determine who last reconciled allergy list (clinician, credentials), when (date/time) and where • Hard to determine which allergies are missing	**No**
Immunization List [37.4]			
	Immunization List Management	Uncertainty as to immunization list management • Hard to determine which immunizations have been given, by whom (clinician, credentials), when (date/time) and where • Hard to determine which immunizations are due and when	**No**
Surgery, Intervention and Procedure List [37.5]			
	Surgery, Intervention and Procedure List Management	Uncertainty as to surgery, intervention and procedure list management • Hard to determine who performed surgery, intervention or procedure (clinician, credentials), when (date/time) and where • Hard to determine who last reconciled surgery, intervention and procedure list (clinician, credentials), when (date/time) and where • Hard to determine which surgeries, interventions and procedures are missing	**No**