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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Baltimore, MD 21244-1850

Donald Rucker, MD
National Coordinator for Health Information Technology
US Department of Health and Human Services
Washington, DC 20201

Submitted electronically to www.healthit.gov

Dear Administrator Verma and Dr. Rucker: Thank you for the opportunity to provide comments on the draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.

The Alliance for Nursing Informatics (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represents more than 8,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 3 million nurses in practice today. We have reviewed the draft strategy and we offer our comments as nursing stakeholders.

ANI fully 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. We strongly support efforts to reduce clinician burden and strongly agree that EHR and HIT-related burdens hinder the achievement of true interoperability. Overall we find the document sufficiently identifies the critical issues that influence EHR-related clinician burden. We endorse the three overarching goals proposed to reduce clinician burden as outlined in the strategy document.

In addition, we offer three overarching recommendations for consideration as this strategy is strengthened and refined.

1. **Engage Nurses as key stakeholders**
2. **Align with existing efforts to develop, implement, and maintain standardized clinical assessment data elements across programs, systems, settings and disciplines**
3. **Plan strategic activities to clarify concepts and terms**

We provide detailed rationale below and comments on individual strategies and recommendations are included in the Appendix.

1. Engage Nurses as Key Stakeholders

Nurses are the largest group of healthcare providers, and as [1]such the largest group of HIT and EHR users. We are therefore discouraged that the nursing profession has been largely ignored in this strategy and conversation around documentation burden. Nurses have been shown to incur significant documentation burden, such as data entry every 1-2 minutes during a 12 hour shift[2]. A 2016 study indicated that more than 20% of nurse documentation needed to be conducted outside working hours[3]. These rates are not sustainable for nurses or patient care. ONC must expand their focus on documentation burden to include nurses practicing in many different clinical roles and settings. Evidence has linked documentation burden among nurses to emotional exhaustion and burnout, posing a threat to patient safety. Therefore, there is an urgent need to address documentation burden among nurses.

Nurses are on the frontline of care and are stakeholders in diverse and robust healthcare use cases. Nurses contribute clinical assessment data used for quality and public health reporting. Clinical care includes various professions and disciplines working together toward the common goal of promoting health for patients, families and communities. With this in mind, ANI emphasizes the importance of approaching the strategies and recommendations for reducing documentation burden from a team-based healthcare perspective. This requires the use of inclusive language and the consideration of all the members of the healthcare team and how they contribute to care provision, as well as documentation and reporting. In addition, nurses must be involved in the design of the EHR functions they use and nursing informaticists are experts in user centered design.

Furthermore, ANI would like to highlight that while many nurses may not directly fall under the definition of 'eligible providers', nurse practitioners are considered eligible providers and have independent practice authority in 25 states and one of the US territories. Nurse practitioners evaluate, diagnose, order diagnostic testing, test, manage and prescribe for patients, as well as perform program reporting and fulfill CMS program requirements. Services provided by nurse practitioners are also in many cases covered by Medicare and Medicaid. Therefore, the physician-focused language found in several places in the draft strategy is limiting.

Professional nursing organizations, many of whom are ANI members, are well positioned to support collaboration with others to reduce documentation burden, reference quality measures that support interoperability, and align with the vision for patient-centered care across the care continuum. We offer our professional nursing support and informatics expertise to ONC, and would welcome the opportunity

[1] Institute of Medicine (US) Roundtable on Evidence-Based Medicine. Healthcare Professionals. In: Leadership Commitments to Improve Value in Healthcare: Finding Common Ground: Workshop Summary [Internet]. Washington, D.C.: National Academies Press (US); 2009 [cited 2019 Jan 21]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK52843/

[2] Collins S, Couture B, Kang MJ, Dykes P, Schnock K, Knaplund C, Chang F, Cato K. Quantifying and Visualizing Nursing Flowsheet Documentation Burden in Acute and Critical Care. Proceeding of the American Medical Informatics Association Annual Fall Symposium; 2018 Nov 3-7; Washington, DC (in press).

[3] Ahn M, Choi M, Kim Y. Factors Associated with the Timeliness of Electronic Nursing Documentation. Healthcare Informatics Research. 2016;22(4):270.

for further collaboration. We are available and interested in supporting future public responses on this important healthcare issue.

2. Align with existing efforts to develop, implement, and maintain standardized clinical assessment data elements

ANI has long been an advocate for the standardization of clinical assessment data elements, and commends the ONC, HHS and CMS for addressing the importance of standardization in their recommendations. One example where nurses are key stakeholders is the standardization of health assessments across post-acute care settings supported by the Common Data Element Library. ANI fully supports existing efforts to guide data standardization and encourages the alignment of strategies and recommendations with these efforts. Standardized data elements, eCQMs and use of built-in standard terminology in clinical documentation systems will contribute to data comparability across post-acute care providers, data exchange and interoperability, care coordination, payment analysis, and longitudinal outcome analysis. **We recommend the inclusion of nursing terminologies and encourage the use of the 2017 report prepared by the Office of the National Coordinator for Health IT entitled, Standard Nursing Terminologies: A Landscape Analysis.**

ANI appreciates the emphasis on necessary harmonization between various reporting programs, as communicated in the strategy document. We endorse the use of standardized data elements across reporting programs, as much as possible. We also recommend that every effort be made to ensure that standardized templates and data elements only contain the minimally necessary information and that data already documented elsewhere in the EHR are reused or auto-populated whenever possible.

3. Plan efforts to clarify concepts and terms:

ANI found instances throughout the document where important terms were not clearly defined or the same term is used in more than one way. Similarly we found terms with conceptual overlap (e.g. user satisfaction/ user experience and harmonization/ standardization). To ensure that any policy built from the recommendations in this strategy document be effective, we recommend that additional efforts focus on ensuring clarity and alignment of definitions and terms.

ANI appreciates the opportunity to offer our comments to advance health IT to improve usability and interoperability, with broad ranging implications to the health of the US population. We are available and interested in supporting future public responses on these important healthcare issues.

Sincerely,

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APPENDIX: ANI RESPONSES TO INDIVIDUAL STRATEGIES AND RECOMMENDATIONS

CLINICAL DOCUMENTATION	
Strategy 1: Reduce regulatory burden around documentation requirements for patient visits.	
Recommendation:	**ANI comment**
1: Continue to reduce overall regulatory burden around documentation of patient encounters.	We support this recommendation and recommend the following additional consideration: • Expand focus on documentation burden to include nurses practicing in many different clinical roles.
2: Leverage data already present in the EHR to reduce re-documentation in the clinical note.	We support this recommendation and recommend the following additional considerations: • Specify examples of data types that do not need to be repeated within notes, such as results and reports. • Add additional details to describe how a billing practitioner would be expected to "review, update, and sign off" on data, including use cases where the data does not require updates or changes.
3: Obtain ongoing stakeholder input about updates to documentation requirements.	We support this recommendation.
4: Waive documentation requirements as may be necessary for purposes of testing or administering APMs.	We support this recommendation and recommend the following additional consideration: • Consider increased adoption of model pilots to better understand innovative models and decrease burden.
Strategy 2: Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements.	
Recommendation:	**ANI comment**
Recommendation 1: Partner with clinical stakeholders to promote clinical documentation best practices.	We support this recommendation and recommend the following additional considerations: • Nurses are also significantly burdened by documentation requirements, but are too often excluded from consideration in this area. • Clinical and documentation workflows between physicians and nurses are tightly linked and require collaborative interprofessional insight to result in optimized solutions to these complex problems.
Recommendation 2: Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models.	We support this recommendation.

Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.	
Recommendation:	**ANI comment**
Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.	We support this recommendation and recommend the following additional consideration: • We encourage the exploration of clinical workflow factors contributing to burden to include all staff and clinical roles, not only prescribing providers.
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.	We support this recommendation and recommend the following additional consideration: • We emphasize that care be taken so that standardized templates and data elements only contain the minimally necessary information and that data already documented elsewhere in the EHR are reused whenever possible.
Recommendation 3: Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.	We support this recommendation and recommend the following additional consideration: • We reiterate that documentation burden is also recognized as a significant problem for nurses with implications for efficiency and quality, and reducing burden should be incentivized.
Recommendation 4: Work with payers and other intermediary entities to support pilots for standardized electronic ordering of services.	We support this recommendation and recommend the following additional consideration: • We encourage pilot work to also focus on nursing documentation burden.
Recommendation 5: Coordinate efforts to advance new standard approaches supporting prior authorization.	We support this recommendation and recommend the following additional consideration: • We emphasize the importance of including all relevant stakeholders in these discussions, including nursing, who is involved in many aspects of these clinical processes and documentation.
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:	**ANI comment**
Recommendation 1: Better align EHR system design with real-world clinical workflow	We support this recommendation, and recommend the following additional considerations: • Consider adding alignment with clinical decision making processes. • We recommend that efforts to improve usability and reduce cognitive workload be evaluated using

	measurable outcomes, (e.g. System Usability Scale, NASA- TLX).
Recommendation 2: Improve clinical decision support usability.	We support this recommendation and recommend the following additional considerations: • In addition to improved usability, appropriateness of each alarm should be carefully evaluated to minimize frustration and alert fatigue. • We also agree that predictive analytics is the next step for improved support of clinical decisions, but believe that the algorithms that underlie the prediction should be transparent and allow for individual decisions making.
Recommendation 3: Improve clinical documentation functionality.	We support this recommendation and recommend the following additional considerations: • We believe this important recommendation must be achieved through testing with metrics including task time and click counts. • We wonder if this is the correct title for the content of this recommendation and encourage clarification of the term functionality.
Recommendation 4: Improve presentation of clinical data within EHRs.	We support this recommendation and recommend the following additional consideration: • Consider including improved search tools, perhaps use google type algorithms and simple, easy to see and use search interface.
Strategy 2: Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.	
Recommendation:	**ANI comment**
Recommendation 1: Harmonize user actions for basic clinical operations across EHRs.	We agree that this would be helpful, but we feel it is important to balance the desire to have a common set of actions for basic clinical operations and the need for substantive innovation in this area.
Recommendation 2: Promote and improve user interface design standards specific to health care delivery.	We support this recommendation and recommend the following additional considerations: • Established best practices must be transparent and easy to access for purchasers, clinician users and consumers. The ONC Certified Health IT Product List has the potential to be a good resource, but this must be widely distributed, easy to find and simple to use.
Recommendation 3: Improve internal consistency within health IT products.	We support this recommendation.
Recommendation 4: Promote proper integration of the physical environment with EHR use.	We support this recommendation.
Strategy 3: Promote harmonization surrounding clinical content contained in health IT to reduce burden.	
Recommendation:	**ANI comment**
Recommendation 1: Standardize	We support this recommendation. However, we disagree that this recommendation is limited to

medication information within health IT.	potentially confusing medications and believe that it should be applied across all medications.
Recommendation 2: Standardize order entry content within health IT.	We support this recommendation but found the narrative to refer to collaboration across HIT developers unclear, and recommend more clarity in concepts and title.
Recommendation 3: Standardize results display conventions within health IT.	We support this recommendation and recommend the following additional considerations: • Clinician users should collaborate on this as part of the collaborative team with EHR developers. • Standards for abnormal displays based on usability heuristics should be easy to understand and aligned with real world (e.g. use of red to indicate concerning abnormality and red not used for any other purpose within HIT.)
Strategy 4: Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.	
Recommendation:	**ANI comment**
Recommendation 1: Increase end user engagement and training.	We support this recommendation and recommend the following additional consideration: • We emphasize the need for all categories of clinical users be engaged
Recommendation 2: Promote understanding of budget requirements for success.	We support this recommendation and recommend the following additional consideration: • Consider making post implementation resources a mandatory feature of all EHR contracts.
Recommendation 3: Optimize system log-on for end users to reduce burden.	We support this recommendation.
Recommendation 4: Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden.	We support this recommendation.
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:	**ANI comment**
Recommendation 1: Simplify the scoring model for the Promoting Interoperability performance category.	We support this recommendation and recommend the following additional consideration: Nursing should be included as a stakeholder to assist with the development of program requirements.

Recommendation 2: Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians.	We support this recommendation.
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.	We support this recommendation and recommend the following additional considerations: • We reiterate that burden reduction efforts should not be targeted solely to physicians. As a contributor to team-based care, the reduction of nurse documentation burden is equally important to include in the approach.
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.	We support this recommendation.
Recommendation 5: Revise program feedback reports to better support clinician needs and improve care.	We support this recommendation and believe an integrated feedback loop will best support behavior change efforts.
Strategy 2: Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.	
Recommendation:	**ANI comment**
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.	We support this recommendation and recommend the following additional consideration: • We recommend the inclusion of nursing as a stakeholder and encourage the use of the 2017 report prepared by the Office of the National Coordinator for Health IT entitled, Standard Nursing Terminologies: A Landscape Analysis.
Recommendation 2: Adopt additional data standards to makes access to data, extraction of data from health IT systems,	We support this recommendation and recommend the following additional considerations: • We agree that the use of API technology alone is not enough guidance. We believe in the potential of FHIR-based APIs and support their adoption whenever possible.

integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals.	
Recommendation 3: Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products.	We support this recommendation.
Strategy 3: Improving the value and usability of electronic clinical quality measures while decreasing health care provider burden.	
Recommendation:	**ANI comment**
Recommendation 1: Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures.	We support this recommendation and recommend the following additional considerations: • We fully support the idea of a first-year test with a thorough evaluation to encourage eCQM participation. • Informatics organizations such as the Alliance for Nursing Informatics, and health IT researchers should be enlisted as needed to participate in the evaluation.
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.	We support this recommendation and recommend the following additional consideration: • We strongly support adding more stakeholder feedback to new eCQM development. Since a good portion of the clinical quality measure involves some aspect of nursing documentation, we strongly suggest that nursing be consulted as a stakeholder.
Recommendation 3: Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives.	We support this recommendation and recommend the following additional consideration: • We agree with the exploration of artificial intelligence and machine learning as well as general automation to make quality measurement less burdensome.
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:	**ANI comment**
Recommendation 1: Federal agencies, in partnership with states, should improve	We support this recommendation.

interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Privacy and Security Rules, to improve timely access to medication histories in PDMPs. States should also leverage funding sources, including but not limited to 100 percent federal Medicaid financing under the SUPPORT for Patients and Communities Act, to facilitate EHR integration with PDMPs using existing standards.	
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.	We support this recommendation and recommend the following additional considerations: • Consider thoughtfully exploring the adoption of electronic prescribing of controlled substances, with emphasis on implementation guide development. • We do want to highlight the importance of inclusive language, as a prescribing practitioner can be a nurse practitioner, dentist, veterinarian and several other professions beside physicians.
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:	**ANI comment**
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	We support this recommendation and recommend the following additional consideration: • We continue to strongly endorse the continued convening of and engagement with key stakeholders, and offer our services as nursing informatics stakeholders. We support the collaborative effort to identify common data elements.

health departments and federal program-specific reporting platforms.	
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.	We support this recommendation.
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.	We support this recommendation.