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Drs. Goodrich and Gettinger:

Allianz Global, LLC 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."

Allianz Global, LLC is a healthcare IT consulting company providing assessments of process, workflow design and solutions, we evaluate how current IT systems are utilized to maximize clinical efficiency and productivity while adhering to principles of revenue cycle management. As a physician informatician, I've been training and educating physicians to use documentation guidelines over 25 years, as CMIO-Physician Advisor to a large urban academic healthcare system in the Bronx, NY, teams under my direction were responsible for the implementation of the hospital's EHR system in the acute, ambulatory and emergency environment, while also serving as the physician advisor to hospital's utilization-case management, social work and continuous documentation improvement departments. Serving as Vice President for Outcomes and Value and CMIO at a global healthcare IT solutions vendor, I had the privilege of working with clinicians and hospitals throughout the United States, England, Canada, Singapore and Australia; gaining insights and experiences practicing medicine while also learning about the delivery of medical and healthcare from numerous perspectives. It was through these experiences and countless engagements with clinicians that I gained insight and respect for the policies, rules, regulations, and programs of HHS, CMS, and OIG.

Allianz Global vigorously supports the HHS Strategy and compliments CMS and ONC for its meticulous efforts articulating an encompassing assessment of health IT regulatory and administrative burdens encountered by clinicians in the USA. From my thousands of conversations with physicians; each seeks to best support their patient's care, provide optimal experiences and outcomes, and believe that the administrative and regulatory requirements should be a byproduct of the clinical documentation provided in the care of their patients.

Administrative and regulatory burden has increasingly grown since the passage of the Social Security Act in 1965. Yet there are many other sources of health IT related burden; various HHS programs including the Promoting interoperability Program and Merit-based Incentive Payment System, the Office of Inspector General Work Plan, the State Operations Manual, and the Medicare Claims Processing Manual that contribute to ever increasing responsibilities of clinicians.

Allianz Global LLC, worked very closely with the American Medical Informatics Association's contributions to their presentation thus you may identify similarities in our presentations.

Most EHRs are designed to support business processes for regulatory / administrative compliance while clinical observation and treatment become secondary to documentation of care delivery. Many EHRs struggle to develop seamless, efficient, easily adopted workflows associated with delivering the complex regulations, rules and standards described in the Medicare Conditions of Participation (CoP), 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[1] describes a multi-step process for hospital discharge planning, which includes a CMS Hospital Discharge Planning Worksheet[2] 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[3] 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.

- 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

These activities and administrative concerns are appropriate and serve our nation well, yet they highlight some of the tremendous complexity of clinician contributed documentation requirements taking place in their offices, hospitals, clinics, ambulatory centers, skilled nursing facilities, rehabilitation centers, patient's homes, and other point-of-care locations related to patient visits. Refer to Appendix A for more detail. Health informatics, health information management, and health IT professionals need

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

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.

The following represents my observations and recommendations across the Strategy's four areas, commenting how to supplement and prioritize the Strategy's numerous Recommendations.

Clinical Documentation

While Allianz Global supports CMS efforts to revise documentation E/M documentation guidelines we have concern that the approach relying on Medical Decision Making (MDM) will increase burden to our providers, particularly those with complex cases.

Current MDM documentation requirements are characterized by the (1) number of diagnoses or management options, (2) amount and /or complexity of data to be reviewed, and (3) risk of significant complications, morbidity and/or mortality.

We foresee similar counting algorithms to the numeric scoring of HPI, ROS, PFMSHx, and PE to produce an E/M level by "click counts" will not reduce the burden to providers.

We recommend evaluating and funding new technologies such as natural language processing to efficiently scan a provider's notes, then using internal algorithmic matrices defined by CMS, tag the record with an E/M code.

When discussing Documentation CMS holds sway over requirements for payment, not clinical utility. While billing documentation might be simplified, we should then seize the opportunity to refocus physician (and other care providers') efforts on optimizing clinically relevant documentation – that which optimizes clinical communication and subtends measurement (e.g. "quality metrics") and importantly enables meaningful computer-assisted clinical decision support.

Allianz Global 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 / transmitted. Indeed, many specialty societies have developed their own resources providing documentation guidelines to their members.[4,5,6,7,8,9] 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.

[4] American Academy of Orthopedic Surgeons
[5] American College of Obstetrics and Gynecology
[6] American College of Cardiology
[7] American Psychiatric Association
[8] American College of Emergency Physicians
[9] American College of Physicians

Health IT Usability and the User Experience

As part of this Strategy, Allianz Global 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.

Below are our recommendations in greater detail where we address the Strategies specific Recommendations. Should you have any questions or require additional information, please contact my office at Robert.Leviton@AllianzGlobal-Consulting.com or (914-715-8102). Again, thank ONC and CMS for the opportunity to comment and look forward to our continued dialog and collaboration.

Sincerely,

Robert Leviton MD

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CEO and Founder
Allianz Global, LLC

January 28, 2018

ONC Recommendations			Allianz Global 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	Allianz Global supports CMS efforts to reform E/M documentation guidelines as part of the CY2019 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. In current E/M documentation guidelines, points are allocated for documenting elements of the HPI, ROS, PE, and MDM. The revision documentation relies upon documenting MDM; yet this has been characterized by the (1) number of diagnoses or management options, (2) amount and /or complexity of data to be reviewed, and (3) risk of significant complications, morbidity and/or mortality. Each of these categories are further divided into “countable” factors; “straightforward (minimal), low complexity (limited), moderate complexity (moderate) and high complexity (extensive). We foresee similar counting algorithms would require clinicians to accumulate click counts to achieve an MDM driven E/M level of service and believe that the current proposal will not reduce the burden to providers.
		Recommendation 4: Waive documentation requirements as	Efforts to implement this recommendation should be aggressively pursued through existing demonstration projects

ONC Recommendations			Allianz Global Comments
		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.	and pilot programs within the CMS Innovation Center, CMMI.
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,96 and increase awareness of tools and resources that can support implementation of best practices	Allianz Global vigorously supports HHS partnering with clinical professional societies promoting an understanding of documentation best practices. Each professional society brings a wealthy perspective to the requirements their clinicians must fulfill to the requirements of their specialties. Furthermore, the partnerships should extend beyond clinical professional societies and include professional societies such as AMIA, AHIMA, HIMSS, etc.
		Recommendation 2: Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models.	Allianz Global vigorously supports CMS developing, promoting and distributing technical assistants, 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

ONC Recommendations			Allianz Global Comments
		• 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 that states and private sector partners can incorporate them into their own initiatives as well.	important learning and education provided by these programs would be embraced by all professionals.
Clinical	**Strategy 3: Leverage health IT to standardize data and processes around ordering services and**	**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	Allianz Global agrees that the current processes for prior authorization requests is burdensome for clinicians. 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 develop a easily understood and widely educated definition of the reasonable and medically necessary

ONC Recommendations			Allianz Global Comments
	related prior authorization processes.	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.	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 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			Allianz Global Comments
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	Allianz Global recommends methods for evaluating the current methodology for 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			Allianz Global 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.	Allianz Global supports incentivization programs that would create new and efficient methods to streamline the prior authorization process and ordering. This would include collaborative efforts with payers, equipment suppliers and EHR vendors. Updating CMS Conditions of Participation (CoP) and State Operating Manual (SOM) guidelines, rules and regulations to define optimal business relationships between the healthcare provider, hospital or healthcare system, patient and provider would provide relief from the tremendous burdens encumbered by the current processes utilized today. Allianz Global 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			Allianz Global 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	Allianz Global strongly encourages CMS to support payers and intermediaries support APM models for standardized electronic ordering of services. 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. Allianz Global fully supports an APM pilot that focuses on efficient ordering of ancillary services.

ONC Recommendations			Allianz Global 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	Allianz Global supports and applauds CMS efforts such as the DaVinci project and P2 FIHR 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. Allianz Global would encourage the NCVHS to carefully align any new ICD-10 diagnosis adoption 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 effortlessly 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	Allianz Global agrees that EHR system design should represent real-world clinical workflow. However, it would be 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			Allianz Global Comments
		help reduce burden by reducing the amount of information required by the physician or supporting staff.	

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*,100 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,	Allianz Global 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. Must 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.

ONC Recommendations			Allianz Global Comments
		standards-based, and patient-centered.	
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.	Allianz Global agrees that speech recognition brings tremendous benefits to the clinical care of patients and should be encouraged by funding pilot programs continued research to improve the technology and adoption.

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	Allianz Global 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, 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, ease of adoption, and present a potential safety risk. 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			Allianz Global Comments
		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.	

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	Allianz Global 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, health care-specific user interface components used to support clinical workflows.

ONC Recommendations			Allianz Global Comments
		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.	
Health IT Usability and the User Experience		**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.	See above regarding the development of standardized symbols, shapes, and colors.

ONC Recommendations			Allianz Global Comments
		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.	See above for NIST funding and support

ONC Recommendations			Allianz Global 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.	Allianz Global 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. It may be a consideration to have Tall Man Lettering become a component of the US Food and Drug Administration's efforts enforcing Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360, the National Drug Code Directory.

ONC Recommendations			Allianz Global 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.	See above for standardized medication information and ancillary test code data.

ONC Recommendations			Allianz Global 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.	See above for shapes, colors, and symbols. CMS should adopt national standards for the representation of data in EHR's. Imagine our national roadway, rail or inland water system functioning without a common set of colors; red, yellow, and green that are clearly understood and appreciated by everyone regardless of education, culture, regional location, etc. EHR must have a similar set of codes, rules and regulations.

January 28, 2018

ONC Recommendations			Allianz Global 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.	Allianz Global 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. Allianz Global would also 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 providers who refine CDS tools, documentation and template designs would greatly benefit end user engagement and training.

ONC Recommendations			Allianz Global 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.	Allianz Global 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]. Allianz Global supports 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 Allianz Global supports adopting language in these sections to include planning and budgeting for Health IT and EHR ongoing support.

ONC Recommendations			Allianz Global 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.	Allianz Global supports this recommendation and we encourage ONC to reevaluate the relevance of the Certification program to assure providers have tools more appropriately focused to support the objectives outlined here.

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	Allianz Global supports CMS efforts to improve the Promoting Interoperability program and should continue to seek insight to evidence based clinical care, aligning measurement of clinical workflow and data collection items from the professional societies, providers, and patients.

ONC Recommendations			Allianz Global Comments
		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.	

ONC Recommendations			Allianz Global 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.	Allianz Global 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	As cited earlier in these comments (Health IT Usability, Strategy 1 Recommendation 1), ALLIANZ GLOBAL 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). Allianz Global 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, Allianz Global 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			Allianz Global Comments
		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.	Allianz Global 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. Allianz Global 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			Allianz Global 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.	Allianz Global 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.

ONC Recommendations			Allianz Global Comments
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.	Allianz Global 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.

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ONC Recommendations			Allianz Global 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.	Allianz Global 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. Allianz Global 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.	Allianz Global 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.

ONC Recommendations			Allianz Global 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.	Allianz Global 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			Allianz Global 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.	Allianz Global 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 Allianz Global enthusiastically supports.

ONC Recommendations			Allianz Global 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.	Allianz Global 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			Allianz Global 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.	Allianz Global 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.

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ONC Recommendations			Allianz Global 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.	Allianz Global 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. Allianz Global also notes 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			Allianz Global 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.	Allianz Global 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. Allianz Global 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			ALLIANZ GLOBAL 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.	ALLIANZ GLOBAL 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. Allianz Global 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			ALLIANZ GLOBAL 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. ALLIANZ GLOBAL 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			ALLIANZ GLOBAL 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.	Allianz Global 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			ALLIANZ GLOBAL 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.	Allianz Global 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. Allianz Global 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 appropriate administrative concerns 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.

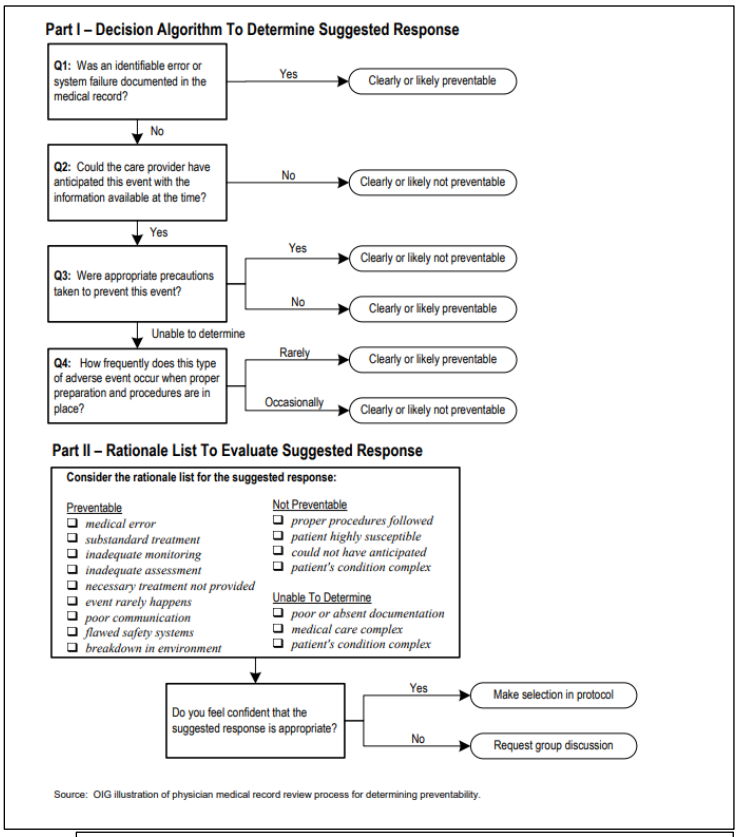
Table B-1: The National Quality Forum (NQF) List of Serious Reportable Events

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. Nonketotic 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.