January 28, 2019

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

Drs. Goodrich and Gettinger:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the Department of Health and Human Services' "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs."

AMIA is the multidisciplinary professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who collect, analyze, and apply data systematically to transform health and healthcare. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in the development of evidence-based public policy through evaluation of informatics interventions and innovations across settings and patient populations.

AMIA strongly supports this HHS Strategy and we commend CMS and ONC for its diligent work in articulating an inclusive assessment of health IT-related regulatory and administrative burden. As early as 2012, AMIA called for a national strategy to "review and amend public policies to better support technology-enabled data capture and documentation practices."[1] We noted that the core purpose of documentation should be to support patient care and improved outcomes for individuals and populations, and that documentation for other purposes should be generated as a byproduct of care delivery. We are encouraged by National Coordinator Rucker's introductory message echoing this vision.

Given the adoption trajectory and the ongoing evolution in the design of EHRs, we recommend this final HHS-wide Strategy be oriented towards a long-term goal of decoupling clinical documentation from billing, regulatory, and administrative compliance requirements. We have a tremendous opportunity to leverage informatics tools and methodologies to decouple clinical documentation from billing and better integrate regulatory compliance

[1] Cusack CM, Hripcsak G, Bloomrosen M, The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. *J Am Med Inform Assoc. 2013 Jan 1;20(1):134-40. doi: 10.1136/amiajnl-2012-001093.*

requirements so that clinical decision support (CDS) and quality/performance reporting are better positioned to improve care for patients and reduce burden for clinicians. Numerous informatics tools and methodologies are being leveraged to more easily capture clinical data and represent intensifying quantities of data at the point-of-care. Natural language processing, remote sensing, video capture, and data mining are improving, yet these improvements only impact administrative burdens of EHRs at the margins.

As we look to reduce IT-related burden, we must look to root causes. Administrative and regulatory burdens have expanded steadily over more than 30 years. As we transitioned from paper records to digital data, we did not reevaluate these paradigms. The implementation of health IT simply replicated our paper processes and has magnified and modified pre-existing burdens and challenges. While the Promoting Interoperability Program and Merit-based Incentive Payment System are visible sources of health IT-related burden, there are many different sources of burden related to the use of health IT and EHRs. Notably, these include regulatory and administrative requirements that originate from public and private payers, various HHS programs, and assorted accreditation bodies.

The core challenge and dominant threat to this Strategy is that most EHRs are designed to support transaction-based, fee-for-service (FFS) billing requirements and business processes for regulatory/administrative compliance, rather than reflect clinical observation and treatment. Constraining our scope to what is within purview for HHS, we note that documentation challenges go far beyond patient visits and Evaluation and Management (E/M) documentation guidelines. The design of EHRs – and the workflows such EHR designs compel – can be traced to a multiplicity of regulations and programs that are both deep-seated and arcane, such as Medicare Conditions of Participation, the Medicare Claims Processing Manual, and the Office of Inspector General (OIG) Work Plan. For example:

- Conditions of Participation impact clinical workflows and processes heavily, which in turn greatly influence EHR design and configuration decisions. For example, Section §482.43, Discharge Planning[2] describes a multi-step process for hospital discharge planning, which includes a CMS Hospital Discharge Planning Worksheet[3] containing more than fifty (50) discreet documentation requirements to be compliant with §482.43. Each element requires the hospital to develop clinician processes, policies, and procedures to be collected and EHRs are relied upon to develop solutions capable of compiling forms, such as the Hospital Discharge Appeal Notices[4] or the ability to obtain electronic signatures on these CMS forms and documents; e.g., "Important Message from Medicare," "Detailed Notice of Discharge," Advanced Beneficiary Notice of Non-Coverage," "Hospital Issued Notices of Non-Coverage," and many others.

[2] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-32.pdf
[3] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-3.pdf
[4] https://www.cms.gov/medicare/medicare-general-information/bni/hospitaldischargeappealnotices.html

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- The OIG Work Plan identifies areas of concern to the OIG and sets priorities for the sequencing and proportion of resources to be allocated. Rightly, hospitals, physicians, and other clinicians must be responsive to these concerns and plan accordingly. The November 2018 OIG Work Plan describes a forthcoming focus on adverse events in hospitals affecting Medicare Beneficiaries (Report No. OEI-06-18-00400). In response to this specific Work Plan, hospitals and their clinical and administrative staff must develop definitions of serious reportable events and hospital acquired conditions; design methods for identifying events and determining preventability; and create methodologies for maintaining and reporting statistics and outcomes. Clinician review processes for determining preventability must be designed, tested, then implemented into the EHR; education must be provided to all providers concerning the processes and expectations; and analysts must be prepared to provide cogent reports that are submitted to committees for review, provide recommendations, then implement corrective action strategies. This is one example from the OIG November 2018 Workplan, and there are an approximate 400 more equally complex activities described by the OIG.

Layered upon these workflows are functional requirements compelled by programs, such as the Promoting Interoperability Program and Merit-based Incentive Payment System. These and other HHS programs do not depend on data that reflects the patient's clinical story. Instead, these programs compel different workflows designed to collect relevant data elements for specific functions like clinical decision support, performance measurement, and quality reporting.

While we do not suggest that these activities or administrative concerns are uniformly inappropriate, these examples (described in more detail in Appendix A) highlight the enormous complexity of documentation demanded of clinicians at the point-of-care and related to patient visits. Health informatics, health information management, and health IT professionals need to be engaged in the design, development, and implementation of CMS requirements as well as the workflows those requirements compel. Otherwise, front-line clinicians become over-burdened and are forced to rely on poorly designed and inefficient EHRs.

To make meaningful progress on regulatory and administrative burdens, both HHS and regulated industry (developers, providers, and payers) must agree to decouple clinical documentation from billing, administrative, and regulatory requirements with the expectation that documentation is used downstream for clinical decision support and quality/performance reporting as a biproduct of care delivery. If we are prepared to migrate from our paper-based paradigm where clinicians are expected to check boxes and move into a digital paradigm where clinicians are free to treat patients (and are not subject to being "trained" how to document by billing experts), then we can markedly reduce clinical burden.

Below, we offer observations and recommendations across the Strategy's four areas, commenting on how to supplement and prioritize the Strategy's numerous Recommendations. We also provide

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comment to each of the Strategy's recommendations as an attachment to this transmittal letter in Table 1.

Clinical Documentation

We recommend that efforts to improve clinical documentation should not focus on reduced documentation per se. Rather, we reiterate that burden reduction and increased value come from refocused and clinically purposeful documentation. A parallel goal should be to decouple documentation for clinical care and documentation for billing. In our 2012 report, AMIA developed seven guiding principles for computer-based documentation, which bear repeating:

1. Be clinically relevant and patient-centric
2. Work within EHRs that contain other patient data
3. Be efficient and usable; support capture of high-quality information
4. Enhance efficiency, effectiveness and productivity
5. Support downstream uses without additional effort on the part of the author
6. Enable decision-making, collaboration, care process management, and clinical decision support
7. Leverage multiple sources of data, e.g., other systems and devices

The goals outlined in the Clinical Documentation section of the Strategy are laudable – especially those focused on reducing documentation for patient visits and standardizing data / processes for ordering services and prior authorization. **However, we recommend that CMS chart a course towards more dramatic E/M documentation guidelines reform – or abandon the methodology altogether.** Generally, clinicians agree that E/M based documentation does a poor job of capturing the complexity of the patient's clinical status, the relevant clinical decision making, and the sizeable administrative demands related to patient care. In addition, a great deal of superfluous and duplicative information is recorded in the chart as a defensive strategy to assure compliance with E/M coding requirements. Much of this documentation is not only unnecessary, but it also makes it more difficult for clinicians to find and absorb the important elements of the documentation. Evidence that this is due to billing requirements is that EHR documentation by US physicians is much greater than in other industrialized countries where billing does not depend on similar E&M documentation requirements.[5] Greater reform or development of a new approach should be the central workstream towards decoupling clinical documentation from billing requirements.

AMIA recommends CMS convene specialty societies to develop documentation guidelines and that these organizations work with informatics and health IT professionals. These groups are well positioned to identify what aspects of their patients' records should be structured, what should be narrative, and how the corresponding documentation should be gathered /

[5] Downing, et al. Physician Burnout in the Electronic Health Record Era: Are We Ignoring the Real Cause? *Ann Intern Med.* 2018;169(1):50-51.**DOI:** 10.7326/M18-0139)

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transmitted. Indeed, many specialty societies have developed their own resources providing documentation guidelines to their members.[6,7,8,9,10,11] In turn, clinical informatics and health IT professionals should provide expertise on how to develop such strategies within an electronic / digital environment. While we expect a variance among specialties to produce documentation guidelines, CMS should consider ways to encourage such work and collaboration. Additionally, CMS should develop a standard format for publishing these guidelines and there should be a central repository to make it easy for providers and EHR vendors to keep their documentation compliant with the guidelines

AMIA emphasizes the achievable goal of decoupling clinical documentation from billing, regulatory, and administrative compliance requirements by creating an authoritative body from professional and specialty societies to: (1) assess clinical documentation requirements; (2) evaluate technological capabilities available today to extract then report data; and (3) define a financial mechanism to remunerate clinicians, hospitals, and healthcare systems for their work. This work will be challenging, but informatics-enabled clinical documentation practices must include guidance and policies on how to capture:

- patients' stories;
- clinicians' interpretations and analyses of these stories and findings;
- clinicians' rationale for decision-making and application of best available evidence; and
- clinicians' plans/actions to achieve clinical and patient-directed outcomes.

We offer our members' expertise in helping CMS and ONC to re-think documentation strategies that better balance clinical and administrative elements and needs.

AMIA also recommends more funding from ONC, the National Library of Medicine, and the Agency for Healthcare Research and Quality be dedicated to documentation-related R&D. The 2012 report also included a research agenda to minimize entry burden, support collaborative care, use/integrate data from sources beyond the EHR, and advance standards for the representation of clinical data, among other things.[12] While we have made progress along some fronts – namely NLP and data mining – the federal government must hasten progress.

Finally, we reiterate our stance that data collection is an intervention and should be understood as such. In comments submitted to ONC in 2018,[13] AMIA recommended that ONC

[6] American Academy of Orthopedic Surgeons
[7] American College of Obstetrics and Gynecology
[8] American College of Cardiology
[9] American Psychiatric Association
[10] American College of Emergency Physicians
[11] American College of Physicians
[12] The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. *Journal of the American Informatics Association*
[13] AMIA Response to ONC Draft USCDI, Feb. 20, 2018. Available at: https://www.amia.org/sites/default/files/AMIA-Comments-on-USCDI.pdf

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work with partner agencies, including the Agency for Healthcare Research & Quality, the National Library of Medicine, National Institutes for Standards and Technology, and CMS, to develop a generalizable metric that captures the cost of data collection and identifies ways to leverage this metric across programs that require deliberate collection of data outside routine care delivery.[14] In the same way that CMS and other payers rely on quality-adjusted life-years (QALY) to examine specific interventions, we must develop a similar measure to capture the cost-effectiveness of collecting electronic data. There may be additional concepts, such as the Number Needed to Treat or Number Needed to Harm (NNH), that may be worthwhile to incorporate as well. Together, the concepts of QALY and NNH could help inform which data elements are likely to yield the most return for collecting, and this metric would help stakeholders assess data collection pros/cons using a common methodology and nomenclature. Efforts to gather, summarize and document data should be compensated. Methods for quantifying such work should be developed that do not encourage gratuitous information gathering and documentation.

Health IT Usability and the User Experience

While we are cognizant of policymakers' hesitation to "regulate" usability, AMIA sees a need to make more uniform aspects of certified EHRs that have a demonstrated impact on patient safety. Again, AMIA and its members have been thinking about health IT usability and user experience within the context of patient safety for years. A 2013 report, "Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA," highlighted a series of recommendations that warrant revisiting.[15] This work identified a nascent, but growing body of evidence tying EHR design to patient safety and adverse events. A key recommendation was the use of common "style sheets" among EHRs.

As part of this Strategy, AMIA encourage ONC to leverage its Certification Program more explicitly and adopt a national universal set of standards for EHR symbols, shapes, and colors for ancillary service reporting and medication labeling nomenclature. Similar to the National Transportation Communications for ITS Protocol, US Railway Signaling Rules (General Code of Operating Rules), and Federal Navigation Regulations, common symbols, shapes, and colors will enable critical alerts to be understood as such across EHRs and users. Similarly, we recommend ONC engage with the US Food and Drug Administration efforts enforcing Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360, the National Drug Code Directory, to include "Tall Man Lettering" standards for all medications, food, and drugs, to improve patient safety and limit risk of error.

[14] https://www.amia.org/sites/default/files/AMIA-Comments-on-USCDI.pdf
[15] Middleton B, Bloomrosen M, Dente M, et al. Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA J Am Med Inform Assoc. 2013 Jun; 20(e1): e2–e8. Published online 2013 Jan 25. doi: 10.1136/amiajnl-2012-001458

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Additionally, we note that CEHRT developers collect and analyze tremendous amounts of data on usability and user experience. This data could provide researchers with new opportunities to learn from user complaints and user problems, which could then be leveraged to inform safer designs. **We recommend ONC consider ways to make available such data so that we can learn from tracking, trending, aggregating, investigating patterns of problems at the transaction unit of the patient encounter.** Collaboration among clinician users, experts in User Centered Design (UCD) and Human Factor Engineers (HFE), and the broader informatics research community is vital, and we strongly recommend an evidence base be established through the use of such data to help guide policy development related to usability / user experience.

Lastly, AMIA recommends HHS increase funding research and evaluation for (1) enhanced EHR data retrieval techniques to support rapid understanding of clinical contexts; (2) enabling efficient data entry through automated means (e.g. natural language processing, remote sensing, enhanced voice recognition/integration, etc.); and (3) evaluate efforts to learn from users' experience and improve EHR safety, usability, and clinician training, including the use of cognitive theory for design of EHRs.

EHR and Public Health Reporting

AMIA enthusiastically supports CMS and ONC efforts to transition the Promoting Interoperability Program away from its legacy structure and requirements. Specifically, identifying program requirements that encourage clinicians to engage in higher-value health IT functionality and meet multiple programmatic requirements (many of which are established in statute) for engaging in those functions is commendable. We also find intriguing the shift in compliance approach from a push equation (where clinicians and clinical entities send data to HHS according to tightly prescribed parameters) into a pull equation (where health plans and regulators request the data they need to do their evaluation). A standardized search process would be needed to implement such an effort, but the benefits to burden reduction could be significant.

As it pertains to public health reporting, we note that an impetus for reducing burden relates to the diversity of standards and requirements across federal, state, and local jurisdictions. While we understand the CMS inclination to reduce or eliminate public health reporting measures, we have not and do not support this approach. Keeping such measures in place will be a primary force for enabling convergence on these standards and not perpetuating differences. We encourage CMS to partner with other federal agencies, state and local agencies and professional groups to develop "model" reporting standards that would foster greater consistency in public health reporting.

Below, in Table 1, we outline our recommendations in more detail, and we address the Strategies specific Recommendations. Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank ONC and CMS for the opportunity to comment and look forward to continued dialogue.

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January 28, 2019

Sincerely,

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President and CEO
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Table 1

ONC Recommendations			AMIA Comments
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** • CMS will reduce burden associated with physician payments under the PFS starting in 2021 by paying a single payment rate for several levels of office based/outpatient E/M visit codes, which will enable a minimum documentation standard for the majority of office/outpatient visits billed to the PFS • 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 • HHS recommends other payers consider adopting a similar approach	AMIA supported CMS' efforts to reform E/M documentation guidelines as part of the CY19 Physician Fee Schedule and we supported the use of add-on codes to distinguish different kinds and lengths of E/M visits within streamlined levels. We view this streamlining and modification to E/M coding as a step in the right direction, but we do not envision that these steps will materially impact regulatory burden for patient visits. CMS will thus need to more comprehensively review the fundamentals impacting clinical documentation. AMIA emphasizes the achievable goal of decoupling clinical documentation from billing, regulatory, and administrative compliance requirements by creating an authoritative body from professional and specialty societies to: (1) assess clinical documentation requirements; (2) evaluate technological capabilities available today to extract then report data; and (3) define a financial mechanism to remunerate clinicians, hospitals, and healthcare systems for their work. Once the deliberative work and recommendations have been completed, provide funding to meet these challenges.

ONC Recommendations			AMIA Comments
Clinical Documentation		**Recommendation 2: Leverage data already present in the EHR to reduce re-documentation in the clinical note** • CMS is expanding and clarifying current policy for history and exam of office/outpatient E/M visits, such that certain data already present in the medical record need not be re-documented. Rather, it can be reviewed, updated, and signed off on by the billing practitioner • 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 • They could also facilitate a review and verification process for existing information that is seamless for the end-user while allowing for audit functionality which could reassure payers of review and verification if systems are sufficiently interoperable	We believe that more data from all sources is better. However, the problem is data organization, visualization, extraction for metrics, and exposure to CDS algorithms. We concur, for example, queries or algorithms can derive the reason why things 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 clearly in the current encounter with intuitive but explicit terminology is important for understanding what was actually done or thought about during the current encounter. Here too, decoupling of clinical documentation from billing documentation would be useful. SNOMED terms used for problem list documentation and guiding of longitudinal clinical care have a different structure and different purposes than the ICD-10 terms using for billing purposes. When both sets of terms are used at different points in the same documentation with slightly different wording, clinical communication becomes paradoxically less explicit and less clear.

ONC Recommendations			AMIA Comments
Clinical Documentation		**Recommendation 3: Obtain ongoing stakeholder input about updates to documentation requirements** • 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…through a representative task force	Documentation guidelines vary across care settings and as required by third parties. For example, documentation to demonstrate Joint Commission compliance versus Medicaid compliance may have similar aspects, but those too will also have variances. State-specific regulatory requirements and context-dependent requirements (e.g., behavioral health, patient-centered medical home) add to the potential for mismatches in documentation requirements. Further description is needed on what aspects of documentation guidelines are important along with consideration of how those documentation guidelines intersect with other documentation guidelines and requirements. There are already efforts internationally to support harmonization of documentation and reporting requirements between funders/national governments, etc. in other contexts. These can be used to inform similar efforts in the US.
		Recommendation 4: Waive documentation requirements as may be necessary for purposes of testing or administering APMs • CMS should, where feasible, explore further use of this concept by waiving certain documentation requirements in APMs.	Efforts to implement this recommendation should be aggressively pursued through existing demonstration projects and pilot programs within the CMS Innovation Center, CMMI. APMs demonstrate quality of care via audit of many metrics, whereas MIPS is more focused on "promoting interoperability" and more limited metric reporting. We also note that the vast majority of providers will not be working in APMs and some sites may not have all patients in APMs. Further, if documentation requirements can be reasonably waived, then they should be waived across the board. Waiving requirements selectively or having unique requirements for some areas (e.g., general hospitals vs. behavioral health) is problematic for EHR design/build.

ONC Recommendations			AMIA Comments
Clinical Documentation	**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.** • 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 initiatives, and increase awareness of tools and resources that can support implementation of best practices	AMIA vigorously supports HHS partnering with clinical professional societies promoting an understanding of documentation best practices. Each professional society brings a wealth of perspective to the requirements their clinicians must fulfill as they relate to their specialties. HHS should pursue this, however, with the full appreciation that even within specialties, different workflows and different types of documentation may be essential. Furthermore, the partnerships should extend beyond clinical professional societies and include professional societies such as AMIA, AHIMA, etc.
		Recommendation 2: Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models. • CMS should incorporate best practices for reducing documentation burden into technical assistance provided as part of CMS practice transformation initiatives such as the Transforming Clinical Practice Initiative (TCPI), MACRA Technical Assistance (QPP-SURS), Innovation Center model learning and diffusion activities, and Quality Improvement Organizations (QIOs) • Learning materials developed for these initiatives should be made public so	AMIA supports CMS developing, promoting and distributing technical assistance, models and learning materials for these initiatives. CMS may consider partnerships with professional societies to provide continuing education units for the professionals who complete these courses, increasing the likelihood that the important learning and education provided by these programs would be embraced by all professionals. However, if HHS' goal is to reduce/eliminate documentation burden, then such training should be seen as, at best, a temporary measure.

ONC Recommendations			AMIA Comments
		that states and private sector partners can incorporate them into their own initiatives as well.	
Clinical Documentation	**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.** • Within the framework established by HIPAA, HHS could consider ways to engage with stakeholders to further address these challenges, including but not limited to discussion of o (1) developing and disseminating best practices for optimizing electronic workflows around prior authorization; and o (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.	Among factors relevant to obtaining authorization is the broad definitions applied to describe reasonable and medically necessary conditions for care services. It would benefit all providers for CMS and impacted professional societies to develop an easily understood and widely educated definition of the reasonable and medically necessary conditions for care services as described in the Social Security Act 1862(a)(1). It is equally incumbent upon the payers to promote a transparent process that would be easily adopted by all providers enhancing the authorization request and process. The best way to address prior authorization burden is for CMS to develop requirements for insurers to justify their prior auth policies and that any justification for requiring a prior auth on a med needs to establish the benefits of such authorization for patients' care. Prior authorization that primarily increase clinician burden, regardless of any technological assistance, should be prohibited (e.g., requiring that every med on a certain tier or previously authorized brand name drugs be reauthorized at the beginning of each calendar year). The simple feature of permitting an electronic signature on a Durable Medical Equipment order be accepted by DME suppliers is one step that could be easily implemented; another would provide an ability for provider proxy signatures, such as independent licensed practitioners or licensed social workers.

ONC Recommendations			AMIA Comments
			Ordering medications by indication is another way to leverage existing data in the EHR to address prior authorization burden. The EHR would already have a series of data (e.g. what the patient has already tried, allergies, renal function, etc.) and what the problem/indication for the drug is. The EHR would thus suggest a drug of choice which should already be pre-authorized. An indications ordering screen/interface could even become a standardized vendor neutral use interface, so that no one would have to learn to prescribe on multiple different systems. A similar paradigm, of ordering by indication, with the EMR populating the approved medical supplies etc, would be also a direction to pursue.
Clinical Documentation		**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.** • HHS should continue to partner with the clinicians, payers, medical product manufacturers, and health IT developers to expand existing work on ordering services and prior authorization processes	AMIA recommends methods for evaluating the current methodology for National Coverage Decisions and Local Coverage Decisions (NCD/LCD) relation to ICD-10 and CPT-4 coding and simplify the process for clinicians. The cross walk between NCD-LCD-ICD10-CPT4 contains thousands of selections for clinicians. EHR vendors have yet to adopt methodologies that simplify the process or fully appreciate the complexity between government standards and the healthcare payer / supplier industries for obtaining an authorization for medical services or equipment.

ONC Recommendations			AMIA Comments
Clinical Documentation		**Recommendation 3: Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.** • HHS should consider providing incentives or access to streamlined auditing processes in cases where health IT could relieve health care provider burden and provide standardized documentation.	AMIA supports incentivization programs that would create new and efficient methods to streamline the prior authorization process and ordering drugs and equipment. This would include collaborative efforts with payers, equipment suppliers, and EHR vendors, all being cognizant of that the fact that services and equipment can vary in a highly individualized way. Updating and streamlining CMS Conditions of Participation (CoP) and State Operating Manual (SOM) guidelines, rules and regulations would provide relief from the tremendous burdens encumbered by the current processes utilized today. AMIA also believes that it is incumbent upon CMS to include the Office of the Inspector General (OIG) when developing their annual Work Plan. Efforts to improve efficiency may impact OIG's oversight requirements of Medicare and Medicaid program, including but not limited to audits, investigations, and evaluations of existing program compliance.

ONC Recommendations			AMIA Comments
Clinical Documentation		**Recommendation 4: Work with payers and other intermediary entities to support pilots for standardized electronic ordering of services.** • HHS should actively engage with efforts to pilot these functionalities with other payers, health IT developers, and third-party exchange organizations to accelerate adoption. • HHS could facilitate participation in pilots by participants in CMS APMs focused on increasing efficiency	AMIA strongly encourages CMS to support payers and intermediaries to support not only APM models for standardized electronic ordering of services, but MIPS-eligible clinicians, as well. One important area to evaluate concerns the current processes for ordering ancillary services; e.g., laboratory, cardiology, radiology, and pathology services. Associating these servicers with National and Local Coverage Determinants (NCD/LCD) codes, then requiring clinicians to provide the appropriate matching ICD-10 and CPT-4 codes to order a patient required service is wrought with tremendous variability in practice, adding significant burden to clinician practices. AMIA fully supports pilots that focuses on efficient ordering of ancillary services.

ONC Recommendations			AMIA Comments
Clinical Documentation		**Recommendation 5: Coordinate efforts to advance new standard approaches supporting prior authorization.** • HHS should continue to pursue standards that aim to improve the prior-authorization ecosystem through multi-stakeholder groups (e.g., clinicians, health care information technology vendors, and payers), such as but not limited to the Da Vinci project and P2 FHIR Task Force. • Once new standards are mature, HHS should pursue consensus through the National Committee on Vital and Health Statistics (NCVHS) in order to adopt standards that support multi-payer, real-time, prior authorization and reduce provider burden	AMIA supports and applauds CMS efforts such as the DaVinci project and P2 FHIR Task Force and recommends that these projects receive federal funding to accelerate their adoption by the provider communities. It would benefit all providers for CMS to coordinate and systematically expand the horizon of opportunities provided by the DaVinci project and P2 FHIR task force. AMIA would encourage the NCVHS to carefully align any new ICD-10 diagnosis adaption with provider practices and EHR vendors. Increasing the numbers of available diagnoses available for selected ancillary services and procedures, adds to clinical and administrative burden of the providers to select the "best" diagnosis. As NCVHS continuously updates ICD-10 codes and diagnoses, EHR vendors must be encouraged to adopt technologies to seamlessly and effortless notify providers of the change, providing simplified technology to accept, modify, and / or delete the new diagnosis into the patient's EHR.

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.** • 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. • Clinical organizations can help to improve workflow alignment by interfacing regularly with health IT developers to ensure workflow requirements are present in products that will be acquired. Individual clinicians can also contribute by providing feedback to their institution's IT staff and/or the developer when clinical workflow needs are not being met by the EHR system. • Integration of patient-based data collection into the clinical workflow could help reduce burden by reducing the amount of information required by the physician or supporting staff.	AMIA agrees that EHR system design should represent real-world clinical workflow, and we believe that is the vendors' existing goal. However, we recommend either mandates or incentives for UCD and HFE experts to work with health IT developers, providers, and organizations on optimizing EHR usability. Currently, there is little incentive for health IT vendors to redesign their interfaces-based end-users' needs nor share the data they have on user feedback and challenges. We additionally recommend improved access to data maintained by EHRs on usability and user experience for human factors engineers to run usability evaluation and to attempt to improve workflow. Currently, health IT vendors require organizations to agree that only active providers are able to view, let alone interact with, the EHR. Informaticians are trained to bridge the gap between health IT developers and providers. Usability will not improve unless expert informaticians are allowed to view and run experiments on health IT products. Finally, it is incumbent on CMS to carefully review the numerous regulations provided in the Conditions of Participation (CoP), State Operations Manuals (SOM), and Office of Inspector General Work Plan (OIG-WP) to be evaluated from the perspective of streamlining workflow processes that are currently mandated by regulation. Once the structural foundation of carefully analyzed workflows have been defined, health IT developers can use new and evolving technologies to integrate patient based data into the clinical workflows, reducing the amount of information required by the physicians and supporting staff.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience		**Recommendation 2: Improve clinical decision support usability.** • A robust CDS framework must be implemented. The National Academy of Medicine has recently published *Optimizing Strategies for Clinical Decision Support*, describing what this framework should include: the development and adoption of technical standards; tools to measure efficacy of CDS; collaboration surrounding a common repository for CDS tools; a legal framework for CDS; and research into the safety, quality, productivity, and outcomes of successful CDS implementation that will help drive the business case for future CDS adoption. • AHRQ's CDS Connect project recommends project evaluation inform the translation of clinical guidelines into computable content for interoperable CDS that are shareable, standards-based, and patient-centered.	AMIA supports a CDS framework, but notes that it should additionally address data management and algorithm access. AMIA also supports CDS Connect project evaluation to inform the translation of clinical guidelines into computable content for interoperable CDS that are shareable, standards-based, and patient centered. Much like clinical documentation and APM pilots, it would be beneficial for CMS to promote CDS pilots and partner with clinical professional societies to achieve enhanced understanding of CDS practices and strategies. Maintenance will be critical to ensuring that the CDS system remains up to date. This includes everything from terminology maintenance used in CDS rules to changes in underlying architecture to changes in clinical knowledge. Open sharing of standardized CDS Rules within and between vendors should be incentivized, as well.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience		**Recommendation 3: Improve clinical documentation functionality.** • Speech recognition in clinical care documentation holds promise but has not yet achieved widespread adoption. Health IT developers (and speech recognition developers) can consider collaborative partnerships with large health care institutions to improve their speech recognition capabilities through machine learning. • Policies regarding copy-and-paste functionality should be put in place at an institutional level for the management of copied text that balances efficiency with safety. • The use of EHR logging functionality can help identify the time clinicians are spending interacting with the EHR.	AMIA agrees that speech recognition brings tremendous benefits to the clinical care of patients and should be encouraged by funding pilot programs and continued research to improve the technology and adoption. AMIA agrees that management of copied text is an important policy issue. Policies that prohibit copy-and-paste functionality are likely to introduce safety concerns (e.g., lost information about clinical impressions and treatment plans in successive notes) as well as reducing efficiency. On the other hand, use of copy-and-paste functionality can also serve as a means of propagating errors. All too often however, the primary concerns related to copy-and-paste functionality is related to billing compliance if notes are thought to be "cloned". If clinical documentation is decoupled from billing as we have recommended, these concerns should become moot. Under such circumstances, with copy-and-paste functionality used only when clinically indicated, the risk of error propagation will also be reduced. AMIA also agrees that EHR logging functionality can be leveraged to identify the time that clinicians are interacting with the EHR. Even more importantly, such logging functionality and associated data analytics may help in identifying specific EHR processes and documentation requirements that generate significant burden without being offset by value to clinical care/outcomes. Usability challenges can also be identified through such approaches as a complement to other forms of usability testing and can assess usability across a much broader range of users.

ONC Recommendations			AMIA Comments
		Recommendation 4: Improve presentation of clinical data within EHRs. • Health IT developers can help to reduce cognitive load on the end user by working to optimize and improve information display and by using health care-specific GUI elements.	AMIA supports this recommendation and believes that the aforementioned recommended documentation initiatives should enable more creative and useful visualizations. One important example of such visualizations is related to longitudinal views of medication histories, which can be valuable for clinical decision-making and would also facilitate burdensome tasks such as medication pre-authorization requests.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience	**Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.**	**Recommendation 1: Harmonize user actions for basic clinical operations across EHRs.** • Consistent with antitrust requirements, health IT developers should have the opportunity to discuss and jointly arrive at a shared understanding of common interface and workflow design elements for common clinical tasks, beginning with those workflows that directly impact patient safety. • Examples of functionalities that health IT developers could standardize might include, but are not limited to medication reconciliation; medication, laboratory and imaging ordering; results review; problem list interaction; medical history interaction; and clinical documentation authoring and review. Similarly, harmonizing laboratory test codes could support better mapping across systems, better presentation of laboratory information, and better laboratory order entry as part of the clinical workflow. • Clinicians and clinical professional societies have the opportunity to collaborate with health IT developers to best inform how to potentially harmonize these across health IT systems.	AMIA recommends that CMS approach basic clinical operations across EHR's much like the Federal Navigation Regulations, the International and Inland Rules, US Railway Signaling Rules (General Code of Operating Rules), or the National Transportation Communications for ITS Protocol (NTCIP) by adopting a universal set of regulations and rules for the representation of clinical data in EHR's. Symbols, colors, and shapes adopted by various EHR vendors to represent laboratory values; e.g., critical, normal, abnormal, etc., make it increasingly difficult to efficiently and immediately appreciate the significance of the symbol, color, or shape from one EHR vendor to the next vendor. Providers who work in different healthcare organizations with different EHR's must learn the different symbols, shapes, and colors used by each EHR vendor decreasing their efficiency, reducing ease of adoption and presenting potential safety risks. CMS should encourage a national effort to collaborate with professional societies, then adopt a universal standard of representative symbols, shapes, and colors to be represented in EHR systems. ONC could also view harmonization as a certification opportunity.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience		**Recommendation 2: Promote and improve user interface design standards specific to health care delivery.** • Developers can review and utilize these resources, such as the NIST health IT usability resources, and in the future can take the lead by formulating health IT specific UI best practices. Steps in this new direction should include a focus on user interfaces to support the clinician's cognitive thought process in terms of complex pattern recognition, as well as the creation of health care-specific user interface components designed to support the clinical workflows found in health care. • EHR developers can then work together to identify and select from these resources to create a shared repository of EHR usability practices. • EHR developers can augment their internal usability design and testing programs with larger teams, additional human factors experts, and expanded open-ended testing that focuses on clinical usability… results of these developer efforts should be highlighted on the ONC Certified Health IT Product List, where prospective EHR customers can view an EHR product's Safety Enhanced Design report.	AMIA applauds the efforts of the US Department of Commerce NIST health IT usability resources and would request that CMS consider increasing funding for the study and piloting of UI best practices including complex pattern recognition and health care-specific user interface components used to support clinical workflows. HHS could also work to improve the research environment that would allow researchers to freely and publicly share their findings on improving interface design standards. We thus also recommend building guidelines that govern the relationship between health IT vendors, health providers, and researchers.

ONC Recommendations			AMIA Comments
Health IT Usability and the User		**Recommendation 3: Improve internal consistency within health IT products.** • Software developers can review their suite of software solutions to ensure that all aspects of the system share a common user interface and style guide. • Health care institutions also have a responsibility during the implementation phase of an EHR to thoughtfully make decisions that will not drastically alter the internal interface consistency of a health IT product.	As mentioned, CMS should encourage a national effort to collaborate with professional societies, then adopt a universal standard of representative symbols, shapes, and colors to be represented in EHR systems. A related effort could focus on common mental models. For example, an octagonal icon is commonly associated with concept of stopping outside of the EHR so it would be problematic to choose such an icon to represent some other concept. Divergence from standard mental models also can contribute to errors. One example would be prescription writing interfaces or ways of expressing medication orders that don't align with typical mental constructs for such tasks.
		Recommendation 4: Promote proper integration of the physical environment with EHR use. • Health care institutions contemplating renovation or new construction have the opportunity to keep in mind EHR usage and clinical team interaction when designing environments such as emergency departments, surgical units, and intensive care units, while also considering patient privacy concerns.	AMIA supports this recommendation and suggests that ONC publish best practices for proper integration. These best practices should be applicable across settings and specialties, not just those areas specified in this recommendation. Considerations should include ergonomics, clinical communication, potential provider distractions, workflow efficiencies and engagement with patients and, where applicable, family members. CMS can further encourage utilization of NIST health IT usability resources to assist in this effort.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience	**Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.**	**Recommendation 1: Standardize medication information within health IT.** • Prescription drug information in EHRs should be displayed in a standardized format to avoid confusion, increase patient safety, and reduce burden. This standardization is necessary during both the ordering of medications and the display of existing medication information. • Health care institutions should refer to ONC's *SAFER Guide: Computer Provider Order Entry with Decision Support* and *Report on the Safe Use of Pick Lists in Ambulatory Care Settings* for guidance on implementation decisions that can help optimize medication information display to reduce cognitive load and clinician burden.	AMIA encourages CMS to evaluate existing regulations and rules surrounding National and Local Coverage Determinants (NCDs and LCDs), seeking simplified methods for providers to appreciate selecting the best diagnosis for a particular ancillary service or procedure. It would be beneficial for CMS to coordinate a collaborative effort by CLIA, LOINC, and ACP to refine and simplify ancillary test codes to provide clear, concise definitions. The Tall Man Lettering concept for medication naming convention would be best utilized by standardizing the naming conventions utilized by all EHR vendors. At the same time, HHS should avoid standardization with excessive detail, making it hard for the clinician it to process information clinically and synthesize information.

ONC Recommendations			AMIA Comments
		Recommendation 2: Standardize order entry content within health IT. • 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. • 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.	As mentioned, AMIA recommends that CMS promote a more standardized and efficient methodology for ordering ancillary services (laboratory, cardiology, radiology, and pathology) and procedures by evaluating the current system for National and Local Coverage Determinants (NCDs and LCDs) then engage EHR vendors, CLIA, LOINC, and ACP to adopt standardized ordering protocols to complement provider activities. Also, we agree with the use of favorites. This is another area where billing issues and clinical documentation become intermingled and further confounded by compliance concerns. Clinicians should not have to guess which of many similar indications are covered.

ONC Recommendations			AMIA Comments
		Recommendation 3: Standardize results display conventions within health IT. • EHR developers can collaboratively work to identify a common format for displaying results. • Developers can arrive at a standard for chronological display (older results on left vs. right), abnormal display (flag symbols vs. different colors), and reference range inclusion • Health care institutions can check to see that they have followed ONC's *SAFER Guide: Test Results Reporting and Follow up*120 to both improve patient safety and reduce clinician burden in this area.	As mentioned, CMS should encourage a national effort to collaborate with professional societies, then adopt a universal standard of representative symbols, shapes, and colors to be represented in EHR systems.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience	**Strategy 4: Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.**	**Recommendation 1: Increase end user engagement and training.** • Clinical users should be involved 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. • After implementation of an EHR system, it is essential that clinical end users are actively involved with ongoing optimization of the EHR system, including workflow refinements, CDS tool review, and documentation and template optimization.	While we agree that clinical users need to be involved, we also recognize that involvement is only as good as the vendors' ability to incorporate feedback. Oftentimes, it is also the organizational policies and decisions that can contribute to poor usability, as well. Therefore, AMIA would suggest that CMS update the Conditions of Participation to include requirements for Health IT governance within all hospital and healthcare organizations. The HIT governance model would also define requirements for provider engagement, training and ongoing optimization. AMIA would additionally support CMS CoP stipulating the qualifications of certification programs for providers who are involved with the ongoing optimization of EHR Systems. Much like other areas of the CoP where characteristics and qualifications of providers are defined by regulation; standardizing the qualifications of professionals who refine CDS tools, documentation and template designs would greatly benefit end user engagement and training.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience		**Recommendation 2: Promote understanding of budget requirements for success.** • Health care institutions can transition from a model that revolves around a fixed implementation budget to a budget model that incorporates ongoing technical support for end users, ongoing training of clinical staff, and required technical resources to support upgrades, system maintenance, troubleshooting, system backup, and disaster recovery functionality. • Health care institutions can refer to ONC's *EHR Contracts Untangled* to be aware of important contracting issues and for ideas on how to approach contract negotiations.	AMIA would support CMS inclusion into the CoP a proposed Health IT Governance section that would delineate budget requirements for the ongoing technical support of the organizations EHR system. Today, hospitals must have in effect an overall plan and budget that meets the requirements of section1861(z) of the Act [42 CFR 482.12, Governing Body] and meets any other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution [42 CFR Parts 482 and 489, among others]. We Support CoP regulation optimization for hospitals to have an overall plan and budget requirement in section1861(z) of the Act [42 CFR 482.12, Governing Body] to include a Hospital IT Governance section describing: a. Provider engagement, training and ongoing EHR optimization b. Standardized qualifications of clinicians who refine CDS tools, documentation, and template designs c. Delineate budget requirements for the ongoing technical support of the organization's EHR system. We would be open to less prescriptive ways to encourage fully funding continuous improvement in IT and informatics tools.

ONC Recommendations			AMIA Comments
		Recommendation 3: Optimize system log-on for end users to reduce burden. • EHR developers can offer various modes of authentication and system sign on with their products, including traditional user name and password log-on and other modes, such as token based authentication (e.g. swipe cards) or biometric authentication. As biometric authentication for health care applications becomes more readily available, health care institutions could incorporate these alternate modes to reduce the burden of frequent end user sign in/sign out.	AMIA agrees that EHR developers should optimize system log-ons and other authentication requirements to reduce burdens for end users. Such optimization should include, but not be limited to, re-entering the software after screen time-outs and prescription-related authentication. Similarly, CMS should seek optimized technical methodologies for acknowledging the ordering, review, and forwarding of progress and consult notes as well as ancillary services and procedures.

ONC Recommendations			AMIA Comments
Health IT Usability and the User Experience		**Recommendation 4: Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.** • Health care developers can continue efforts to conform to relevant standards pursuant to ONC and CMS policies. Since the passage of the 21st Century Cures Act, HHS and other federal partners have worked to implement 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.	AMIA supports this recommendation and we encourage ONC to reevaluate the relevance of the Certification program so as to assure providers have tools more appropriately focused to support the objectives outlined here.

ONC Recommendations			AMIA Comments
EHR Reporting	**Strategy 1: Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.**	**Recommendation 1: Simplify the scoring model for the Promoting Interoperability performance category.** • 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. • CMS is working to improve the Promoting Interoperability program to reduce burden and increase value by (1) continuing efforts to be evidence-based and relevant to clinical care; (2) promoting higher-value functionality, such as wide-spread interoperability and clinical support tools; (3) aligning measurement with clinical workflow, so that data collection for each measure does not contribute to extra or unnecessary steps in the use of health IT in patient care; and (4) increasing patient and/or authorized caregivers' access to health information to make fully informed health care decisions.	AMIA recognizes that significant improvements in interoperability are essential, even among systems that are technically interoperable. Consequently, AMIA concurs that CMS should continue to seek insights into evidence based clinical care and align measurement of clinical workflow and data collection items from professional societies, providers, and patients. In addition, AMIA supports CMS efforts to improve the Promoting Interoperability program and reduce the documentation and other burdens associated with the Promoting Interoperability program for providers.

ONC Recommendations			AMIA Comments
EHR Reporting		**Recommendation 2: Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.** • The nature of these incentives could range from simple bonus scoring for the use of health IT to specific use cases that might serve as alternate pathways of program participation • Similarly, HHS should look for opportunities within existing reporting programs to incentivize clinicians that participate in activities that demonstrate advanced interoperability. • Finally, HHS should look at innovative uses of health IT that can reduce the reporting burden itself by making it easier for federal agencies to pull data directly from health IT to facilitate reporting.	AMIA supports the ONC Trusted Exchange Framework and Common Agreement to bridge the gap between provider's and patient's information systems enabling interoperability across disparate health information networks in the US Core Data for Interoperability (USCDI). We strongly recommend that ONC includes comments from the numerous other sectors within HHS to include their data sets within the USCDI to electronically harmonize and standardize their data so workflow designs will be aligned to easily capture the data. Suggested HHS data systems include but are not limited to: 1) HRSA Uniform Data System Resources 2) SAMHSA Treatment Episode Data Set 3) CDC National Vital Statistics System 4) National Information Exchange Model 5) National Notifiable Disease Surveillance System 6) National Syndromic Surveillance Program 7) National Violent Death Reporting System 8) National Death Index 9) Vaccine Adverse Event Reporting System 10) USFDA National Drug Code Directory

EHR Reporting		**Recommendation 3: 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.** • CMS is actively working to engage stakeholders, clinicians, and patients in burden reduction efforts. One example of this is the EHR Call for Measures activities, in which CMS highlighted a need for measures geared toward promoting interoperability and focused on health information exchange. • This approach has been strongly supported by the hospital and clinician communities, both of whom have been heavily involved in suggesting new measure concepts for these programs. We believe the approach above will not only reduce unnecessary clicks and steps within health IT that are attributable to program measurement, but will also result in measures of health IT usage that contribute to health care provider efficiency and patient care.	As cited earlier in these comments (Health IT Usability, Strategy 1 Recommendation 1), AMIA recommends that relevant specialty-specific evidence-based care measures be aligned with interoperability, clinical support tools, and data collection care after defining the structural foundation of clinical workflows (e.g., admission care, continuing care, discharge planning and referral, transitions of care to the community). AMIA also supports the continued "EHR Call to Measures" activities for promoting EHR interoperability, enhancing the process by developing enrollment notifications, updates, web conferencing, and notice for public comment be widely popularized similar to the CMS Email Updates As health IT interoperability and the use of health IT in patient focused care evolves, AMIA believes that CMS must develop methodologies for EHR vendors and users (from academic and suburban, urban, and rural hospital and healthcare systems) be actively engaged in the eCQM process to test, comment, then assist with the development of the proposed solutions. Measures could be tested for value relative to burden before rolling them out. If value is small relative to burden, then they should not be added. Measures should also be designed in a way that optimizes useful information without necessarily being a perfect measure. By way of example, many measures have detailed exclusion criteria, which can result in burden relating to collecting exclusion information. Ignoring those exclusions and simply adjusting the range of acceptable measure ranges would be far better than having a fully specified but highly burdensome measure.

ONC Recommendations			AMIA Comments
			AMIA also recommends that CMS adopt an interdisciplinary multi-professional governance structure providing decision authority to meet the needs and requirements of the clinical, administrative, and technical communities. AMIA suggests members would serve a 1 or 2 year rotation with representatives from specialty societies, health IT vendors, hospital and healthcare system organizations, management, financial, medical record coding associations, and the public assisting with the evaluation and recommendations promoting measures of health IT usage. For example, if a goal is to use Health IT to strengthen healthcare, provide a safety net, optimize revenue management; then EHR vendors would provide the necessary knowledge to develop a technical infrastructure that would support easily adopted solutions to add new quality measures, values and data requirements, that result in optimized implementation timelines.

ONC Recommendations			AMIA Comments
EHR Reporting		**Recommendation 4: 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.** • CMS intends to work with states to integrate health IT into larger Medicaid Enterprise systems. To the practicable and appropriate extent, state Medicaid Enterprise systems should leverage or build upon existing federal investments including projects supported by Medicaid Promoting Interoperability Program funding, such as state efforts to establish secure and trusted health information exchange.	AMIA recommends that CMS aggregate and standardize the data elements required for the numerous Medicaid activities enhancing the interoperability of EHRs to support completion of required data fields for demographics, insurance and finance, social determinants of health (SDOH), medical / surgical history, medications, activities of daily living, diagnoses, assessments and treatment plans. These same data elements then may be used to promote and support development of objectives and measures for the Medicaid Promoting Interoperability Program.
EHR Reporting		**Recommendation 5: Revise program feedback reports to better support clinician needs and improve care.** • CMS should continue to enhance the MIPS performance feedback based on their user research findings. • HHS should also explore an open API approach to integrate these feedback reports and supporting data with health IT. If health IT can support a consistent, integrated feedback loop, it could reduce burdens related to program participation and improve overall quality and patient care.	AMIA supports the open API approach to integrate feedback reports and supporting health IT data. This data must include beneficiary level data, and expanded information around cost and utilization inside and outside a clinician's practice for attributed beneficiaries.

ONC Recommendations			AMIA Comments
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.** • 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.	AMIA finds the Interoperability Standards Advisory (ISA) site and annual Reference Edition ISA to be exemplary models of interoperability standards and implementation specifications that can be used by the healthcare industry establish best practices for data mapping and data integrity. AMIA recommends wider representation by specialty societies, hospitals and healthcare systems, and EHR vendors to increase and broaden the scope of participation in ISA activities. An MLN education program, providing CEU's, would include an overview of ISA, how to use JIRA and Confluence, how to promote adoption of the standards, develop pilots, and determine costs associated with implementation of programs.
EHR Reporting		**Recommendation 2: Adopt additional data standards that 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.** • 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 collaborative processes that promote interoperable data exchange while also relieving physician and hospital burden related to health IT use.	AMIA recognizes the importance the 21st Century Cures Act placed upon identifying the interoperable exchange of electronic health information. The US Core Data for Interoperability (USCDI) is a promising approach to expand the availability of predictable, transparent and collaborative processes. The migration of data classes from emerging to candidate status onward to USCDI, and the opportunity for public comment must include widespread publication and socializing of the process to ensure inclusion of physicians, hospitals, and healthcare systems. Please see our comments to the draft USCDI here.

ONC Recommendations			AMIA Comments
EHR Reporting		**Recommendation 3: Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products.** • To reduce wasted time and effort on the clinician side, and to improve overall data accuracy, HHS should implement an open API interface for its own electronic systems such as the National Plan & Provider Enumeration System (NPPES) and the Provider Enrollment, Chain, and Ownership System (PECOS) that use and maintain administrative information. • Ideally, HHS should 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.	AMIA supports an open, bidirectional API approach to HHS electronic administrative systems promoting integration with existing health IT products, including but not limited to the National Plan & Provider Enumeration System, the Provider Enrollment Chain and Ownership System.

ONC Recommendations			AMIA Comments
EHR Reporting	**Strategy 3: Improve 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 the newly developed electronic clinical quality measures.** • 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.	AMIA concurs that CMS adopt a first-year test reporting approach for newly developed eCQMs to encourage physicians, hospitals and healthcare systems to accept or refine the data measures. The use of program incentives to foster participation in the testing programs is an exemplary model that AMIA enthusiastically supports.

ONC Recommendations			AMIA Comments
EHR Reporting		**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 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. • 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.	AMIA congratulates CMS for the development and support of the eCQM Strategy Project especially the principles set forth: (1) Move eCQM calculation out of EHR vendor/systems making standardized calculation engines available to vendors and providers, (2) the required data must be available in current EHR systems, is clinically valuable, widely used across programs and is efficient to record in the electronic health record, and (3) aligns with existing data standardization, including but not limited to the US Core Data for Interoperability (USCDI).

ONC Recommendations			AMIA Comments
EHR Reporting		**Recommendation 3: Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.** • 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. • 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.	AMIA supports pilot programs that aim to facilitate electronic quality measurement by mining health IT databases and applying machine learning and artificial intelligence. These programs could have significant impact on the quality of patient care and simultaneously reduce clinician burden, while increasing accuracy of reporting on clinician and organizational performance and outcome trends.

ONC Recommendations			AMIA Comments
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 EHRs 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.** • 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.	AMIA supports timely access to medication histories in PDMP's and recommends that CMS coordinate provider prescribing workflow analyses to include federal and state funding agencies, state PDMPs, EHR vendors, and representatives from specialty societies with the explicit goal of producing standardized documentation and reporting of medication histories. This coordinated effort would include standardization of the matching fund application process provided by the SUPPORT for Patients and Communities Act to harmonize the efforts across all states, provider groups and EHR vendors and ensure project activities are uniform and aligned to integrate a provider's workflow to facilitate accessing medication histories. We also note the importance of electronic case reporting (eCR) and syndromic surveillance with their ties to national biodefense preparedness, or the other core reporting measures that are part of the CMS Promoting Interoperability programs. These aspects of public health reporting should not be forgotten as part of this conversation.

ONC Recommendations			AMIA Comments
Public Health Reporting		**Recommendation 2: HHS should increase adoption of electronic prescribing of controlled substances with access to medication history to better inform appropriate prescribing of controlled substances.** • Through the implementation of the SUPPORT for Patients and Communities Act, CMS will require controlled substances covered under Medicare Part D to be electronically prescribed. States receiving the 100 percent federal matching funds for qualified PDMPs will need to meet the requirement for the integration of medication history from PDMPs into the prescribers' workflow and health IT for EPCS. • The SUPPORT Act also requires DEA to update multifactor authentication requirements that will permit biometrics and modern approaches to authentication that can be more easily integrated into provider workflows.	AMIA supports increasing adoption of electronic prescribing of controlled substances (EPCS) and we recommend prioritization of efforts to support seamless integration of PDMP data with patient medication histories as part of the provider's medication-related workflow. Existing models that may be adapted to increase interoperability of patient medication histories and PDMPs include the National Information Exchange Model (NEIM) and the National Council for Prescription Drug Programs (NCPDP) that create national standards for electronic transactions used in ePrescribing. AMIA further supports the use of multifactor authentication requirements permitting biometrics and other modern approaches to authentication that will be easily integrated into a provider's workflow.

ONC Recommendations			AMIA Comments
Public Health Reporting	**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 1: 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.** • By identifying common and disparate data reporting requirements across all programs, aligning similar reporting requirements with data collected in normal workflows, and harmonizing reporting requirements across programs, data collection and reporting burdens can be reduced.	State and local reporting represents the vast majority of the interoperability between public health and clinical care. Given the relative absence of public health law at the Federal level, public health reporting to the Federal government is largely incidental. As public health is already well-versed in reporting requirements and transport/data element standards are largely known and understood, we believe that the primary obstacle to more commonality is lack of funding of public health at all levels of government. AMIA strongly recommends that ONC includes comments from the numerous other sectors within HHS to include their data sets within the USCDI to electronically harmonize and standardize their data so workflow designs will be aligned to easily capture the data. Suggested HHS data systems include but are not limited to: 1) HRSA Uniform Data System Resources 2) SAMHSA Treatment Episode Data Set 3) CDC National Vital Statistics System 4) National Information Exchange Model 5) National Notifiable Disease Surveillance System 6) National Syndromic Surveillance Program 7) National Violent Death Reporting System 8) National Death Index 9) Vaccine Adverse Event Reporting System 10) USFDA National Drug Code Directory 11) CDC Provisions for State Tuberculosis Prevention and Control

ONC Recommendations			AMIA Comments
Public Health Reporting		**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.** • 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.	AMIA recommends that CMS and the Interoperability Standards Advisory provide funding to specialty societies, academic and non-academic hospitals and healthcare systems, to collaborate creating implementation pilots as described in the ISA Case Reporting to Public Health Agencies to examine, harmonize and define the common data elements for reporting public health data.

ONC Recommendations			AMIA Comments
Public Health Reporting		**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.** • HHS should coordinate across federal agencies to educate health care providers and health IT vendors about 42 CFR Part 2 requirements and provide more clarity on when health care providers and their health IT vendors need to comply with 42 CFR Part 2 patient consent and health information re-disclosure requirements. • This education and outreach should include the availability of new technical standards and technologies to enable privacy and data segmentation of health information, as well as technical assistance to help health care providers and organizations adopt and use existing health IT solutions for protecting patient privacy and managing patient consent.	AMIA agrees and strongly affirms that HHS must provide guidance to HIPAA privacy and federal confidentiality requirements governing substance use disorder health information to best facilitate electronic exchange of health information for patient care. The Federal Confidentiality of Substance Use Disorder Patient Records, 42 CFR Part 2, lays out a complicated set of definitions and requirements relating to patient consent and health information disclosure, which are typically unclear to health care providers and their health IT vendors. We also note a need to align 42 CFR Part 2 with HIPAA to clarify EHR customizations, reduce provider and administrative burdens, and facilitate interoperability. EHR vendors and professional societies must be convened to review the availability of new technical standards and technologies to enable privacy and data segmentation of health information, then provide the technical assistance to providers and their organizations adopt and use these health IT solutions for protecting privacy and managing patient consent. AMIA believes and recommends that HHS provide web based training and education through the Medicare Learning Network, that gives continuing education units to providers who complete required course work.

Appendix A

The following are examples where administrative concerns but lead to an increased clinician and administrative burden for documentation when clinicians and administrators are not engaged in the design, development, and implementation of the workflows associated with CMS requirements.

OIG Work Plan
OIG assesses relative risks in HHS programs and operations to identify those areas most in need of attention then sets priorities for the sequence and proportion of resources to be allocated. In evaluating potential projects to undertake, OIG considers numbers of factors, including:

- mandatory requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget;
- top management and performance challenges facing HHS;
- work performed by other oversight organizations (e.g., GAO);
- management's actions to implement OIG recommendations from previous reviews; and

potential for positive impact.

- Investigating Fraud, Waste and Abuse
- Facilitating Compliance in the Health Care Industry
- Excluding Bad Actors from Participation in Federal Health Care Programs

Beginning in June 2017, OIG began to update work planning efforts monthly. Below are examples from the downloadable November 2018 Work Plan

Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries - Report No. OEI-06-18-00400: OIG has conducted studies about adverse events (patient harm) in various healthcare settings since 2008, with 15 reports released or in process through 2019. The series includes a congressionally-mandated study released in 2010 that found that 27 percent of Medicare beneficiaries experienced adverse events or temporary harm events while hospitalized in 2008. The current study will replicate the methodology used in the prior work for a sample of Medicare beneficiaries admitted to acute-care hospitals in 2018. We will measure the incidence of adverse events and temporary harm events, the extent to which the harms were preventable given better care, and the associated costs to Medicare. We will compare the 2018 results with the prior study results to assess progress in reducing harm at the 10-year mark, and identify differences in harm rates, types, contributing factors, preventability, and costs.

Impact: Hospitals, their clinical and administrative staff must develop responses the meet the definitions of serious reportable events, hospital acquired conditions, methods for identifying events and determining preventability, create methodologies for maintaining and reporting statistics, and outcomes. These activities, at times, are not aligned with EHR vendor capabilities thus creating an added expense to the hospitals, healthcare systems and providers who seek to be compliant with the requirement to reduce adverse events.

For one example, the National Quality Forum Serious Reportable Events (Appendix B, page 37) contains 28 adverse events where each event data element must be designed, then implemented into the EHR with each discipline's identification of workflow design, then training of their clinicians, administrative staff, medical record coding, report analyst, quality assurance / performance improvement, and education teams.

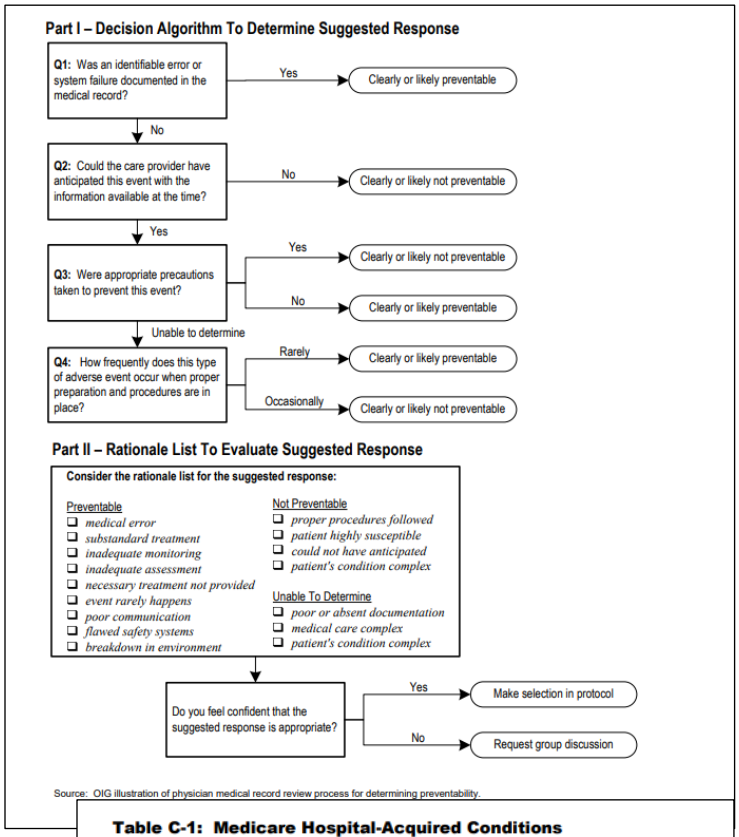
Table B-1: The National Quality Forum (NQF) List of Serious Reportable Events

Surgical Events	
A.	Surgery performed on the wrong body part
B.	Surgery performed on the wrong patient
C.	Wrong surgical procedure performed on a patient
D.	Unintended retention of foreign object in a patient after surgery or procedure
E.	Intraoperative or immediately postoperative death
Product or Device Events	
A.	Patient death or serious disability associated with use of contaminated drugs, devices, or biologics provided by the health care facility
B.	Patient death or serious disability associated with use or function of a device in patient care in which the device is used or functions other than as intended
C.	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility
Patient Protection Events	
A.	Infant discharged to the wrong person
B.	Patient death or serious disability associated with patient elopement
C.	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility
Care Management Events	
A.	Patient death or serious disability associated with a medication error
B.	Patient death or serious disability associated with a hemolytic reaction because of administration of incompatible blood or blood products
C.	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while cared for in a health care facility
D.	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient is being cared for in a health care facility
E.	Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
F.	Stage III or Stage IV pressure ulcers acquired after admission to a health care facility
G.	Patient death or serious disability because of spinal manipulative therapy
H.	Artificial insemination with the wrong donor sperm or wrong egg
Environmental Events	
A.	Patient death or serious disability associated with an electric shock while being cared for in a health care facility
B.	Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
C.	Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility
D.	Patient death or serious disability associated with a fall while being cared for in a health care facility
E.	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility
Criminal Events	
A.	Care provided by someone impersonating a health care provider
B.	Abduction of a patient of any age
C.	Sexual assault on a patient within or on the grounds of a health care facility
D.	Death or significant injury resulting from a physical assault that occurs within or on the grounds of the facility

Source: NQF, *Serious Reportable Events in Health Care 2006 Update: Consensus Report*, NQF, Washington, DC, 2007, p. 7.

Clinician review process for determining preventability (Appendix E, page 45) must be designed, tested, then implemented into the EHR, education must be provided to all providers concerning the processes and expectations, analysts must be prepared to provide cogent reports that are submitted to committees for review, provide recommendations, then implement corrective action strategies.

This is one example from the OIG November 2018 Workplan, there are an approximate 400+ other equally complex activities described.



Source: OIG illustration of physician medical record review process for determining preventability.

Another example from the OIG "Adverse Events in Hospitals: National Incidence among Medicare Beneficiaries," concerns Medicare Hospital Acquired Conditions (HACs). Clearly, the work efforts engaged to develop these patient safety guidelines for the identified conditions relied upon extremely knowledgeable individuals with great integrity and understanding of the topics. The guidelines become problematic though, when EHR vendors are not included in the development of the guidelines and their products cannot meet the requirements of the guidelines.

Table C-1: Medicare Hospital-Acquired Conditions

Conditions
1. Foreign object retained after surgery
2. Air embolism
3. Blood incompatibility
4. Pressure ulcers (stages III and IV)
5. Falls
A. Fracture
B. Dislocation
C. Intracranial injury
D. Crushing injury
E. Burn
F. Electric shock
6. Manifestations of poor glycemic control
A. Hypoglycemic coma
B. Diabetic ketoacidosis
C. Nonkeotic hyperosmolar coma
D. Secondary diabetes with ketoacidosis
E. Secondary diabetes with hyperosmolarity
7. Catheter-associated urinary tract infection
8. Vascular catheter-associated infection
9. Deep vein thrombosis/pulmonary embolism associated with the following
A. Total knee replacement
B. Hip replacement
10. Surgical site infection
A. Mediastinitis after coronary artery bypass graft
B. Associated with certain orthopedic procedures involving the
a. Spine
b. Neck
c. Shoulder
d. Elbow
C. Associated with certain bariatric surgical procedures for obesity
a. Laparoscopic gastric bypass
b. Gastroenterostomy
c. Laparoscopic gastric restrictive surgery

Source: *Fiscal Year 2009 Final Inpatient Prospective Payment System Rule*, 73 Fed. Reg. 48434, 48471 (Aug. 19, 2008).

For example, in the National Healthcare Safety Network (NHSN) Patient Safety Component Manual that addresses the HACs, the complex guidelines are carefully described, flowcharted and referenced to evidence based literature. The guidelines for Urinary Tract Infection (pages 7,1-17) are thoroughly detailed. The Catheter Associated Urinary Tract Infection (CAUTI) data collection form used each surveillance month to report the requisite criteria involves a tremendous amount of data extraction from the patient's medical record. If the

EHR vendor has not provided the capability of these data elements to recorded then extracted from their solution, then providers must rely upon manual extraction and completion of the forms. If providers are not aware of the importance for documenting the recommended data elements, they become overwhelmed by the amount of mouse click counts required to capture the information.

CMS Conditions of Participation

Hospitals are required to be in compliance with the Federal requirements set fort in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment. As set forth in the 546 pages of 42CFR Part 482, hospitals must be surveyed to determine if they are in compliance with the CoP. Certification of hospital compliance is accomplished through observations, interviews, and document / record reviews. The hospital survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that the beneficiary receives safe, quality care and services. The survey process focuses on a hospital's performance of patient-focused and organizational functions and processes. In addition to 6 detailed Survey Protocols, there are 25 sections in the CoP, each with complex requirements to meet CMS standards.

Section §482.43, Discharge Planning describes a process for hospital discharge planning that involves determining the appropriate post hospital discharge destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his/her discharge destination: and beginning the process of meeting the patient's identified post-discharge needs.

The CMS Hospital Discharge Planning Worksheet contains 50+ discreet documentation requirements for a hospital to successfully fulfill the requirements of §482.43, Discharge Planning. Each element requires detailed review the development of hospital and clinician processes, policies, and procedures.

Some examples include

- Does the discharge planning policy address circumstances where changes in patient condition would call for a discharge planning evaluation in patients not previously identified as needing one?
- Can both discharge planning and unit nursing staff personnel describe the process for a patient or the patient's representative to request a discharge planning evaluation, even if the hospital's screening concluded one was not needed?
- Can discharge planning personnel describe a process for physicians to order a discharge plan to be completed on a patient, regardless of the outcome of the patient's evaluation?
- If the hospital identified preventable readmissions and problems in the discharge planning process were identified as a possible cause, did it make changes to its discharge planning process to address the problems?
- Was the discharge planning evaluation and, as applicable, the discharge plan developed by an RN, Social Worker, or other qualified personnel, as defined in the hospital discharge planning policies and procedures, or someone they supervise?

- Did the evaluation include an assessment of the patient's ability to perform activities of daily living (e.g. personal hygiene and grooming, dressing and undressing, feeding, voluntary control over bowel and bladder, ambulation, etc.)?
- If the assessment determined the patient would need HHA or SNF care, did the hospital provide the patient with lists of Medicare-participating HHAs or SNFs that provide posthospital services that could meet the patient's medical needs?
- Does the hospital send necessary medical information to providers the patient was referred to prior to the first post-discharge appointment or within 7 days of discharge, whichever comes first?
- Is there documentation in the medical record of providing the results of tests, pending at time of discharge, to the patient and/or post-hospital provider of care, if applicable?

Each of these sub-set of regulations requires diligent review of the existing policies and procedures of the hospital with all members of the interdisciplinary multi-professional team; not just physicians, but Physical and Occupational Therapy, Speech Language Pathology, Nutrition, Pharmacy, Respiratory Therapy, Pastoral Care, Wound / Ostomy Care, Social Work, Nursing and others as defined by the hospital / healthcare system.

Then the question arises whether the EHR vendor has provided the solutions within their products or whether the solution is capable of being delivered in the EHR, such as the many forms associated with Hospital Discharge Appeal Notices or the ability to obtain electronic signatures on these CMS forms and documents; e.g., "Important Message from Medicare," "Detailed Notice of Discharge," Advanced Beneficiary Notice of Non-Coverage," "Hospital Issued Notices of Non-Coverage," and many others.

Medicare Claims Processing Manual

The associated complex workflow associated with complying with these regulations (Medicare Claims Processing Manual, Chapter 30 Financial Liability Protections) is a large and vast undertaking for any hospital or healthcare system seeking to be compliant with the rules and regulations.

For example, the Important Message from Medicare must be presented to the beneficiary on admission and signed /dated (Sections 200.3.1; 2005.1). Then no less that 24-48 hours prior to discharge, and no greater than 6 hours prior to discharge, the patient is presented the same document for their second signature where they affirm their agreement with the discharge plan (section 200.3.2). If the beneficiary is not in agreement with the discharge plan, then the beneficiary must notify the Quality Improvement Organization (Section 200.4.1). The hospital must notify the beneficiary that the QIO has been provided a copy of the medical record by issuing the Detailed Notice of Discharge (sections 200.6.3).

The QIO must then obtain a complete copy of the patient's hospital record (Sections 200.5.2; 200.5.3, 2005.6) requiring an efficient seamless process for printing the EHR, which is then sent by

courier to the QIO for their review. If the QIO agrees with the discharge plan, the hospital must have a policy in place to discharge the patient, sometimes involving security teams. If the patient still refuses to be discharged, issuance of the Hospital Issued Notice of Non-Coverage is required (section 240.4.1-6; 260.3.1-10).

If the QIO disagrees with the discharge plan, the clinician must cancel the discharge order, while the entire interdisciplinary team gathers to review and plan for a new discharge program.