Alex M. Azar II
Secretary of Health and Human Services

Donald W. Rucker, MD
National Coordinator for Health Information Technology

Seema Verma, MPH
Administrator, Centers for Medicare & Medicaid Services

Dear Sir/Madam,

As a member of a Quality Management team at a local non-profit community based healthcare hospital my focus is to review regulatory requirements and monitor/manage those activities to assist providers in being successful in meeting Interoperability requirements. I also participate in a vendor based Regulatory Council with 10-15 other members who are involved in their regulatory/Promoting Interoperability (PI) initiatives. This Council provides input and feedback to the EMR Vendor on how the vendor can assist in meeting the needs of the healthcare industry in meeting the regulations via software development/enhancements. As a result, the Council is well informed on regulatory requirements and how those impact organizations having to meet PI requirements. I believe my role/responsibilities allow me an insight into regulations as an individual who supports an organization and I appreciate the opportunity to provide valuable feedback to CMS, ONC and HHS with respect to the Burdens of Regulatory and Administrative impacts related to Health IT and EHR's and look forward to continue Promoting Interoperability through use of EHR systems.

Sincerely,

Raymon Nance

Acute MU/eCQM Coordinator

Comments: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (by Raymon Nance)

Comment Period due January 28, 2019

Topic: BURDEN REDUCTION GOALS
This report outlines three primary goals informed by extensive stakeholder outreach and engagement for reducing health care provider burden:

(1) Reduce the effort and time required to record information in EHRs for health care providers during care delivery.
(2) Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations.
(3) Improve the functionality and intuitiveness (ease of use) of EHRs.
 (page 10)

Comment: While I support and commend ONC/CMS and HHS on the development and focus on Burden Reduction Goals, with specific emphasis on #3 (Improve the functionality and intuitiveness, ease of use, of EHR's) these goals independently make sense but collectively are, in many cases, counterproductive. For example, (#1) in order for organizations to implement/modify the EHR's such that the time and effort taken to record information providers collect is reduced, significant time and effort is required by vendors and organizations. Physicians are typically trained in a systematic process for documentation such that data is both discrete and text. Not only is adjusting to using a EHR difficult (different than what they trained on and/or implemented to meet PI) but in order to meet (#2) the goal of reducing time required to collect data for regulatory requirements, EHR's are modified to increase (for data collection ease) the amount of data required in a discrete format that limits the provider's ability to easily and quickly document information for the current encounter while creating data standards (i.e. CCD's) for the next provider of care. So while both of these are independently achievable, collectively they create challenges and issues for (#3) improving the functionality and ease of use of the EHR's. Therefore, in order to meet all three goals, allowing vendors and organizations the ability to (with ease and utilizing the EHR to generate data as a 'byproduct' of the collection of the data) have systems which are able to collect discrete data that is key in the care of the patient at the next step in their care but to also allow (for example progress notes) textual notes that are free text to allow provider to provider communication in a way they were trained. Additionally, there should be (and will be as the new age of physicians enter the patient care arena) a way that that providers who embrace a fully discrete collection of data and those who need 'textural' notes for communication to the next provider of care can be supported while making access to and use with the EHR's 'easier'. With this approach (having their cake and eating it too versus a round peg in a square hole) providers should be able to engage in the EHR, while collection of data becomes a byproduct of the tool all reducing the burdens for BOTH Providers and Data collectors.

Topic: Evolution of the HITECH Act and impact on EHR's for meeting meaningful use of technologies.
 (page 10)

Comments: I would like to commend HHS, CMS and ONC on the efforts undertaken to get the healthcare industry (primarily EH, CAH and EP providers) to the point it is today with respect to Interoperability. While there have been challenges (and continue to be) meeting the aggressive timelines established (by that meaning final regulations released with quick implementation requirements versus a 18-24 month final rule to implementation), the overall intent of moving to platforms where data can be exchanged as a byproduct of EHR data collection efforts is supported. The comments contained within should be considered supportive of the overall strategy with emphasis on specific challenges seen in implementation and workflow considerations. Again, I support the overall strategy/goals outlined in the HITECH Act and Meaningful Use (Promoting Interoperability), but request continued patience and end user input into the goals, objectives and overall timelines required to meet the regulations.

Topic: HEALTH IT USABILITY AND THE USER EXPERIENCE
As EHR adoption has increased in health care settings, so too have concerns about the user experience.[22] The user experience is often closely related to the usability of a health IT product.
(Page 30)

Comments: I agree that usability is related to the health IT product. However, usability (in the case of MU/PI) has been complicated because of the ever changing regulatory requirements that 'force' collection of data in a specific way for specific measures. For example, healthcare organizations that have implemented their current EMR in the last 5+ years have multiple years of implementation, custom workflow implementations, design decisions that defined how customized data collection occurs. At the start of MU/PI, many organizations started the daunting task of redesign work to modify workflows and data collection strategies (i.e. moving from non-discrete data elements to discrete data elements) to satisfy the requirements. This, depending on the organization, can be a significant resource challenge using in house and consulting resources. Some EMR's provide 'content' with implementations/upgrades to help with implementation however, the ability to customize the system to meet end user and operational requirements is available. As organizations continue down the path of customization, they vary away from the 'content' method that the vendors develop everything towards. Therefore, organizations which have implemented new installations of EMR's **during** the MU/PI program, have the benefit to adjust workflows and processes while those regulatory changes are happening. However, organizations which have EMR's in place for multiple years where workflow strategies and systems are developed, trained and educated to have a greater challenge for 'reinventing the wheel'. I agree that usability is a challenge and while it is possible for mature installed systems to be 're-engineered' to meet the requirements, it is not something that can quickly change, be retrained and implemented. Therefore, it is my recommendation that ONC/CMS/HHS consider appropriate timelines for vendor and/or organizations changes to meet the requirements. It my opinion that a runway of 18-24 months for vendor development and 18-24 months for organization/provider implementation would be optimal for usability improvements.

Topic: ONC also works closely with other federal agencies, including the Agency for Healthcare Research and Quality (AHRQ) and NIST, on matters concerning health IT usability.
(Page 30)

Comments: I appreciate ONC's attempts to coordinate the efforts across multiple agencies where possible. And while all coordination of regulations, reporting requirements and data needs is appreciated and benefits the overall goal of interoperability, there are other opportunities that ONC and other regulatory bodies should consider when developing and/or validating the needs of the vendor/participant community. I realize that ONC may include end user community input, but the challenge is that typically organizations that are 'academic institutions' have the resources and time to dedicate for user experience input. That said, greater emphasis for those community based, non-profit organizations to be able to provide input given their challenge should be considered. That input could be considered at the development, testing and prior to finalization of the rules for consideration. As noted before, the biggest challenge for these smaller, community based, non-profit organization is the time at which changes are finalized and then expected to be implemented. Resources (both financial and physical) are limited and having an appropriate 'roadway' to allow for the vendor development (18-24 months) and then organization implementation (18-24 month) post finalized rule would be beneficial.

Topic: Technical standards have been developed and balloted to enable better EHR-PDMP integration, but have not been consistently implemented across state PDMPs. States also have varying rules governing the use of PDMP data, which translates to variation in technical architecture and the electronic interfaces that enable integration. This variation also means that EHR vendors need to accommodate up to 50 different PDMPs in onboarding users across states. HHS appreciates the need to encourage providers to consult PDMPs. As a result, in the FY 2019 IPPS/LTCH PPS final rule, CMS finalized adding two new measures to the Electronic Prescribing objective that are based on EPCS: Query of PDMP and Verify Opioid Treatment Agreement. These align with broader HHS efforts to increase the use of PDMPs to reduce inappropriate prescriptions, improve patient outcomes, and promote more informed prescribing practices. (Page 43)

Comments: It is my opinion that the utilization of a PDMP solution will improve quality of health care by reduction of opioid use. And while many organizations are aggressively working towards the full implementation of a electronic PDMP solution, CMS/HHS has accurately identified one of the key challenges with implementation of a PDMP solution (or any other technical requirement). The fact that vendors will have to 'accommodate up to 50 different PDMP's, outlines the greater challenge for providers and organizations for implementation. Yes, Vendors will eventually be able to (at significant cost and time) create a solution but it will be left to the individual providers/organizations to work through the workflow, integration and interface issues with the state. Because the states are different, in the absence of one industry/national standard, one size DOESN'T fit all. Therefore, I believe the implementation of a PDMP regulation can be valuable, the amount of time and resources at the vendor and organization level is significant and thus the timeline which has been outlined is unrealistic. And while the PDMP requirement for Promoting Interoperability is 'optional' in 2019, vendors still have/need 18-24 months to create the solutions and providers/organizations need an additional 18-24 months to implement. The greatest challenge with that is the need to fight and address the Opioid crisis 'demands' quick and immediate solutions/options. However, those must be developed cost effectively and with streamlined processes to implement in order for them to be most effective in EHR systems.

The following details comments related to each of the 'recommendations' outlined in the report:

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. (Page 46)

Comments: I agree that the documentation in the EHR to meet billing requirements is excessive and can cause 'note bloat'. However, until all payers (commercial, private pay, etc.) embrace this process, the provider/organization will still be required to document required information needed for payment purposes regardless of the reduction for CMS billing needs. And while it could be considered to document only what is needed for the payer of the patient, doing this would create a greater burden of systems that would 'lead' the provider down a path of required documentation and/or updated documentation if payers change during the billing cycle to be compliant. Therefore, it is my

recommendation that while this reduced documentation is beneficial for Medicare billing, CMS should work to get other payers to accept this reduced documentation so that 'one size WOULD fit all'.

Recommendation 2: **Leverage data already present in the EHR to reduce re-documentation in the clinical note.** (Page 46)

Comments: I concur that initial implementations of EHR's translated a paper based systems into an electronic version of the paper based system. Much of that was due to the fact that end users (and vendors) struggled with how to effectively transition having been based in paper processes for years. Not until an electronic solution is implemented and utilized in a real working environment does an organization understand how building the electronic EMR can be more effectively designed. However, that requires a complete 'rebuild' of the implemented system (which creates significant challenges in modifying a solution that is being used while being modified) or a 'rip and replace' strategy so you can design/build a new solution while the current one is being used till go live. Regardless, either of these are (for the most part) not cost effective for many organizations. Therefore, in order for most organizations to be able to transition effectively, required changes (i.e. regulations) have to be slower and structured such that appropriate time, resources (financial and human) can be utilized without significantly impacting the financial position of the organization.

Recommendation 3: **Obtain ongoing stakeholder input about updates to documentation requirements.** (Page 47)

Comments: I think CMS/HHS is on the correct path by aggressively including all resources in input to the documentation requirements. For that, I commend you. What I would additional recommend (or expand on this recommendation) is to utilize 'test partners' for those inputs. This means that once the documentation requirements are in place, allow time for a group of validation partners (both vendor and end users of various size and complexity) to enter into a testing pilot which would take the information and develop a solution and utilize in a normal workflow to see how and what impact these changes would have on an industry. Once those validation partners provide input, then take those suggestions/recommendations into consideration before publishing a final regulation. This would help to maximize the acceptance of the changes as well as reduce removal of regulations that in a year or two are removed because of complexity or lack of support.

Recommendation 4: **Waive documentation requirements as may be necessary for purposes of testing or administering APMs.** (Page 47)

Comments: Similar to recommendation 1 comments, while reducing documentation requirements will be overall beneficial to providers, until such documentation requirements are eliminated/reduced for ALL payers, the need to be able to document isn't reduced and in fact, can increase complexity. Therefore, having solutions (which will be costly to vendors) that can flex based on payer requirements or standardization of documentation requirements across all payers will be the ultimate burden reduction strategy.

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. (Page 48)

Comments: I support and embrace this recommendation. And while 'best practices' can/will be utilized as success stories are provided, it is still a challenge in making changes (at the local level) quickly due to the embedded workflows in place which will be somewhat disruptive until in place. This recommendation is a powerful one and I support the direction with the understanding it is a slow/every changing process that will require resources (for research, system modification and implementation).

Recommendation 2: Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models. (Page 48)

Comments: I believe implementing Best Practices (as long as they are appropriate and applicable to quality care) are overall beneficial. However, there is one 'key' word in the recommendation that CMS/HHS needs to focus on.
"Learning materials developed for these initiatives should be made public so that states and private sector partners <mark>can</mark> incorporate them into their own initiatives as well."
I recognize (and appreciate) that CMS/HHS is not in the business (nor desires to be in the business) of forcing workflows and best practices on providers/organizations. However, when using the word 'can', CMS/HHS has left the option open such that providers/organizations CAN choose to accept and/or reject best practices. CMS has through regulations 'forced' the implementation of Best Practices in the past. Once example is the introduction of the PDMP requirement for Promoting Interoperability Stage 3. A byproduct of the PDMP regulation 'forces' all organizations, should they choose to continue down the Promoting Interoperability path, to implement EPCS in order to comply with the PDMP requirement. By doing so (outside the needed implementation timeline recommendations), CMS/HHS improves the EHR usability and interoperability throughout all organizations. Additionally, CMS standardized CCD's such that the exchange, incorporation of the CCD's can be across all venues thus promoting interoperability. Therefore, while I understand CMS/HHS desire to not 'force' best practices across the healthcare industry, by providing incentives (or penalties) from lack of utilization of those best practices may encourage a quicker and more robust utilization of best practices. With that said, best practices should be documented and supported by leading healthcare organizations across the majority of systems and not just academic healthcare or large for profit institutions.

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. (Page 48)

Comments: I support the concept of including clinical stakeholders in the development of strategies to reduce the burden of clinical documentation. Additionally, I would suggest, in addition to professional society members, inclusion of smaller organizational stakeholders in those discussions and pilots to assure a comprehensive look at how large and small entities approach documentation requirements.

Recommendation 2: Advance best practices for reducing documentation burden through learning curricula included in CMS Technical Assistance and models. (Page 48)

Comments: I fully support the idea by CMS to include best practice documentation reduction in the technical assistance of the transformative initiatives such as TCPI, QPP-SURS, QIOs, etc. Making these materials public will assist organizations in having access to best practices to consider when attempting to reduce documentation burden.

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

Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization. (Page 49)

Comments: I agree that the prior authorization ecosystem is challenging and presents many roadblocks for workflow efficiencies. In addition to the 2 noted ways to engage stakeholders in this process review, I believe that standards set for all payers preauthorization requirements would streamline (at the vendor development level) the work and options across payers and thus as a byproduct would streamline the data collection and preauthorization tasks. These 'standards' would be best developed by utilizing (as noted in item 2 by CMS) existing data in the EMR to reduce the total authorizations needed.

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. (Page 49)

Comments: I agree that this 'standardization' of transactions would provide the base in reducing burden in prior authorization processes. These 'standards' do not only impact prior authorizations but all data requests across payers/states and standardization will help to streamline not only the workflow processes at the end user level but the development phase were vendors can focus on system improvements and less time on variations across payers and states for the 'same' data requests that are expected in different forms.

Recommendation 3: Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes. (Page 49)

Comments: Everyone loves incentives. And while that certainly is an option, I believe that system wide standards (not only in prior authorization but in many other solution needs) that most vendors and organizations/providers will embrace standards that are applied across all payers/states. By having ONE standard, it streamlines the vendor development requirements (to support multiple payer/states) which should reduce costs and thus would mean less cost to organizations. Having one standard (in prior authorizations for example), staff can be trained to a single/standard process, tools can/would be developed to function the same way for all payers and costs for reducing those burdens would be realized. One example is the recent requirement of API requirement for the View, Download and Transmit measure for PI (Promoting Interoperability). By allowing vendors to develop proprietary API solutions and not requiring those to follow the SMART on FHIR standards, organizations (while compliant with meeting PI), do not have solutions that will quickly and easily 'fit' into the industry that is

moving forward utilizing the FHIR standards. Therefore, setting standards where it makes sense (and cost effective) reduced reporting burdens while at the same time saving costs long term.

Recommendation 4: Work with payers and other intermediary entities to support pilots for standardized electronic ordering of services. (Page 49)

Comments: I support and agree that HHS/CMS involvement in engaging appropriate payers/intermediaries in these standards will pay huge dividends long term to development as well as acceptance in the end user communities.

Recommendation 5: Coordinate efforts to advance new standard approaches supporting prior authorization. (Page 50)

Comments: I support HHS commitment to work to develop/advance new standards across payers/states. In addition, I believe (and this may be where incentives will pay dividends) that 'forcing' payers/states to adopt those standards (once appropriately vetted and finalized) as well as vendors/organizations to implement in systems and workflows will be necessary for these standards to provide reductions in burdens for reporting and administrative work.

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. (Page 51)

Comments: I concur that EHR systems should align with 'real-world clinical workflows'. However, one size does not fit all. Many organizations have been fortunate enough to have a solution that allows for flexibility/customization to fit the needs of the organization through vendor designed customization tools. Many EHR vendors also provides a 'best practice content' packages which if followed would streamline data collection. However, because of years of system needs and workflow practices, these customizations sometimes create (years after initial implementation) challenges. Some EHR vendors do not allow customization FORCING organizations to follow the EHR's steps in data collection which means re-engineering the practice workflow and retraining staff. Therefore, while I understand the recommendation, the development of standards for data collection of information needed to share across payers, states and systems is a greater need than forcing what some (primarily academic) institutions believe are best practices. The development of standards will have an underlying impact on workflows creating streamlined efficiencies.

Recommendation 2: Improve clinical decision support usability. (Page 51)

Comments: I support the argument that improved CDS and integration with critical clinical data information is valuable in not only reducing burdens but improving patient care. Alert Fatigue is a real issue but with better solutions that are more specific to conditions by diagnosis which require immediate attention versus notification alerts based on general conditions efficiencies will be identified. The development of 'computable content for interoperable CDS that are shareable, standards-based, and patient-centered' is a methodology that will yield great benefits to patients and caregivers.

Recommendation 3: Improve clinical documentation functionality. (Page 52)

Comments: While I agree that less burdensome methods of data collection (for free text, template completion and 'smart' document creation) is needed, the greater challenge is the costs associated with those solutions. I am aware of an enterprise speech recognition solution estimate for a small organization, the cost was near the $500,000 range (plus training and maintenance). In addition to the costs, the speech recognition software had not matured to the point that would reduce 'edits' and 're-typing' of commands to the point where efficiencies would be gained. While I support the idea, organizations who have to decide whether to invest budgets in software/hardware IT solutions or patient care needs (i.e. MRI's, Cat Scans, etc.) it easy for to make the decision in delivering quality patient care. As CMS moves forward on this recommendation, finding ways that new technologies are cost effective is key to adoption by all organizations.

Recommendation 4: Improve presentation of clinical data within EHRs. (Page 52)

Comments: Significant advancements in how data is displayed to clinicians have been made over the past several years. Longitudinal views of patient information are possible, subject to the EMR vendor's capabilities, but is also a decision that the end user community has to embrace. Being able to provide this information to the patient in a longitudinal format should be relatively easy (as it has been accomplished at the provider level) but should be configurable by the patient because patient may want episode views instead. Scanned documents do present the greatest challenge but until such technologies are vetted that effectively scan/index the scanned documents themselves, the utilization of physical resources to extract and index the data. Because of the financial pressure on healthcare organizations, any solution to automate extraction/indexing of scanned documents will be prohibitive in nature thus creating a greater gap in the market. If standards (for document storage like in a library) could be implemented with artificial intelligent means, then maybe vendors can provide solutions which are cost effective and able to streamline searches and retrievals. Until such time, entities (regulatory, vendor, payer and healthcare) should work together to develop tools and standards that would be used across industries (similar to FHIR standards) used to improve efficiencies.

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. (Page 53)

Comments: In the absence of a EMR monopoly, standardizing the GUI and workflow steps within disparate EMR's will be a challenge. In fact, the competition created by 'uniqueness' in systems is what provides a competitive market for organizations to choose from. That said, having a forum where EMR vendors can collaborate in workflow designed and user interfaces can benefit the end user community where end users work in various environments. I understand this would be a great challenge in that no other industry, like Banking is required or forced to have standard GUI and workflow steps. It would be my recommendation to start with a subset of the identified elements (i.e. Med Reconciliation, Lab/Rad/Med ordering, etc.) to see what possibilities exist with respect to standardization without breaking antitrust laws. Therefore, while I'm supportive of the idea it needs to be understood that it could come with significant hesitation on the part of vendors unless it comes with penalties that force that collaborative interaction.

Recommendation 2: Promote and improve user interface design standards specific to health care delivery. (Page 53)

Comments: While I support the concept/idea of improved user interface design standards, it has to be understood that these 'differences' across EMR systems is what vendors use as a marketing tool. So to take away the variations without allowing EMR systems to be 'unique' and have a better way of managing data (than the competition) means creating a similar system that is developed by multiple vendors. This, in essence, eliminates a market with variations (i.e. a Chevy Silverado LT package versus a Chevy Silverado LTZ package) whereby vendors can differentiate themselves and 'charge' for that variance. It will be a delicate balance to force vendors to have standard workflows but at the same time allow variations that make them competitively different. Being able to include/incorporate end user resources, input and design into the final products can improve GUI and workflow designs. Therefore, focusing on that aspect of the standards may prove to offer greater benefits than to force EMR vendors to have similar screens, clicks and designs.

Recommendation 3: Improve internal consistency within health IT products. (Page 54)

Comments: I have seen (when the systems were designed and built within the EMR's vendor wheelhouse) improved consistencies across systems. Where the challenge becomes greater is vendors that purchase third party products and attempt to 'merge' them into their suite of products without consideration of workflow. Additionally, organizations who take the 'best of breed' approach for system selection/implementation find themselves with inconsistencies across the solutions. That said, being able to purchase and/or integrate solutions that provide the greatest value to the organizations (vendor or provider) can mean better pricing and meeting the specific needs. I feel if standards for data output were created (similar to the API and/or CCD requirements of PI3), then the resulting system development would support those standards and less variations would be found. Yes, systems may have a different approach (clicks) on how to get to the data but if the underlying requirements are standard, it generally tends to force development to be more consistent. For example, eRX ordering requires identification of the pharmacy, identification of the drug name, route, frequency, dose, etc. and an authorized individual. Since there is limited variability in what data is required for a eRX (and more specifically a EPCS) order, the variation of how that is accomplished is minimized. Thus creating the standard elements needed to meet the needs drives the design as well as workflow in many situations.

Recommendation 4: Promote proper integration of the physical environment with EHR use. (Page 54)

Comments: The Implementation of an EMR is only one aspect of the overall total cost (initial as well as ongoing) of a project. And while technology plays a key role in the overall success and utilization of that solution, it is not always evident of the 'best practice' of the technology use until it is actually implemented and used in a production environment. For example, organizations can spend many man hours designing a new ER suite to include in room workstations, remote devices (computers on wheels), portable devices (laptops), etc. However, once the systems are in place and patients are being seen in the new ER Suite, it is typically learned that placement of devices, number of remote and/or portable devices was not as optimal as initially thought. Therefore, redesign, reengineering and relocation of equipment occurs to streamline utilization. This is an ongoing process as 'one size does not fit all' and means significant resources (both financial and human) to make adjustments.

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

Recommendation 1: Standardize medication information within health IT. (Page 55)

Comments: I support the concept of standardizing medication information with the EMR. Most organizations look to the EMR vendor for best practices/approaches for utilization and displaying of that data. Developing standards that EMR vendors will utilize/adapt to and forcing those standards at the industry level will assist in reducing burden.

Recommendation 2: Standardize order entry content within health IT. (Page 55)

Comments: I support this recommendation. In fact, this type of 'standardization' would allow for common data collection/entry needs while allowing vendors to create solutions that are different in presentation, workflows, etc. that can provide competitive advantages while standardizing the underlying data needs which will lead to reduction in burdens for clinicians. Additionally, as a byproduct, this should standardize and clarify the information that hospitals have to provide, per regulation, in price transparency so that patients can better understand pricing options as well.

Recommendation 3: Standardize results display conventions within health IT.

Comments: While I understand the intent of this recommendation, providers have different opinions (sometimes based on specialty, training, etc.) on the order of how results should be displays for their specific needs/requirements. Therefore, while I support the idea of a standard for WHAT information should be displayed for results (to create consistency across solutions), having the ability for organizations at the specialty and/or provider level to create the view (order, format, etc.) of those results will provide more acceptance of EMR solutions by providers versus a 'one size fits all'.

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.   (Page 56)

Comments: I concur that inclusion of clinical users in the design, implementation and ongoing training is key to successful EMR implementation. However, with that comes a price. Typically, resources pulled to participate in system design and implementation and resources required for ongoing training are not 'profit' department. With the ever increasing pressures for reimbursement in healthcare the challenge of finding the balance of support departments is ongoing. Where the organization can drive the design/implementation timeline (meaning not rush due to unrealistic deadlines), success of those solution implementation seems to be more successful and less burdensome. However, regulations create/require quick action from vendors to develop solutions that will meet regulation requirements thus forcing organizations to rush timelines to implement. This makes it where organizations typically put in place solutions that are designed, developed and implemented by vendor/consulting resources with minimal in house clinicians. And once solutions are implemented, the costs to 're-engineer' or replace those systems become challenging to overcome. Therefore, for this recommendation to

become 'valid', the timelines which regulatory requirements are forced to be implemented in must be more realistic with respect to vendor development and organizational implementations.

Recommendation 2: Promote understanding of budget requirements for success. (Page 56)

Comments: In general, if asked, EMR vendors can and will provide the total estimated ownership costs associated with a system/solution implementation. The issue is not the lack of information about the costs of ownership, resources who know budgeting and budget planning or qualified resources (both local and healthcare groups like Vizient, etc.) to assist with budget negotiations. Rather, the challenge is the needs that compete with the financial resources (capital and operating) that are needed. For example, organizations have to work through the budgeting process in order to determine what fiscal resources are available for capital investment which includes renovations, new/replacement of imaging technology, lab system and/or IT requirements, etc. Therefore, the challenge is not just linked to better knowledge of costs and negotiation techniques but access to funds in an ever challenging reimbursement model. Therefore, it is my opinion that this recommendation is already in place, just the challenge is associated with finding additional funds in a reimbursement model that keeps small, rural not for profit healthcare organizations at a near breakeven margin.

Recommendation 3: Optimize system log-on for end users to reduce burden. (Page 57)

Comments: Once again, I concur that inclusion and expansion of bio-metric authentications can, and possibly will, improve end user satisfaction and reduce burden of multiple logins and passwords. I am aware of one such solution (excluding costs of training and maintenance) was close to $500K for a 400 bed hospital. Therefore, decisions have to be made whether to spend those funds on end user ease of access solutions or patient care needs. In an environment where there are not competing projects for finances, organization will have embraced many of the ideas/recommendation that are noted in this document to reduce the burden of the end user. However, difficult decisions MUST be made and most organizations will choose to put the patient first. I have seen collaborative work with EMR vendors to reduce login time and issue outside of the costly and complex solutions on the market today.

Recommendation 4: Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability, and reduce burden. (Page 57)

Comments: I support this recommendation by the implementation of standards that EMR vendors (and organizations) must follow. For example, the API requirement for PI is the future of functionality and interoperability. However, since CMS didn't require SMART on FHIR specifications as the baseline for the solutions, there are vendors who are developing proprietary API solutions (which is allowed by the regulation) making the integration of systems/data a greater challenge than if all vendors were required to follow the same standard. I believe that once these standards are in place, a quicker approach to data interoperability as well as alternative solutions for patients to access their health data will occur.

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. (Page 58)

Comments: I agree that the modifications made in the 2019 rulemaking cycle assists in the reduction of burden of the healthcare providers. It wasn't necessarily a change that reduced (initially) the burden of healthcare vendor's workload as challenges still exist in vendor development with not only meeting PI requirements but Certification Code requirements (some independent of each other) in a short 'runway' due to deadlines of regulation changes and program reporting deadlines. I think it would be beneficial to see an alternative to the Quality reporting measures to something similar to the PI reporting. Moving to eCQMs is challenging but to reduce burden and have data collection to be a byproduct of the EMR, it is necessary. I would propose that moving to a point system with Quality reporting across all regulatory agencies would significantly reduce reporting burden and allow organizations to focus on those measures that are meaningful for patient care at the same time migrating to electronic measures as resources (both human and fiscal) allow. Here is an example which I believe would be beneficial for progressive organizations as well as those working hard to move forward but find themselves overwhelmed with variations in reporting requirements due to lack of standards across regulatory agencies:

The greatest program changes which would reduce eCQMs cost would be the alignment of program reporting across multiple agencies. While, via this proposed rule, CMS has made an attempt to do that by eliminating redundant measures the continued alignment where a set of measures could meet ALL programs would be the ultimate goal. Understanding that can be complex and would not be something that could be done in a year (because of the 'runway' needs for 24 months of development/implementation once finalized) being able to have a list of 15-20 Measures that could be submitted by organizations in a format best suited for their organization (i.e. Abstracted, Claims based, Hybrid and/or eCQMs) that would meet all measures would be ideal. For example, CMS (for MU) and TJC aligned so that a selection of 4 measures from a self-selected quarter would meet BOTH measures inclusively. While that has been successful for some, it could be that organizations could meet 3 of those but the 4th would need to be abstracted. If CMS could align all programs such that (for example) out of 20 possible measures, an organization could submit 6 (and they could choose to submit via any of the afore mentioned methods) measures that would satisfy ALL programs, the reduction in costs would be tremendous (long term – as it would take significant time/resources to convert some measures to eCQMs and/or be able to submit. Additionally, if CMS and the State Medicaid agencies could work more closely together to allow/force State Medicaid organizations to accept 100% of the data submission on CMS timetable the data it would significantly reduce the burden of reporting for organizations. For example, because of CMS delays in reporting requirements the past 2 years (2016 and 2017 CY), the state's Medicaid organizations would not alter/adjust their timelines and thus forced organizations who had successfully submitted the appropriate eCQM's to manually submit all 16 eCQM's to meet the states deadlines. This added (at the last minute) significant burden of reporting to organizations which were faced with this process.

Similar to the PI Objective Measures, maybe CMS could implement a 'point system' that could be used in the Quality Measure segment. Reporting of each Quality Measure is granted 3 points for abstracted or claim based measures, 4 points for Hybrid measures and 5 points for eCQM measures. Bonus points are given (up to 5 points) for voluntary measures that are being considered for inclusion. With a selection choice of 20 total measures, a minimum of 30 points is required to meet the requirement. This would satisfy ALL reporting programs including (but not limited to) CMS/PI, TJC, IQR, VBP, etc. Overall the idea is to have the ability to choose measures that are best suited for the organizations quality needs, reduces

the requirements for complex abstracted and electronic measures across various programs if eCQMs are easily available and allow measures to satisfy multiple programs with single data submissions.

Therefore, I support the change in scoring model and encourages CMS to consider similar models within the Quality area as well as aligning all regularity agencies to use/accept quality measures across venues.

Recommendation 2: Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians. (Page 58)

Comments: Because 'one size doesn't fit all', I support the concept of looking at alternative ways for incentivizing organization in using health IT to promote interoperability. By having alternatives, it opens the options for organizations to meet specifics requirements that make sense from a resource perspective as well as patient care. It should be noted that creating the underlying standards for these alternative strategies (i.e. utilization of SMART on FHIR specifications) should be considered as an element to assist in reducing variations in reporting across EMRs, regulatory agencies, etc.

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. (Page 59)

Comments: I support the recommendation of reducing burden by improving and/or developing health IT measures that focus on interoperability, relevance to clinical practice/patient improvement and electronic data collection that aligns with clinical workflow. Reducing steps/clicks is a key 'satisfier' for end user acceptance.

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. (Page 59)

Comments: Probably one of the greatest challenges is the differences between the requirements of Federal Medicare reporting requirements and other agencies. Aligning the federal and state programs where there is similar reporting needs would reduce the reporting burden for organizations.

Recommendation 5: Revise program feedback reports to better support clinician needs and improve care. (Page 60)

Comments: I agree with other clinician feedback and supports the ongoing efforts to revise program feedback reports to assist clinicians in understanding current trends, ways to improve care and analyzing data provided.

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. (Page 61)

Comments: I concur with this recommendation. Additionally, creating 'standards' that are enforceable and beneficial to the overall long term interoperability strategy should be a focus.

Recommendation 2: Adopt additional data standards to makes access to data, extraction of data from health IT systems, integration of data across multiple health IT systems, and analysis of data easier and less costly for physicians and hospitals. (Page 61)

Comments: Use of standards such as FHIR API and USCDI and their application/enforcement of use should provide benefits long term to interoperability. The challenge becomes when solutions (such as API's) are not 'required' to use standards such as FHIR or other industry accepted standard rather allowing (through certification processes) vendors to develop their own proprietary solution. This creates differences in standards (i.e. not all HL7 messages are the same across vendors as some segments are utilized differently) which ultimately negate the overall goal of reducing the burden to achieve interoperability.

Recommendation 3: Implement an open API approach to HHS electronic administrative systems to promote integration with existing health IT products. (Page 62)

Comments: While I agree and support the implementation of an API by HHS to achieve these goals, the term 'OPEN' needs to be considered carefully to assure that this will not create a set of non-standard systems that create additional vendor development needs across solutions. For example, a hospital implements an interface (assumed to be based on HL7 standards) between their registration/billing system and their clinical system, it is assumed they are developed following standards that could be a 'plug and play' for another organization with the same registration/billing and clinical systems. However, that is typically not accurate and additional modifications and customizations to make the interface work for the second hospital is required. Therefore, solidifying the standards that hold all vendors, organizations and development teams to the same requirements could reduce rework and burden by organizations and vendors in system integration/interfaces. Without this, costs are generally higher and updates are unique to the specific modifications made in interfaces between one organization to another. So while developing an API is the best approach, making sure that the data that is needed is 1) present in the systems, 2) available to be collected as a byproduct of data entry, 3) is based on standards so that connecting solutions can do so without custom development and 4) the benefit outweighs the costs both fiscal as well as human.

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

Recommendation 1: Consider the feasibility of adopting a first-year test reporting approach for newly developed electronic clinical quality measures. (Page 63)

Comments: I concur with the recommendation to have a first-year test reporting approach. I also believe that this first year reporting period should be AFTER appropriate 'runway' has been provided for vendor developed (12-18 months) and provider implementation (12-18 months). While I recognize this now makes the implementation of new quality measures 36-48 months out till production status, there does needs to be ample time from regulation finalization to first year reporting versus the current process where proposed rules are submitted, comment periods and then finalization of the rule occurs in Q4 of the year proceeding Q1 of the year that measures are to be made productive.

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. (Page 63)

Comments: I agree with the recommendation noted here. In fact, I feel that a full transition to electronic quality measures is the optimal solution but as stated, comes with significant challenges. Because Chart Abstraction allows for review of text based notes, the electronic collection of that data comes with some resistance because providers are required to take on more clicks to get discrete data for data collection. This move to discrete data collection is possible but will require significant time, training and possible system redesign which in an organization that has limited funds can be overwhelming. Therefore, allowing for an option of Chart OR Electronic submission of Quality Measures that would meet multiple regulatory agency needs (i.e. Joint, IQI, CMS, etc.) seems to be a reasonable approach for that transition for all. An example of this is noted above but also shared here:

Similar to the PI Objective Measures, maybe CMS could implement a 'point system' that could be used in the Quality Measure segment. Reporting of each Quality Measure is granted 3 points for abstracted or claim based measures, 4 points for Hybrid measures and 5 points for eCQM measures. Bonus points are given (up to 5 points) for voluntary measures that are being considered for inclusion. With a selection choice of 20 total measures, a minimum of 30 points is required to meet the requirement. This would satisfy ALL reporting programs including (but not limited to) CMS/PI, TJC, IQR, VBP, etc. Overall the idea is to have the ability to choose measures that are best suited for the organizations quality needs, reduces the requirements for complex abstracted and electronic measures across various programs if eCQMs are easily available and allow measures to satisfy multiple programs with single data submissions.

Using a points based quality system encourages organizations to move to eCQM's as quickly as possible but allowing for alternative chart abstracted method due to other limitations.

Recommendation 3: Explore alternate, less burdensome approaches to electronic quality measurement through pilot programs and reporting program incentives. (Page 64)

Comments: I believe that the 'less burdensome' approach examples provided in this recommendation would, in the long term, be beneficial. However, many of those have to be evaluated (particularly at organizations which are faced with difficult decision on funding projects) annually and compete with other patient care needs. Therefore, as those larger academic and for profit organizations provided feedback, I believe input from smaller, rural, not for profit

organizations be taken into consideration so that there is not a significant burden financially in an attempt to reduce administrative and clinical burdens.

PUBLIC HEALTH REPORTING
Strategy 1: Increase adoption of electronic prescribing of controlled substances and retrieval of medication history from state PDMP through improved integration of health IT into health care provider workflow.

Recommendation 1: Federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with ONC and CMS policies and the HIPAA Privacy and Security Rules, to improve timely access to medication histories in PDMPs. States should also leverage funding sources, including but not limited to 100 percent federal Medicaid financing under the SUPPORT for Patients and Communities Act, to facilitate EHR integration with PDMPs using existing standards. (Page 65)

Comments: I believe CMS and ONC are on target with the creation of industry standards which will apply to all states in meeting the timely access to medication histories in PDMP's. By creating standards, this will allow organizations which are border states to be able to have ONE implemented system integrated into our workflow versus state specific needs. Additionally, the number of patients that are 'passing through' create an even greater issue in the absence of national standards with respect to data sharing.

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. (Page 65)

Comments: By increasing the adoption of EPCS access to medication history, the overall benefits to patients and providers is increased. Better options, monitoring and resolution of epidemics (such as the Opioid Crisis) could result in faster response to improved care and alternatives. Therefore, I support this recommendation.

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. (Page 66)

Comments: I concur that alignment of reporting data and standards not only creates EMR solutions that provide better information to the clinicians but also streamlines data collection requirements reducing the administrative and reporting burdens of clinicians. Anytime that standards can be embraced across agencies as well as at the state level, the efficiencies which it brings lessens the burden of the providers as well as the organizations.

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. (Page 66)

Comments: Industry standards not only lead to efficiencies in reporting but system development and ongoing support. i believe that the development/creation of these standards is the key to reducing burden at the vendor and organization level (with appropriate time for implementation).

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. (Page 67)

Comments: Many times vendors and providers find themselves challenged between HIPAA privacy requirements and the need to share/exchange data for continuum of patient care. I concur that as HHS evaluates the overall requirements governing substance use data that careful and appropriate HIPAA privacy and federal confidential requirements are considered.

SUMMARY:
It's evident that the offices of HHS, ONC and CMS have a good understanding of the challenges that many clinicians and providers face in dealing with data collection and submissions. I believe a common theme in the recommendations lend to a creation of standards that are industry wide, enforceable to assure data element collection is achieved and vetted to assure that standards across all types of provider entities (physician offices, academic entities as well as acute hospital/CAH facilities) are beneficial. In general, the recommendations noted appear to be such that if implemented the overall strategy of reducing regulatory and administrative burden would be achieved. However, appropriate timelines, costs and implementation strategies should be considered to avoid 'forcing' organizations into costly solutions and/or re-engineering activities that may or may not be long term beneficial for the regulatory reporting bodies.