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Don Rucker, MD

National Coordinator

Office of the National Coordinator for Health Information Technology (ONC)

Department of Health and Human Services (HHS)

Hubert Humphrey Building, Suite 729

200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:

<https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs>

Dear Dr. Rucker:

Health Level Seven (HL7®) International welcomes the opportunity to submit comments onthe draft *Strategy for Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (Strategy),* released as required by the *21st Century Cures Act* (P.L. 114-255). HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related interoperability standards, including the rapidly evolving Fast Healthcare Interoperability Resources (HL7® FHIR®), the Consolidated Clinical Document Architecture (C-CDA®), and the widely used V2 messaging standards. HL7 has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms. The products of our organization provide the underpinnings for connected, patient-centered health care and an information highway for precision medicine.

HL7 appreciates the efforts of both HHS and the ONC to identify and address electronic health record (EHR) and health information technology (Health IT) burdens that can hinder seamless and truly interoperable healthcare. We applaud and share ONC’s vision of clinicians’ use of the medical record as a tool to fulfill its original intention: supporting the best possible care for the patient, rather than as an encounter-based document to support billing. As the global authority on interoperability in healthcare, HL7 is available to help and stands ready to meaningfully support HHS in this initiative. HL7 strongly supports the three overarching Strategy goals designed to reduce clinician burden including to:

* Reduce the effort and time required to record health information in EHRs for clinicians;
* Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and
* Improve the functionality and intuitiveness (ease of use) of EHRs.

Indeed, HL7 and its Work Groups focus significant initiative on making EHRs and other health IT more efficient, effective, functional and intuitive. Our comments are organized into an overarching section and then, observations and recommendations in each of the four EHR-related burden issue areas:

(1) Clinical Documentation;

(2) Health IT Usability and the User Experience;

(3) EHR Reporting; and

(4) Public Health Reporting.

HL7 also applauds the emphasis on high-impact feasible strategies that are achievable within the near- to medium-term (a 3–5 year window) and able to be implemented through existing or easily expanded Department of Health and Human Services (HHS) authority.

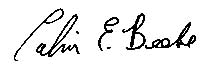
As a general point, although the draft Strategy did an excellent job of identifying areas of potential clinician burden and potential solutions, we urge HHS to focus its efforts on those areas where HHS program implementation itself causes a burden directly or indirectly (e.g., requirements for encounter documentation incentive program reporting, quality measurement, and preauthorization). HHS should leave to the private sector — including professional associations, provider organizations., standards developing organizations, requirements, and health IT developers — those areas, such as defining optimal workflows and usability approaches, that are best handled by these stakeholders, working collaboratively, outside of a government or regulatory context.

In submitting these comments, we want to recognize our HL7 Workgroups, which have substantial resources and whose ongoing work can inform this HHS strategy. Specific groups with recommendations included in these comments are:

* Clinical Decision Support;
* Clinical Quality Information; and
* Electronic Health Records.

HL7 is ready to further share our expertise by meeting and discussing our recommendations with HHS. Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at [cjaffe@HL7.org](mailto:cjaffe@HL7.org) or 734-677-7777. We look forward to continuing this discussion and offer our assistance to HHS and ONC.

Sincerely,

Charles Jaffe, MD, PhD Calvin Beebe

Chief Executive Officer Board of Directors, Chair

Health Level Seven International Health Level Seven International

# HL7 Responses to HHS Strategy and Recommendations

Below are HL7’s responses to the HHS Draft *Strategy for Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*, released as required by the 21st Century Cures Act (P.L. 114-255).

# HL7 Comments - General

**Proper Naming and Citation -** Throughout the Strategy document, there are multiple instances of acronyms introduced without definition. HL7 suggests that all acronyms be defined on first use.

**Additional Resources for Reducing Clinical Burden -** Since early 2018, the Health Level Seven (HL7) Electronic Health Record Work Group (EHR WG) has discussed reducing clinician burdens. These discussions have identified clinician burden topics compiled from various sources, including trade publications, professional society journals, articles, studies and personal experience. See Appendix A for the list of burden topics identified by the EHR WG. These topics, many of which are addressed in and appropriate for an HHS strategy, may be helpful to HHS in further contextualizing burden reduction.

**Coordinated Action Statement on Page 4** **-** “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.”

**Comment:** We encourage HHS to be broadly inclusive in its outreach, beyond the minimum defined in the 21st Century Cures Act. These stakeholders above are important but implementation of this statutory list, which should be viewed as a floor, should also include accreditation bodies (of healthcare organizations), EHR/HIT standards development organizations (SDOs), public health agencies, pharmaceutical companies and medical device manufacturers.

**HHS Burden Reduction Steps on Page 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.”

**Comment:** 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 and encourage HHS to do so.

**Clinical Note for Billing and Quality Reporting Purposes Statement on Page 6 -** “We see a future where those best suited to define the required content of a clinical note for billing and 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.”

**Comments:**

* + 1. HL7, Health Service Platform Consortium (HSPC) and professional societies have coalesced into the Clinical Information Interoperability Council (CIIC) (to address these issues and evolve standards and clinical workflow in the direction suggested by the report.
    2. The HL7 Fast Health Interoperability Resources (FHIR®) standard is developed and available specifically to address capturing and retrieving data in a consistent manner, in concert with data currently available in clinical information systems. Further, FHIR specifies methods for standard expression of information to establish re-usable queries for existing data to evaluate processes and outcomes (e.g., FHIR Clinical Reasoning, Clinical Quality Language) and for enabling local asynchronous and synchronous interventions with clinical decision support (e.g., CDS Hooks). HL7 recommends that HHS seriously consider such standard capabilities for use across all requests for data and reporting, referencing existing data stored within the clinical software, including, but not limited to:
       1. Prior authorization;
       2. Evaluation and Management activity determination;
       3. Quality reporting;
       4. Public health reporting;
       5. Syndromic surveillance; and
       6. Registry reporting.
    3. HHS should encourage EHRs and other clinical software, including APIs, to address documentation using standard terminology (which may be mapped to local interface terminology to enhance usability). Such terminology standardization is required to improve semantic interoperability and data re-use without requiring additional documentation based on each quality, public health or registry use case.
    4. HHS should coordinate consensus and publish best practices regarding management of common elements needed for all reporting and clinical decision support (CDS) use cases. This requirement is separate and distinct from data reconciliation efforts required in past efforts. Such common elements include:
       1. Problem Lists (i.e., how can they best be formatted and used for usability and to improve CDS and clinical workflow?);
       2. Allergy and Adverse Event documentation;
       3. Medication lists (including immunizations); and
       4. Special cases for highly clinically relevant patient risks including active pregnancy status, travel and exposure risks, and other concepts not currently managed consistently, if at all.
    5. Finally, we recommend that a request intended to validate information should be used only when the additional information has specific value to enhance the clinician’s workflow and address patient safety and outcomes.

# HL7 Comments – Clinical Documentation

**CLINICAL DOCUMENTATION**

*Strategy 1: Reduce regulatory burden around documentation requirements for patient visits.*

*Recommendation 3: Obtain ongoing stakeholder input about updates to documentation requirements.*

### *HHS states:* *As part of the effort to revise the documentation guidelines, HHS should continue to receive wide stakeholder input that includes key participants (e.g., government, industry, heath care providers, payers, EHR developers, standards developers) to inform future documentation guideline modifications. Stakeholders have suggested that a representative task force would be useful, given the widespread uses of medical record information by clinicians of all specialties, public and private payers, EHR vendors, and others. Clinical specialty societies could continue to provide input to define proper clinical standards for documentation and establish what is required for high quality patient care. Payers could continue to provide input about the information necessary for claims payment. Health IT developers could continue to advise the agency about what technology solutions would best support the agreed-upon guideline revisions.*

**Comment:** Wenote that the result of this recommendation, given the rationale in the body of the Strategy, may, in fact, be the opposite of what is intended here. Unless conducted with great care, solicitation of documentation guideline modifications could end up introducing additional documentation burden. If services that inject functionality into the clinical workflow do so by just requiring or presenting additional narrative documentation, that will increase provider burden. Context-based API integration standards (such as CDS Hooks) should be used carefully and should only be an interrupter for clinically appropriate and streamlined content. The use of this technology means that CDS Service developers share in the responsibility for providing good provider user experience. Fundamentally, payment drivers should not interrupt clinical workflow.

# HL7 Comments – Health IT Usability and the User Experience

**HEALTH IT USABILITY AND THE USER EXPERIENCE**

*Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.*

*Recommendation 2: Standardize order entry content within health IT.*

*HHS states: Order entry for laboratory orders, imaging orders, and procedure orders can be burdensome for end users due to the number of test options available. Frequently, differences in selectable orders are represented by variances of only several characters. EHR developers have the opportunity to collaborate with each other and relevant stakeholders to refine descriptions for unique imaging tests that are clear, concise, and reduce confusion. Similarly, laboratory orders also contain potentially confusing options. Organizations such as the CMS Division of Laboratory Improvement and Quality (which regulates CLIA), the American College of Pathology, the Regenstrief Institute (which administers the Logical Observation Identifiers Names and Codes (LOINC) code set), and commercial laboratory corporations can refine test codes and names that are clear, concise, and reduce burden. To increasing the clarity of test options, developers and their collaborators can further improve this functionality by improving default listings of common tests and “favorites” capabilities so that the end result also shortens the available list to reduce end user cognitive load. Health care institutions can refer to ONC’s SAFER Guide: Computer Provider Order Entry with Decision Support to further help optimize systems in this area and reduce clinician burden.*

**Comment:** Relevant SDOs should be meaningfully included in efforts to harmonize clinical content.

# HL7 Comments – EHR Reporting

**EHR REPORTING**

*Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.*

*Recommendation 1: Recognize industry-approved best practices for data mapping to improve data accuracy and reduce administrative and financial burdens associated with health IT reporting.*

*HHS states: Physicians and hospitals have consistently noted data and reporting accuracy issues related to the methods by which data is mapped within health IT, and how measure calculations are incorporated into certified health IT products. Mistakes in data mapping, and poor data integrity overall, not only necessitate added costs for health care providers but may result in adverse payment adjustments through a variety of reporting programs. ONC should coordinate stakeholders focused on best practices for data mapping and data integrity and include industry-approved mappings as part of the Interoperability Standards Advisory, that all stakeholders, including certified health IT developers, could then use.*

**Comment:** Clarification is needed here. Although there are standardized mappings and rules about terminology, local variability remains a problem with the proposed approach. HL7 asks if this recommendation suggests that an EHR vendor would be expected to release standardized mappings? It is not clear that this recommendation will fully address the stated mapping-related problem, because there is inherent complexity due to natural variability across systems. HHS should expect that improvements resulting from this recommendation will be incremental and achieved in the longer term. We note that this is an area that active exploration into the use of machine learning and natural language processing (NLP) techniques has potential, but caution that these tools will require long-term investigation and development, and are certainly not a “silver bullet”.

**EHR REPORTING**

*Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.*

*Recommendation 2: Adopt additional data standards to make 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 physician and hospitals.*

*HHS states: Physicians and hospitals routinely cite access to data, both within their own health IT systems and across*

*health IT and other electronic platforms, as a significant challenge not only for participating in and*

*reporting to quality programs, but also in repurposing the data for multiple uses. Difficultly in accessing*

*data hampers numerous industry-wide efforts related to quality improvement, patient access to personal*

*health information, and reduction in health care costs. While the introduction of API technology*

*certification criteria as part of ONC’s 2015 Edition Health IT Certification Criteria is poised to make it easier*

*for physicians and hospitals to access and integrate certain data, the continued standardization of*

*electronic data and health IT functionality is also needed. For example, the use of the Health Level Seven*

*(HL7®) Fast Health care Interoperability Resources (FHIR®) standard could 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. FHIR could also potentially support*

*data segmentation for privacy in health information exchange and recently released mobile solutions,*

*which can integrate clinical data with a patient’s personal health tracking applications on their mobile*

*device. Further, HL7 is currently working on an update to the FHIR standard to support API access to*

*request data on populations of patients, which could potentially address additional use cases, including*

*supporting payer needs, public health and quality improvement efforts, and health research*

*organizations. The adoption of FHIR-based APIs, especially for population-level data exchange, has the*

*potential to reduce clinician burden and overall cost to clinicians. Similarly, ONC recently proposed the*

*Draft US Core Data for Interoperability (USCDI), which aims to specify a common set of data classes*

*required for interoperable exchange and identify a predictable, transparent, and collaborative process for*

*expanding the USCDI’s scope. The data referenced in the USCDI is currently proposed for use within the*

*Trusted Exchange Framework; however, ONC should explore the potential for use of the USCDI beyond*

*the Trusted Exchange Framework in order to expand the availability of predictable, transparent, and*

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

*collaborative processes that promote interoperable data exchange while also relieving physician and hospital burden related to health IT use.*

**Comment:**  HL7 supports and applauds Recommendation 2. HL7 FHIR, and other HL7 standards, can make it easier to interoperate consistently at a data element level. The broad stakeholder involvement in HL7’s standardization initiatives, including development and maintenance of implementation guidance, is a good example of private sector collaboration. Further development of these implementation guides will be a cornerstone of real world implementation, and an important venue for cooperation across all relevant stakeholder interest perspectives.

**EHR REPORTING**

*Strategy 3: Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden*

*Recommendation 1: Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures.*

***HHS states:*** *Many physicians and hospitals note that the measurement and reporting of completely new eCQMs poses significant burdens for clinicians and organizations. Often the timelines on which clinicians are expected to update health IT systems and adopt new eCQMs pose data mapping, financial, and workflow training challenges that result in poor performance and increased costs. HHS should reevaluate its approach to the adoption of new eCQMs to reduce these burdens. For example, HHS could introduce a “test year” into programs for new eCQMs wherein reporting on these eCQMs is optional, with program incentives made available to encourage physicians and hospitals. This would encourage provider participation in eCQM testing. HHS could use this measure data to refine new eCQMs as needed, but not as part of public reporting or performance evaluation.*

**Comment:** HL7 supports appropriate testing for implementation of new eCQMs using HL7 standards, consistent with testing all standards. Such testing should allow implementers to receive credit for participation in testing and reporting output without addressing performance rates. Only after such tested eCQMs are shown to capture and evaluate information reliably and consistently, should performance reporting using these measures be implemented.

**EHR REPORTING**

*Strategy 3: Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden*

*Recommendation 2: 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.*

***HHS states:*** *Ideally, the electronic measurement and reporting of quality performance data should result in less time and money invested by clinicians than the use and reporting of traditional chart-abstracted measures. However, there are a number of challenges to making a full transition to health IT use for quality measurement. Similar to its approach with the Promoting Interoperability performance category of MIPS and the Promoting Interoperability Program for hospitals, formerly known as the Hospital EHR Incentive Program, HHS should, after consultation with stakeholders, both revise existing eCQMs and develop new eCQMs that will allow physicians and hospitals to increasingly transition to electronic measurement and reporting. The beginning of this effort is underway through CMS’s eCQM Strategy Project. After evaluating current state processes of eCQM development and soliciting public feedback to make future state recommendations, CMS is currently implementing project recommendations 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, with an emphasis on ensuring that electronic data collection for quality measures does not contribute extra or unnecessary steps to the use of health IT in patient care. CMS and ONC should also work together to refine and develop eCQMs so that quality measurement aligns with clinical workflow, with an emphasis on ensuring that electronic data collection for quality measures does not contribute extra or unnecessary steps to the use of health IT in patient care.*

**Comment:** We strongly support the goals and objectives of the CMS eCQM Strategy Project.

**EHR REPORTING**

*Strategy 3: Improving the value and usability of electronic clinical quality measures while decreasing health care provide burden*

*Recommendation 3: Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.*

### *HHS states:* *Developing eCQMs that align with clinical workflow and do not contribute extra or unnecessary steps to the use of health IT in patient care can make a major impact on the burden associated with electronic quality measurement. However, there may be other approaches to electronic quality measurement that are even more efficient and less burdensome than our current approach to quality measurement. One example is data element reporting in which health care providers would submit specified indicators instead of pre-defined eCQMs. Alternatively, mining health IT databases for clinician performance trends could yield more robust and detailed quality measurement and improvement strategies while simultaneously eliminating much of the physician burden associated with current quality measurement and reporting programs. Similarly, artificial intelligence and machine learning present opportunities to assess quality performance and improvement in wholly new ways that can yield more detailed feedback. HHS should explore the feasibility of programs that can help develop and evaluate future approaches to quality measurement that will be less burdensome, more accurate, and more impactful in assessing the quality of care provided to patients.*

**Comment:** We support exploring alternative mechanisms for measurement, however, the expressed approach has potential challenges. For example, data points used out of context may be misinterpreted and sufficient metadata and provenance will be required to effectively use data to evaluate outcomes. Alignment with other approaches (such as registries) is important to avoid overburdening providers. Existing eCQM implementation by EHRs and other patient care systems includes understanding the concepts used by their respective systems to carefully align with the information requested by the eCQM. Aligning with data-specific information requests may cause provider burden to persist rather than be reduced.

# HL7 Comments – Public Health Reporting

**PUBLIC HEALTH REPORTING**

*Strategy 1: 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.*

*Recommendation 1: 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.*

### *HHS states:* *Accessing prescription histories from PDMP is typically poorly integrated into the routine workflow of patient care or even electronic prescribing. Federal agencies supporting PDMPs have not consistently recommended or required the same standards for PDMP-EHR integration. The Department of Justice has funded state public safety departments to establish PDMPs which historically have used the National Information Exchange Model (NEIM) standard. HHS agencies and state health departments commonly recognize standards developed by NCPDP that also support e-prescribing transactions. Federal funding agencies should coordinate a shared strategy for all PDMPs to adopt common standards over time to support PDMP and health IT integration. The SUPPORT for Patients and Communities Act now allows states to receive 100 percent Federal Medicaid matching funds in 2019-2020 for qualified PDMPs that integrate into a provider’s workflow and their health IT application for EPCS.*

**Comment:** ONC should attempt to align requirements across states, which will enhance integration with EHRs and data flow across states. HL7 standards such as CDS Hooks and Pharmacy standards can enable and improve EHR integration and data flows. This recommendation is broader than just for PDMPs. When requirements and measures are used across state boundaries, lack of requirements and standards alignment significantly increases burden. Integrating PDMP data into the EHR should occur through open standards at reasonable cost, with national level requirements if possible given variability in state approaches to such integration. Moreover, HHS should seek to open up the mechanism for accessing PDMP data by EHRs and other health IT as many states mandate that PDMP data is only available through specific channels.

**Appendix A – Burden reduction topics compiled by the HL7 EHR Work Group**

1) General Considerations

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