

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

From the HL7 EHR Work Group – “Reducing Clinician Burden” Project
8 January 2019

HL7 EHR WG – Reducing Clinician Burden Project

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

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

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

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

Data Quality Burden (as an example)

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

The Surveys Say

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

“We’re from the Government and We’re Here to Help”

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

21st Century Cures Act – “Interoperability”

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

21st Century Cures Act: Interoperability Definition

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

Our observation...

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

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

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

For HL7...

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

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

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

Vital Data Qualities...
<ul style="list-style-type: none"> • 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):
<ul style="list-style-type: none"> • Who did what when, where and why
Known to retain clinical context and maintain vital inter-relationships with/between (as applicable):
<ul style="list-style-type: none"> • 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:
<ul style="list-style-type: none"> • 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:
<ul style="list-style-type: none"> • 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:
<ul style="list-style-type: none"> • Coding convention – vocabulary/terminology set or value set – and version
Known as to method and purpose of capture
Known as to how external data is integrated with health data/records in the local EHR
Known as to how external data is integrated with other health/data records from other sources

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

Specific Comments

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

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

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

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

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

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

This should be noted.

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

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

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

D. Is TEFCA Viable? In February 2018, a variety of organizations submitted comments on ONC’s proposed Trusted Exchange Framework and Common Agreement (TEFCA). While we understand that ONC’s TEFCA is a requirement of the 21st Century Cures Act, we don’t believe that it offered a viable path forward for widespread exchange nor interoperability of health data/records (as discussed in submitted comments). This concern is only amplified by what is offered in this ONC-proposed DRAFT “Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs”, released on 28 November 2018.

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

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

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 QI 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.”

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

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

Noting that the interoperability necessary to achieve the clinical care goals will require a trust framework suitable for easy accurate HIPAA compliance and data structure, vocabulary, and, communication standards that permit seamless data exchange as described elsewhere in the document.

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

G. Burdens Beyond. Work by the Health Level Seven (HL7) Electronic Health Record Work Group (EHR WG) has identified >30 clinician burden topic areas. The EHR WG “Reducing Clinician Burden” Project has been active since early 2018 and has captured input from trade publications, professional society journals, articles,

studies and personal experience. (See Appendix A for the complete list.) A number of these topics are missing in this proposed ONC Strategy but must be included if HHS is prepared to consider the full extent/impact of clinician burden.

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

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

- “Strategies should be achievable within the near to medium term, roughly 3–5 year window.
 - “HHS should be able to either implement these strategies through existing or easily expanded authority, or should have significant ability to influence the implementation of these strategies.
 - “Strategies should include actions that improve the clinical documentation experience and improve patient care.”
-

H. Burden Reduction Must Be Immediate, Forceful and Unrelenting. A “roughly 3-5 year window” is not acceptable to clinicians who must face the burden in daily practice. How many more clinicians (1000s?) will give up and burn out, never to return to front-line clinical practice?

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

ONC DRAFT Strategy, Page 14, 2nd Paragraph: “We also consider how leveraging data already stored in the EHR can reduce the need for redundant documentation.”

I. When leveraging data, and especially when sharing this data it is vital that the source of the data, the individual who provided the data, the date the data was recorded and collected as well as the clinical location where the data was collected be attached to the data. Without this information, clinicians viewing the data will have no idea as to the how old the data is and how to use the data in terms of longitudinal care. Also, without this information the data only will contribute to 'Note Bloat'.

ONC DRAFT Strategy, Page 14, 4th Paragraph: “...but prior authorization processes suffer from a lack of standardization and common approaches...”

J. This is something where HL7 can take a lead developing a standard by which EHR systems can communicate with payors to send:

- Type of Pre Authorization (set of Pre Authorization codes)
- Clinical Data to support medical necessity
- Patient Information
- Receiving back a Pre Authorization approval or denial from the insurance company.

The current incentive program does not work for small providers. Based upon the 2017 experience a provider who achieved a MIPA score of 100 has earned a cumulative bonus of only about 2%. The average provider does not consider this bonus enough to offset the burden of working with certified technology. The bonuses for utilizing certified technology need to be increased.

HHS could also explore ways to incentivize clinicians to adopt technology certified. Another approach is to require that all Medicare MAC's support electronic pre authorization to ensure prompt payment to providers for services that have been pre-authorized electronically. This would not only reduce the burden associated with obtaining the pre authorization, but would reduce the burden associated with being paid for services provided. Also add in the ability to include the pre-authorization code on a claim to ensure prompt claims processing is also an enhancement (if it does not already exist).

ONC DRAFT Strategy, Page 15-16, Starting with the 3rd Paragraph under Health IT Usability and the User Experience: “There are several ways improvements to the user interface can improve health IT system usability, efficiency, user experience, and end user satisfaction. Health IT developers should consider implementing common approaches to basic clinical operations across EHRs, so that clinicians do not have to utilize a significantly different interface each time they switch between systems.”

K. There are many places where the burden of improving the systems is placed on the Health IT developers. But there is very little incentive for these developers to implement the tools into their systems due to the low level of churn in the industry. What about an incentive program for developers to implement the tools that 'reduce clinician burden'?

Let's take an interesting hypothetical use case for prior authorization. Every time a claim is paid that is based upon an electronic prior authorization, the EHR vendor whose product initiated the electronic prior authorization request and received the prior authorization will be paid \$1.00. Now let's look at the stake holders...

Patient - electronic prior authorization results in quicker adjudication, and faster access to care – the patient benefits

Doctor - electronic prior authorization results in the ability to provide care to patient in a more timely fashion resulting in better outcomes – electronic prior authorization enables faster payment for services rendered – the provider benefits

Insurance provider - electronic prior authorization reduced the burden of processing the prior authorization resulting in improved efficiencies and lower costs. Cost of manually processing a prior authorization is greater than \$1.00 so the \$1.00 fee to the vendor is borne by the insurance provider, they are sharing the cost savings with the vendor. They still have a very significant savings – the insurance carrier benefits.

The Health IT Vendor is now incentivized to develop the software to communicate prior authorizations with insurance carriers. They are incentivized in such a way that they do now want to just build the tool, but they want to build it in such a way that it is extremely usable, since the more it is used the higher the income potential for the IT vendor. The more usable it is, the less the burden on the provider to use it, the more they will use it – everybody wins.

ONC DRAFT Strategy, Page 16, 3rd Paragraph under EHR Reporting: “CMS could continue to explore new incentives within these programs that reward the innovative use of health IT and increased interoperability...”

L. The incentives proposed earlier for HIT Vendors match the objective this statement.

ONC DRAFT Strategy, Page 18, 1st Paragraph: “HHS will also be implementing provisions of the SUPPORT for Patients and Communities Act that offer 100 percent federal Medicaid matching rate to states for PDMPs that can integrate into prescribers' workflows and require electronic prescribing for Medicare Part D covered controlled substances.”

M. Why not include funding for the HIT Vendors as they are half the equation?

ONC DRAFT Strategy, Page 20, under Health IT and User Experience: “Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.”

N. The EHR Certification process can improve usability by becoming 'stratified'. Many of the items required for EHR Certification are not applicable to many specialists, while there are tools that are of value to specialists that are not required in the certification process. What about the ability to certify an EHR for Cardiologists, Orthopedic Surgeons, Physical Therapists, etc. These EHR systems would not be required to have the features that do not relate to the scope of practice of these individuals but would have tools that are of value and use to these individuals. This would go a long way to improving usability of EHR Systems for specialists and therefore reducing clinician burden for these providers.

ONC DRAFT Strategy, Page 23, 3rd Paragraph under Clinical Documentation: "...documentation for prior authorization of medications, items, and services..."

O. Another reference to prior authorization – see Comment J above.

ONC DRAFT Strategy, Page 25, 5th Paragraph: "Another source of burden and frustration related to the electronic documentation tools found in EHRs is the problem of over-standardization. In many cases, a "one size fits all" suite of documentation tools and templates is rolled out to clinical staff. In a larger institutional setting, the clinical staff, made up of a variety of medical specialties and sub-specialties, often run into problems trying to adapt these documentation workflows and templates to their unique clinical workflows. Smaller practices often struggle with a similar issue when a particular workflow that the practice normally follows must be adapted to fit existing over-standardized product functionality. For example, some practices cited this as a roadblock in trying to provide chronic care management services. Poor usability features within EHRs can further exacerbate this issue of documentation over-standardization, as clinicians find it difficult to navigate long records within the EHR interface."

P. This is another reason for 'specialty specific' certification of EHR Systems. In theory a single system could be certified for many specialties with a 'control panel' used to display the proper version/workflow for the specialist using the EHR.

ONC DRAFT Strategy, Page 27, 3rd Paragraph: "This administrative burden is exacerbated by a lack of standardization and effective technology solutions to automate these processes. Clinicians continue to rely on cumbersome processes to complete prior authorization requirements, including payer-specific web-based portals, facsimile exchange (fax), and telephone-based processes, which divert valuable time and resources away from direct patient care. Stakeholders have also raised concerns that these processes can interrupt or delay necessary treatment and can inadvertently lead to negative patient outcomes. A wide group of clinical stakeholders have identified this lack of automation as a key contributor to the burden associated with prior authorization, arguing that these processes should be standardized and made electronic throughout the industry to promote conformity and reduce administrative burdens."

Q. Well said – and a great place for the HL7 EHR WG to focus standards development for EHR system functionality.

ONC DRAFT Strategy, Page 37, 2nd Paragraph: "The eQMs that are currently available through HHS reporting programs are not universally relevant to all physicians, with many specialties underrepresented or not represented at all."

R. Yet another situation that can be alleviated by specialty certification with the certified EHR being integrated with a specialized registry that supports the specialty.

ONC DRAFT Strategy, Page 39, Last Paragraph: "In effect, this 'one size fits all' approach limits health IT innovation."

S. Another instance pointing towards specialized certification.

Another Perspective on Burden...

Key Point

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

Aims of the Strategy and the Problems Identified

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

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

The strategy admits at the outset that:

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

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

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

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

Interoperable EHRs are the wrong model

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

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

Damage limitation is not an answer

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

We need an infrastructure for individual care

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

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

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

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

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

Recommendation Summary	Comments
I1. Clinical Documentation	
I1.S1 Reduce regulatory burden around documentation requirements for patient visits.	
I1.S1.R1 Continue to reduce overall regulatory burden around documentation of patient encounters.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – 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.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – 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.	
<ul style="list-style-type: none"> + 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, health care providers, payers, EHR developers, standards developers” 	<ul style="list-style-type: none"> – Suggests directional intent but realization (of burden reduction) will occur at some point in the future
I1.S1.R4 Waive documentation requirements as may be necessary for purposes of testing or administering APMs.	
<ul style="list-style-type: none"> + Reduces clinician burden by waiving some CMS documentation requirements (e.g., medical review) for certain APM participants 	<ul style="list-style-type: none"> – Suggests directional intent but realization (of burden reduction) will occur at some point in the future – And only for those able to participate in APMs which are too cumbersome and expensive for smaller practices.

Recommendation Summary	Comments
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.	
<ul style="list-style-type: none"> + Reduces clinician burden by development of clinical documentation “best practices” + Establishes collaboration between HHS and clinical professional societies 	<ul style="list-style-type: none"> – Foresees endorsement and implementation of best documentation practices at some point in the future
I1.S2.R2 Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – 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.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – Describes a possible strategy that is likely to have little/no immediate impact on burden reduction – And 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.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – Likely to have little/no immediate impact on burden reduction – And will require a lot more than just "partnering."
I1.S3.R3 Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.	
<ul style="list-style-type: none"> + Reduces clinician burden by standardizing documentation and exchange “for ordering and prior authorization” 	<ul style="list-style-type: none"> – 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.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – Describes long term strategy that is likely to have little immediate impact on burden reduction

Recommendation Summary	Comments
I1.S3.R5 Coordinate efforts to advance new standard approaches supporting prior authorization.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – Awaits development, maturity and consensus adoption of new standards and protocols – Likely to have little/no immediate impact
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.	
<ul style="list-style-type: none"> + Reduces clinician burden by aligning EHR system design and configuration with individual clinician workflow + Suggests HIT developers work with clinical organizations 	<ul style="list-style-type: none"> – 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 are 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.	
<ul style="list-style-type: none"> + 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 + Suggests rapid incorporation of standards-based, computable, evidence-based care guidelines into clinical practice via interoperable CDS 	<ul style="list-style-type: none"> – 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, and many current guidelines are vague, or contradictory, or impose too much cognitive load to implement in the context of workflow
I2.S1.R3 Improve clinical documentation functionality.	

Recommendation Summary	Comments
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – 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
I2.S1.R4 Improve presentation of clinical data within EHRs.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – 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.	
<ul style="list-style-type: none"> + 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 + Suggests clinicians and clinical professional societies work with HIT developers 	<ul style="list-style-type: none"> – 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.
I2.S2.R2 Promote and improve user interface design standards specific to health care delivery.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – 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

Recommendation Summary	Comments
	most) clinicians' "thought processes in terms of complex pattern recognition."
I2.S2.R3 Improve internal consistency within health IT products.	
<ul style="list-style-type: none"> + Reduces clinician burden by ensuring “all aspects of the [HIT] system share a common user interface and style guide” 	<ul style="list-style-type: none"> - Encourages industry to act, but foresees no federal role - Should include SDOs - Again, this is contrary to EHR developers' underlying business model and will never happen voluntarily.
I2.S2.R4 Promote proper integration of the physical environment with EHR use.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> - 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.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> - 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.	
<ul style="list-style-type: none"> + 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), the American College of Pathology and the Regenstrief Institute (LOINC administrator) 	<ul style="list-style-type: none"> - Encourages industry to act, but foresees minimal federal role - Should include SNOMED International and other SDOs
I2.S3.R3 Standardize results display conventions within health IT.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> - 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.	

Recommendation Summary	Comments
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – 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.
12.S4.R2 Promote understanding of budget requirements for success.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – Encourages industry to act, but foresees minimal federal role
12.S4.R3 Optimize system log-on for end users to reduce burden.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – 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?
12.S4.R4 Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.	
<ul style="list-style-type: none"> + Reduces clinician burden by advancing interoperability to enable “secure exchange of electronic health information... without special effort of the part of the user” + 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” 	<ul style="list-style-type: none"> – 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 – See “Vital Data Qualities” table above
13. EHR Reporting	
13.S1 Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.	
13.S1.R1 Simplify the scoring model for the Promoting Interoperability performance category.	
<ul style="list-style-type: none"> + Reduces clinician burden by overhauling the scoring methodology for MIPS and the Promoting Interoperability Program for eligible hospitals and Critical Access Hospitals 	<ul style="list-style-type: none"> – Describes long term strategy that is likely to have little immediate impact on burden reduction – Should include SDOs

Recommendation Summary	Comments
<ul style="list-style-type: none"> + 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” 	
<p>13.S1.R2 Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.</p>	
<ul style="list-style-type: none"> + Reduces clinician burden by incentivizing and rewarding “innovative uses of health IT and advancements in interoperability that improve care for patients” 	<ul style="list-style-type: none"> – 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?
<p>13.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.</p>	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – Describes long term strategy that is likely to have little immediate impact on burden reduction – Should include SDOs
<p>13.S1.R4 To the extent permitted by law, continue to provide states with federal Medicaid funding for health IT systems and to promote interoperability among Medicaid health care providers.</p>	
<ul style="list-style-type: none"> + 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” + Suggests that “state Medicaid Enterprise systems should leverage or build upon existing federal investments including projects supported by Medicaid Promoting Interoperability Program funding” 	<ul style="list-style-type: none"> – Describes long term strategy that is likely to have little immediate impact on burden reduction
<p>13.S1.R5 Revise program feedback reports to better support clinician needs and improve care.</p>	
<ul style="list-style-type: none"> + Reduces clinician burden by revising feedback reports to capture more useful and impactful information, improve report formats, streamline submission and update processes 	<ul style="list-style-type: none"> – Describes long term strategy that may have little immediate impact on burden reduction
<p>13.S2 Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.</p>	
<p>13.S2.R1 Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting.</p>	
<ul style="list-style-type: none"> + Reduces clinician burden by improving data accuracy 	<ul style="list-style-type: none"> – Describes need to improve data integrity but fails to note its negative impact on

Recommendation Summary	Comments
	integrity of the clinical process and most importantly, its risk to patient safety – See “Vital Data Qualities” table above
13.S2.R2 Adopt additional data standards to makes access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals.	
<ul style="list-style-type: none"> + 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
13.S2.R3 Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products.	
<ul style="list-style-type: none"> + 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
13.S3 Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden	
13.S3.R1 Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures.	
<ul style="list-style-type: none"> + 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
13.S3.R2 Continue to evaluate the current landscape and future directions of electronic quality measurement and provide a roadmap toward increased electronic reporting through the eCQM Strategy Project.	
<ul style="list-style-type: none"> + 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)
13.S3.R3 Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.	

Recommendation Summary	Comments
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – Suggests directional intent but realization (of burden reduction) will likely occur at some point in the future
14. Public Health Reporting	
14.S1 Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow.	
14.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.	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – Suggests directional intent but realization (of burden reduction) will likely occur at some point in the future
14.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.	
<ul style="list-style-type: none"> + 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 facilitat[ing] the tracking of prescription fulfillment” + Suggests implementation of DEA-required “multifactor authentication [permitting] biometrics and modern approaches to authentication that can be more easily integrated into provider workflows” 	<ul style="list-style-type: none"> – Describes long term strategy that may have little immediate impact on burden reduction
14.S2 Inventory reporting requirements for federal health care and public health programs that rely on EHR data to reduce collection and reporting burden on clinicians. Focus on harmonizing requirements across federally funded programs that impact a critical mass of health care providers.	
14.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.	
<ul style="list-style-type: none"> + 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 	<ul style="list-style-type: none"> – Describes long term strategy that is likely to have little/no immediate impact on burden reduction – Should include SDOs

Recommendation Summary	Comments
<p>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.</p>	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – 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
<p>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.</p>	
<ul style="list-style-type: none"> + 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” 	<ul style="list-style-type: none"> – Describes long term strategy that is likely to have little/no immediate impact on burden reduction – Should include SDOs

Appendix A – “Reducing Clinician Burden” Topics, compiled by the HL7 EHR Work Group

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