ONC Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs – DRAFT FOR PUBLIC COMMENT as required by the 21st Century Cures Act (Public Law 114-255, Section 4001)
Comments from Intelligent Medical Objects (IMO)

Contents

IMO Reviewers

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General Impression

The ONC Strategy document is a good start in addressing the regulatory and administrative burden issues. IMO realizes the outcome of this work is intended to provide guidelines in upcoming rulemaking and acts, rather than statements to be enacted as written. However, IMO is concerned that the 3 focus areas: clinical documentation, health IT usability and reporting make the recommendations seem siloed.

IMO recommends that the document contain a high-level preamble about collecting data once and reusing it multiple times. The fact that there are separate needs to collect information clinically, financially and from a quality/public health perspective means that there is inherent redundancy. The user should be collecting the most accurate data possible in the easiest and most intuitive way, and the data should be reused/transformed to serve other purposes. It is imperative that readers of the final strategy document clearly understand that these three areas intersect, and the intersections and underlying structures must be standardized and leveraged to support each focus area to reduce burden.

Clinical Documentation

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

Recommendation 1 Continue to reduce overall regulatory burden around documentation of patient encounters.

Original Text: CMS also finalized a series of add-on codes that will be used instead of multiple code levels to distinguish different kinds and lengths of E/M visits within these levels. These changes could ultimately result in a significant reduction in EHR-related burden, and HHS recommends other payers consider adopting a similar approach.

Comment: Traditionally, evaluation and management (E/M) codes and guidelines to distinguish physician work efforts and patient complexity have been debated by physician groups. Even when attempting to revise the documentation guidelines agreement could not be reached, which is why there are two sets of guidelines. The E/M documentation guidelines in some areas are very objective while other areas are subjective. This leads to audit concerns as payments are tied to each level. We agree revising the E/M codes and subsequent documentation to remove subjectivity and criteria which foster unnecessary documentation should have an impact on reducing the clinician burden. IMO recommends CMS provide a 'train-the-trainer' type of environment for the changes for providers, HIM professionals, and payers so all can have the same message of what is essential to meet the new requirements, especially as the clinical documentation of the patient's visit supports other industry activities beyond E/M code assignment.

Recommendation 2: Leverage data already present in the EHR to reduce re-documentation in the clinical note.

Original Text: As a result, many pieces of information that clinicians enter into their clinical notes already exist in other places in the EHR. (and) As technology tools advance, modern computing resources and design space could allow developers to innovate new ways to determine visit complexity beyond what is present in the clinical note.

Comment: IMO concurs, for example, queries or algorithms can derive the reason why aspects of care were not done in CQM reporting rather than requiring clinician interruption. However, it is the

implementation where one must balance all aspects of documentation. Coding professionals are not able to 'derive' diagnoses for each encounter. Having the information documented, or accurately pulled into, the clinical note clearly in the current encounter with intuitive but explicit terminology is important for understanding what was done or thought about during the current encounter.

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

1) 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.

2) 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:

1) Documentation guidelines vary across health care settings for valid of reasons. Provider documentation is used in the industry for a variety of downstream purposes leading to variations in documentation practices. Payment rules are one cause, along with third party industry accreditations and participations. For example, documentation to demonstrate Joint Commission compliance for acute care facilities varies from documentation required for Medicaid compliance for skilled nursing facilities. Further description is needed on what aspects of documentation guidelines are important along with consideration of how those documentation guidelines intersect. Requirements should be harmonized where possible. There are efforts internationally to support harmonization of documentation and reporting requirements between funders/national governments, etc. in other contexts that could foster similar efforts in the US. IMO recommends the international efforts are explored when obtaining input on documentation requirements. (Also, note the typo in yellow)

2) Current technology implementations that provide documentation guidelines using CDS Hooks interrupt clinician care with pdfs containing documentation requirements. This is an example of where technical implementation of documentation guideline assistance has resulted in increased burden. APIs and CDS should be context-specific and only interrupt when appropriate, supported with actionable technology. Recommendations such as this must be carefully worded to encourage astute implementation of requirements that come from such collaborations.

Strategy 2: Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements.

Recommendation 1: Partner with clinical stakeholders to promote clinical documentation best practices.
Original Text: HHS, in partnership with clinical professional societies, will continue to work to promote an understanding of documentation best practices among members, recognize and potentially endorse best practice industry initiative

Comment: The partnerships should extend beyond clinical professional societies and include professional societies such as American Medical Informatics Association (AMIA) and American Health Information Association (AHIMA).

Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.

Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.

Original Text: (1) developing and disseminating best practices for optimizing electronic workflows around prior authorization; and (2) health IT-enabled processes that leverage existing data within the record to reduce the total volume of prior authorization requests that clinicians must submit. These efforts should also consider how making transparent the clinical and coverage guidelines used by payers during the review of a prior authorization request can help to reduce provider burden.

Comment: IMO is aware of the efforts of the Da Vinci project to develop FHIR standards requests and responses that hope to provide solutions for these prior authorization issues. However, standards and the free market of insurance providers are only pieces to and overall solution. Insurance companies, government, standards developers, implementers and clinicians must collaborate from ideation through implementation and debriefing. The outcome of debriefing must lead to agile change as needed. Standards and technology specification are just the beginning. The many existing text/pdf guidelines will need to be "retooled" to use those standards just as the CQMs had to be retooled into eCQMs.

Without these efforts, the opposite impact may increase the burden. For example, providers dealing with individuals with multiple insurance where conflicting rules may exist will be presented with conflicting messages or workflows. Coverage rule CDS will need to be context aware, conflict aware, specific and succinct.

Recommendation 2: 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.

Original Text: While health IT solutions can help to automate these processes, they remain underutilized, in part due to lack of an adopted health care standard for claims attachments.

Comment: 1) Is this referring to an existing standard that is not being adopted or is it suggesting the need for a standard? 2) Existing EHR (and non EHR data) will need to be leveraged. 3) What will be the incentives for non-EHR based services and suppliers to adopt standards?

Health IT Usability and the User Experience

Strategy 1: Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools.

Recommendation 1: Better align EHR system design with real-world clinical workflow.

Original Text: Health IT developers can take the lead by working with practicing clinicians, nurses, laboratorians, administrators, and professional organizations, who can advise developers as they make decisions and prioritize interactive display features during the development stage that will help

streamline workflow. Experts in user-centered design (sometimes referred to as human factor engineering, or HFE) and in human-computer interaction should also be consulted during development, since they understand the processes and challenges of creating usable products, can help developers better support the clinical workflow, and reduce cognitive load on the end user. A priority for workflow optimization should be the reduction of required clicks to complete necessary actions

Comment: IMO recommends a discussion on how prioritizing interactive displays and reducing clicks will be mandated or incentivized in future rules. Potentially, HL7 EHR Functional Models or new supplemental model could provide a standardization forum. Strategies elsewhere defined in the draft (e.g. billing/coding changes, reporting changes) as well as implementation of FHIR Apps and services, and clinical decision support (CDS) Rules, are likely to compete with improving UI design, continuing clinical end user dissatisfaction.

We encourage experts in User Centered Design (UCD) and Human Factor Engineers (HFE) take the lead in working with clinicians, as opposed to Health IT Developers, as suggested in the draft. UCD and HFE are distinct disciplines and have unique principles vital to the user experience. Resource constraints, especially around level of effort, may compromise developers' ability to effectively drive internal requirements to optimize clinical workflows. UCD and HFE professionals, after working with clinicians, can drive requirements to the intended definition of done.

We concur that achieving a balance between standardization and customization is important.   UCD and HFE professionals may be the best to deal with the resistance to change potentially known as "my way is the only way" problem. These professionals are trained to suggest even better workflows, which may evolve to an ideal workflow.

Recommendation 2: Improve clinical decision support usability
Original Text: This opportunity includes CDS for both clinicians and patients. To reach these goals, a robust CDS framework must be implemented.

Comment: Maintenance is a key factor here to ensure the CDS system remains up to date. This includes everything from terminology maintenance used in CDS rules, to changes in underlying architecture, as well as changes in clinical knowledge. Open sharing of standardized CDS Rules within and between vendors should be incentivized.

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.
Original Text: 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: Mapping creates a relationship between two systems which should be based upon industry-standard mapping principles. Even though the principles are standard, actual maps are varied and use-case dependent. The same two systems will generate different maps based upon the use-case along with the starting and ending point of the map. While the industry has produced some standard maps and rules about their use, local variability occurs due to individual provider needs when mapping local dictionaries to standard clinical terms.

While IMO supports appropriate data mapping and overall high data integrity, clarification on 'industry-approved mappings' is necessary. Maintenance and updates to maps is key to maintain the maps integrity as terminology and code systems routinely change. The clarification on 'industry-approved mappings' should include a maintenance process to ensure accurate and up to date maps.

NLP, machine learning and automatic extraction and code tagging of initially unstructured data from clinical notes should be encouraged. Another valuable step would be to include user entered (selected) terms in EHR Reporting and other clinical data exchanges to aid in validation of mappings.

Recommendation 2: 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.
Original Text: … 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®)…

Comment: IMO applauds the insightfulness and awareness identified in this paragraph of the standards work and potential application of them improve to EHR (quality) reporting workflow and value. However, there is also potential to examine the data element requirements and logic present in many eCQMs, particularly the ones that were "re-tooled" from pdf's into eCQMs to ***adjust the expected numerator metrics*** to avoid interruption in clinical care and collection of valueless data. For example, when "reasons for not doing (something)" are required, it interrupts and adds burden to the provider. The list of allowed answers (value set) may contain a few useful answers for quality data recipients, but in most cases, clinicians will use the most generic reason available, such as "Medical Reason".

Public Health Reporting

Strategy 2: 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.

Original Text: 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: Please clarify how federal funding will standardize state variations in rules and regulations in regard to accessing PDMP data. Integrating PDMP data into EHRs should be made mandatory across all states. The mechanism for accessing the PDMP data should be opened and accessible with the same standardized queries and services. Many states mandate that that data is only available through specific channels. This restriction will impede the flow of critical information needed to help combat the epidemic.

Strategy 2: 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.

Recommendation 2: 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.

Original Text: Based on an understanding of all EHR-related data requirements across federally funded public health and health care programs that impact most health care providers, HHS can examine and harmonize common data elements and transport standards across reporting requirements. Agencies should then adopt a common standards-based approach to reporting EHR-captured data as a part of their modernization of reporting systems across relevant government programs.

Comment: Harmonizing and re-use of data are key. Federally funded state program variations in requirements should be examined for clinical validity of the variations. IMO recommends discussions should occur with State funded program officials where the programs are causes of redundancies to see if voluntary harmonization could occur. Standards-based Templates or profiles defined for reporting need to be specific, and as locked down as possible while harmonized. Reporting program requirements that vary by state despite harmonization should require state level implementation guides that further

specify, but do not conflict with the harmonized "national" profiles or templates and provide narrative guidance to clarify conformance variability.

Recommendation 3: 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.

Current Text: HHS should provide additional guidance about the federal confidentiality of alcohol and drug abuse patient records regulation (42 CFR Part 2),131 which requires the protection of the confidentiality of certain SUD-related information, and the privacy requirements of the HIPAA Privacy and Security Rules,132which governs privacy and security of patient health information maintained by or for most providers, and applicable state law requirements

Comment: Facilitating access to SUD data is crucial to combatting the Opioid (and meth) epidemic. Providing support for behavioral and mental health treatment that is federally subsidized is key to our country's health. For this to work there must be legislation to prevent untoward effects from insurance companies declining coverage and private industry employee impacts.

Technical Notes:

- Please review the document for typos
- Please review the documents for first use of acronyms that to not also spell out the term.
- Please consider adding an acronym table in an appendix
- Footnote reference links take you only to the page (in the Notes chapter) where the reference is, as opposed to directly to that numbered reference.
- Footnote Reference #43: We believe you intended to reference the CCD contained in the current version of C-CDA. You are currently referencing C-CDA R1.1 and should reference C-CDAR2.1. Here is the current link: *HL7 CDA® R2.1 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm (C-CDA)*
  http://www.hl7.org/implement/standards/product_brief.cfm?product_id=492