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January 23, 2019

The Office of the National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
330 C St SW  
Floor 7  
Washington, DC 20201

Dear Sir or Madam,

Cerner Corporation (Cerner), a leading supplier of electronic health record, clinical and revenue cycle information systems appreciates the opportunity to submit comments on the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* published by the Office of the National Coordinator (ONC) in November 2018.

In response to the draft report, we offer the following outline of what we believe is important to the future state vision for each of the domains discussed in the report, and the key actionable steps in the next 3-5 years for attaining the future state. This outline is immediately followed by our comments to the draft report.

### **Clinical Documentation**

We appreciate that the draft report is focused on challenging the necessity for requirements supporting administrative and billing information that may not contribute to telling the patient's story for their clinical need or for the care they receive. We also applaud efforts to fully leverage efficient documentation methods, and to eliminate the "note bloat" that can result from redundant documentation.

### **Future State**

To be considered an improved state in the timeline outlined by the draft report, changes in documentation requirements and in documentation practices as supported using HIT must:

- Re-center on telling the patient's story and focus on recording the clinical need, course of care, and outcome for the patient while establishing the justification for the service provided medically and clinically.
- Eliminate inefficiency, waste and redundancy in documentation by reducing the "note bloat" that can come about because of billing and administrative requirements that go beyond what is necessary for complete and accurate clinical documentation for the service or the encounter.

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- Provide documentation to meet transparent authorization requirements for justifying the service and reducing the post service or post payment demands of audit and review necessary for payment.
- Challenge data collection requirements for regulatory, research, billing, and quality needs to be met naturally and organically as byproducts of clinical workflows.

### Actionable Steps

To meet the future state, we believe the following actionable steps most imperative:

- Consider the impact of any changes being considered in the use of HIT, particularly where flexibility replaces prescription (e.g. the E/M policy changes adopted in the 2019 Physician Fee Schedule rulemaking), so adequate lead time can be built into the policy changes. This allows for vendors to develop and providers to adopt necessary system updates and operationalize the flexibility.
  - ONC and CMS must improve engagement with HIT vendors and providers to evaluate the impacts of policy changes on HIT adoption and use as a part of developing policy proposals before they are made. Give greater consideration to the lead time needed to avoid exacerbating burden because of suboptimal design and adoption preparation due to inadequate lead time.
- Simplify or eliminate regulatory requirements for billing or administrative documentation needs that do not contribute to the clinical telling of the patient story in support of clinical care and coordination of care.
  - CMS works with governing specialty societies to help ensure that documentation is representative of the needs of each medical specialty which in turn informs EHR vendors in developing the most clinically relevant documentation solutions
- Provide clarity in regulation to favor reducing redundancy and inefficiency in clinical documentation by recognizing all clinicians and care team members to be able to practice appropriately at the top of their license for the contributions they make to clinical documentation without need for reentry or re-transcription or unnecessary supervision by physicians.
- Promote and take the lead in simplifying and making transparent clinical documentation requirements for Medicare required for authorization or payment of services – and press for normalizing them for unneeded variation as possible across payers.
- Incent adoption of innovative technologies to automate authorization processes including use of FHIR API based services for discovery and evaluation of electronic clinical documentation reducing the need for claim attachment submissions and post payment audit record submission.

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### **Health IT Usability and the User Experience**

We wholly support making HIT more usable for patient safety's sake and to support clear intuitively navigable clinical workflow. We agree that there is a continued need for HIT vendors to emphasize internal consistency for common tasks and information presentation, and to provide for clear, consistent and effective clinical decision support presentation. We believe that ONC should emphasize principle over prescription in HIT certification, and in establishing any regulatory requirements for advancing Safety Enhanced Design.

#### **Future State**

To attain clear effective safe use of HIT,

- Clinical users must be able to use HIT workflows that contextually support their clinical workflow rather than compelling them to adapt to that of the HIT;
- Clinical Decision Support alerting and interaction responses must be clear, consistent, targeted, contextual and presented in effective manners to draw the intended appropriate response from the end user for the situation at hand.
- Clinicians must be engaged throughout the design process from solution development through implementation and for continuous performance improvement ongoing.
- Usability means par level usability for all users including those with accessibility needs.

#### **Actionable Steps**

To that end, the following are musts for achieving the future state for usability and user centered design

- ONC should focus on defining the principles of usability and user centered design significant for HIT vendors to adopt into solution development including for internal consistency but not the prescription of detailing the "how".
- HIT products must demonstrate the ability to support user context and clinical workflows appropriate to the specialty, venue, and role of the user without insistent irrelevant homogenization of the end user experience.
- ONC should consider where standardization and normalization of order content, CDS intervention presentation of alert levels and clinical result information for common orderables, diagnostic tests and clinical tasks should be facilitated through standards developers or industry convention driven by best practices.
  - This could be done through certification criteria development and through industry collaboration
- HIT developers should provide support for enabling accessibility for low vision, hearing impaired or physically disabled users working in healthcare roles using HIT to a reasonable level of par in compliance with federal ADA Section 508 requirements.

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- Vendors should promote use of recommended practices or model guidance for HIT configuration to its best use and help providers understand the economic and usability consequences of customization or localization that deviate from recommended practices.

### **EHR Reporting**

We have been involved in federal electronic clinical quality measure reporting since the first adoption of such measures as requirements of the Medicare Inpatient Quality Reporting program and of the Physician Quality Reporting System. We have been recognized as a measure submitter in various capacities by CMS since e-measures have been a reporting method under Medicare programs. Given what we have experienced, we offer the following summary thoughts on EHR Reporting in this draft report.

### **Future State**

There have been few areas of federal requirement that have been as ripe for progress and for burden reduction and impact on the perception of the utility of HIT by providers as requirements for electronic clinical quality measures and performance measures (e.g. functional measures for Promoting Interoperability, Merit-based Incentive Payment System, and the EHR Incentive program). A better state represents one in which

- Measurement information is not subject to “check the box” or post haste data capture or abstraction. It organically flows from what is otherwise available from clinical workflow.
- Measurement results from electronic measures is par level for comparability, veracity and accuracy with the same types of measurements collected by chart abstraction, through use of claims data or other applicable means.
- Measurement requirements are normalized across federal programs and across federal, state and commercial payers based on measures that hold operational meaning for providers for the whole of their patient population.
- Providers do not question the value of the measures over their relevance, their incremental burden where essential or their efficacy in measuring outcomes.

### **Actionable Items**

To realize this future state, there are several actions that command attention:

- The specification development process needs to be open and transparent.
- The onboarding process for new measures must include “real-world testing” that allows for their efficacy to be tested on the basis of their being able to be supported “organically” by data available from clinical workflow before they are ever proposed for inclusion in any rule making much less precursor measure curation processes overseen by the National Quality Forum (NQF).
  - All e-measures must be evaluated by some concept of a “burden ratio” that measures the percentage of the data necessary for measure calculation that is able to be collected

organically from clinical workflow over all data necessary for measure calculation with a threshold set high to drive out burden introduced by new measures.

- Specification updates should be slowed to allow for adequate lead time for HIT vendors to adopt and providers to implement to no more than one annual update each year. Further, specification updates should be timed to coincide to the start of the fiscal year or calendar year to which they apply. They should be available through sub regulatory processes at least six months prior to need.
- Transition from payer driven measurement requirements to provider defined operational metrics from among available measures applicable to their practice that service across payer interests should be well underway.

### **Public Health Reporting**

There are some significantly diverse topics in this area of the draft report. Given that, we have two primary focus areas of: 1) registry reporting, and 2) PDMP integration. For the former, we have experienced the challenges of attempting to meet specialty registry and state or local public health registry requirements where there is no standard or specification for such registries. We appreciate that CMS was looking to broaden what could credit towards meeting registry reporting objective measure requirements of the EHR Incentive Program and later Promoting Interoperability. However, absent effective expectation management by regulators of providers, registries and intermediaries over the abilities to use the capabilities of CEHRT to meet such registry requirements, this risks needless friction between providers, HIT vendors, and registries. For the latter, we have seen the to date sub-optimal level of interoperability present across states that yields less useful interactivity for clinical workflow in the ordering and prescribing of opioids.

### **Future State**

For us, a future state should be attained where:

For registry reporting;

- Specialty registry requirements for submission of reportable information are transparent and publicly known.
- Common normative standards and specifications are fully utilized for registry reporting wherever possible.

For PDMP integration with EHRs;

- Comprehensive medication history for opioid prescribing and use is available, interoperable and interactive at data element level for a patient supporting of prescribing and treatment involving opioids.

### **Actionable Items**

To attain this future state:

For registries;

- A public resource is available to publish specifications and standards in use by registries (or information that such is proprietary to the registry);

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- This includes providing guiding information on the data types required, the file formats and data specifications accepted and the possible need for post coordination of data extracts to meet complete data submission requirements that can fairly be expected;
- This includes providing information on publicly available resources for the standards and specifications or information on how to obtain any proprietary to the registry.
- CEHRT includes the ability support registry reporting requirements for specific types of public health reporting (e.g. immunizations) using nationally recognized standards. Unfortunately, individual registries and public health agencies used for specialty registry reporting developed proprietary formats that at best are close variants of nationally recognized standards, but more likely substantially different. We continue to strongly urge ONC, CMS, and CDC to work with this community to align on common standards so consistency of data access and exchange can be achieved at a national level.

For PDMP

- States effectively make available PDMP data collected for law enforcement or drug diversion interdiction purposes within and across states also available to EHRs for electronic prescribing, dispensing or ordering of opioids.

What follows below are Cerner's specific comments on the strategies and recommendations discussed in the draft report where we believed we had input to offer to ONC and to CMS.

Cerner hopes these comments will be of value to ONC in considering possible update to the draft strategy document. We are happy to help clarify any of the comments should ONC wish to pursue any such conversations with us during the period of public comment review.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Travis', with a blue dot at the end of the signature.

John Travis  
Vice President and Compliance Strategist  
Cerner Corporation

## Detail Comments on Draft Report

### **Clinical Documentation**

#### **Guiding Points for Clinical Documentation**

In framing the strategies for burden reduction for clinical documentation, we offer the following as guiding principles:

- Clinical documentation should focus on telling the patient story in a seamless way and return to providing a complete and accurate accounting of the patient's condition, assessment, need, plan of care, and the course of care provided that is grounded in clinical significance.
- Information should be able to be entered once without being replicated and available for reference later.
- All contributors to clinical documentation should be able to participate at the top of their license/scope of authority, and review, supervision and concurrence processes should leverage information already contributed without redundant incorporation or transcription by supervising or attending clinicians.
- Quality measurement requirements, billing or other administrative requirements should maximize what is clinically necessary to document in all cases possible.
- Burden reduction opportunities should not be limited to the current scope of prior authorization, but rather consider the holistic authorization and medical necessity topic pre-and post-service or procedure delivery.

#### **Strategy 1: Reduce regulatory burden around documentation requirements for patient visits**

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

We generally support this recommendation, and we note that it echoes CMS's policy adoptions in the 2019 Physician Fee Schedule rulemaking for Evaluation and Management (E/M) services. We note that in the discussion of the related issues of documentation found on pages 23- 26 of the draft strategy, an equal apportionment of the cause of the issue seems to be laid at the feet of EHR systems for "effective electronic automation" of administrative processes and adherence to documentation templates that

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reflect outdated E/M billing guidelines and “one size fits all” approaches to clinical documentation. We understand the points raised in the draft strategy. However, we also want it recognized that a significant contributor to the frustration of providers has been one of a self-fulfilling prophecy in this area. To wit:

- The policies of CMS and of other payers to focus on the encounter and on the structure of the E/M service under the 1995 and 1997 E/M guidelines has led to a rather entrenched and embedded prescription for how E/M services are documented by the provider. This is not a situation created by EHR vendors, but it is one that has led to embedded integration of visit acuity scoring algorithms in clinical documentation reflective of those guidelines.
  - EHRs have become de facto “enforcement” mechanisms for E/M documentation as a result.
- The documentation requirements of E/M services for meeting CMS and other payer requirements has significantly constrained innovative software design and efficient documentation. It has contributed to “note bloat” and has raised the risks of perfunctory documentation as a coping strategy to address the time demands of provider documentation for some. At a minimum, it has led to the perception by many providers that clinical documentation is chiefly for the interests of justifying billing and not substantiating the care delivered to the patient.

We support ONC’s recommendation and we ask that it be recognized that responsibility for the current state is more a fact of providers being driven by billing policy requirements than it is a matter of poor EHR design as EHR vendors cannot unilaterally reduce documentation requirements focusing only on what is clinically relevant.

When looking at how to correct the issue and move forward from current state, we ask that great care be given though in the pace of introducing changes in documentation requirements and approaches. Given that EHR clinical documentation capabilities for visit services have often necessitated embedding the documentation elements and visit acuity scoring algorithms of E/M services, we ask that ONC, CMS and other payers who adopt similar E/M billing requirements be mindful of how quickly they move away from long practiced documentation approaches to less prescriptive ones. We recommend that attention be paid to several factors.

- The pace of change by which such changes are introduced to allow for adequate lead time for EHR vendors to provide new capabilities that support less prescriptive documentation and billing requirements. Even if updated billing requirements allow for optionality, EHR vendors still need time to provide that optionality through new and updated coding, and to conduct thorough testing for usability and functionality with clinical users.
- The need for retraining of clinicians and clinical support staff to adapt to using new less prescriptive approaches.
- The need to maintain concordance with commercial and other payers so that the acceptable documentation and billing approaches that impact the way that E/M services are documented are not driven to variance based on who the payer is.



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- The need to work with professional specialty societies on defining documentation requirements that meaningfully reflect their clinical needs and practice patterns to avoid the “one size fits all” issues of current E/M documentation approaches.
- The need for better clarity on what discretion is available to providers to exercise choice of their approach for encounter documentation. For example, reflecting on the recent CMS policy changes for E/M service documentation, is that discretion applied at the practice level? At the medical staff level if for an institutional setting? At the individual clinician level? We believe that there are significant concerns that payment auditors and recovery auditors will look for consistency of practice, but little has been stated about how such discretion is to be practiced.

In addressing regulatory burden, we also encourage ONC, CMS and other federal agencies to engage in or commission studies that can effectively determine the additional time spent in the EHR by a clinician solely to meet regulatory requirements beyond providing and coordinating clinical care. By that we mean considering the impacts of requirements necessary to be met to assure payment, to report quality, or to report performance that cannot be derived from core data already present in clinical workflow. Cerner has already begun independent studies of this work and would be an eager partner with a willing regulatory agency to help distinguish how measurable this effort can be apart from/additive to what is necessary to support what is needed for the delivery of care on its own.

As a general matter when introducing policy changes that directly and significantly effect EHR design and use, we underscore to ONC and CMS the need to provide sufficient lead time to HIT vendors to modify or create new capabilities and enable new workflows within HIT. In the case of optionality as provided for in the E/M documentation changes adopted by CMS in the 2019 Physician Fee Schedule (PFS) rule, what is optional for the provider is not typically optional to the vendor. For the HIT vendor, these types of changes require strategy decisions, requirements definition, application development, accessibility and usability discussions, testing, validation, and release. Providers need time to plan on taking system upgrades, working those upgrades into their adoption roadmap, and executing on the upgrade, testing, and clinician/workforce training.

There also is often a convergence of a number of distinct regulatory policy driven updates that fall upon a common compliance date and implementation period that gives the appearance that there is no common reconciliation of these demands on HIT vendors and providers by regulators. Whether Promoting Interoperability, ICD 10 CM/PCS adoption or HIPAA regulations, we have often seen postponed compliance dates or non-compliance enforcement policies adopted significantly in part due to industry struggles to be ready on time due to competing priorities and insufficient lead time. We urge that CMS and ONC emphasize reconciliation among these demands across their programs that impact the same providers within the same span of time, and engage HIT vendors more actively to understand the impacts of policy demands. In the era of burden reduction, changes such as many adopted into regulation by CMS introduce additive development needs, project demands and implementation costs. We appreciate that CMS adopted a longer lead time for the E/M policy changes, but only after what was an unrealistic initial proposal of six months. Focusing on just what impacts physicians under Medicare Part B, these changes still fall within a common timeframe within which CMS is adopting wholesale standards updates for NCPDP standards for electronic prescribing, updates for Promoting Interoperability objective measure changes, implementation of Appropriate Use Criteria and adoption of

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Patient Relationship Codes for cost attribution for episode based payment among other policy adoptions that directly impact system use.

We continue to encourage ONC and CMS to consider an adoption model that gives adequate weight to the lead time for policy adoptions and changes that require updates to HIT. In prior comments, both HIMSS EHRA and many HIT vendors have suggested a lead time of 18 or more months for Promoting Interoperability and EHR Certification criteria edition updates from final rule to the opening of a new EHR certification edition for testing. Not every policy change will require the same lead time however we believe that ONC and CMS should work with HIT vendors to develop an “adoption model” to build in both to regulatory impact assessment and to policy adoption timelines where HIT is impacted that accounts for both HIT vendor and client provider work efforts needed to meet compliance requirements. We think that allowing for sufficient lead time significantly improves the quality of the development avoiding the kinds of “check the box” or suboptimal workflow impacts of such updates that have often been highlighted both by all parties, and allows for a more seamless adoption. We support ONC’s and CMS’s efforts to reduce provider burden. We urge better consideration for an appropriate lead time so as to not recreate the kinds of burdensome effects of regulatory changes on HIT use experienced to date.

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

We strongly support this recommendation, and we appreciate the potential for it as having promise for enhancing the efficiency of clinical documentation. We applaud policy directions that support making maximal use of information already present and contemporary in a patient’s medical record or that represent historical information that begs only concurrence and documentation of difference for its ability to be used in a current service context. We have seen our clients confused by how to meet compliance requirements that have called for making use of historical information from prior services or from earlier in the current service. In reducing the burden of clinical documentation requirements, we urge bright line clarity for adopting policy changes for how to make appropriate reference and use of such information in clinical documentation rather than being obligated to re-document with primary aims being to be conservative given regulatory requirements or to meet perceived audit requirements to safeguard against payment recovery. We recommend ONC and CMS consider several guiding points for this recommendation:

- Recognize and affirm the ability of non-physician clinicians to contribute to clinical documentation without requirement for re-entry of clinical information that needs no such re-entry by physicians or licensed clinicians to be considered “authoritative”
- Provide adequate guidance on how concurrence with previous documentation should be documented along with recording of new or changed findings when prior medical record information is referenced and used for, e.g. history and exam components of the E/M service or for use of a prior history and physical exam that was conducted within 30 days of the current procedure or service.
  - We observe that many of our provider clients practice very differently on this point. Many literally re-include on the new or current encounter the entirety of a prior medical record entry and then document concurrence and any new or changed findings as an

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addendum. Many create a clinical document entry for the concurrence and any new or changed findings with a simple reference back to where the prior history and physical document may be found. While we understand that this may be a matter of provider policy, there is little clarity on the documentation expectations of how requirements like CMS Conditions of Participation requirement [482.22\(c\)\(5\)\(ii\)](#) must be met when it comes to making reference to or provide for inclusion of a history and physical completed within 30 days of the procedure or service when documenting concurrence along with any changes or new circumstances regarding a patient's condition. We understand that to support this kind of requirement, EHRs must maintain provenance and persistency of the documentation referenced to maintain proper transparency, trace-ability and responsibility.

*Recommendation 4: Waive documentation requirements as may be necessary for purposes of testing or administering APMs*

We ask ONC to offer clarity as to the intent of this recommendation. We appreciate that in certain APM models, the requirements for documenting services that may be appropriate for a fee for service reimbursement may not apply to capitated models of reimbursement in APMs. However, we are trying to understand the intent of this type of a waiver whether to enable participation in an APM to be simpler and less burdensome or if because documentation requirements for a fee for service model may not apply as directly to a bundled or capitated payment model, particularly if prospective in nature.

**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*

We strongly support this recommendation particularly as it can lead to greater transparency on the part of payers of authorization or documentation requirements necessary to justify a service or procedure. We believe that the current prior authorization processes are inconsistent and incompletely adopted, and that documentation requirements of payers are often not clear to providers before attempting to seek prior authorization when it is required.

We do not think it sufficient to only suggest that payers be transparent with what they require for an authorization. Payers may point to non-interoperable methods of making authorization requirements available such as through use of their websites and published contracts. Our clients tell us that these requirements are subject to frequent change or rendered out of date by payer behavior in adjudicating claims or in processing authorization requests. It is impractical for providers to operationalize authorization requirements if they are subject to frequent irregular update. This is especially problematic for providers to maintain build or processes in systems to be able to accurately apply. Users call into reliance on cheat sheets and workarounds given that the HIT is out of date all too frequently. We urge not only transparency but stability of requirement, and transparency as supported by

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standardization of authorization requirements by procedure or service such as for a given CPT code. This seems possible for simple authorization cases that should work much the same way that medical necessity determination works within most EHR systems. These are instances where payer determination should result in a very quick turnaround amenable to an automated response delivered electronically much as is within the spirit of the HIPAA standards and operating rules. For more complex cases, it may require a person on the payer side to review it in which case the response should come back as pending review and be sent electronically later. Also, if payers had to issue authorizations based on standard requirements defined by procedure (or procedure code), and had changes to make to those standards, it may afford opportunity for a regular cycle of standards update and publication that could be operationalized on a regular basis such as apply to quality measure specifications or medical code set updates. HIT vendors and their provider clients could better prepare for the changes to be implemented. As ONC and CMS are exploring documentation requirements discovery with payers, we also wonder if there could be a controlled process for use of published APIs to implement documentation requirements changes.

The processes of authorization also suffer from often being distinct from common clinical processes of ordering, scheduling or referring and are left as administrative processes on their own. We urge ONC and CMS to take the lead on promoting best practices for how authorization and documentation discovery can be made more an integral part of common clinical processes that may trigger the discovery of the requirements for and the submission of clinical documentation needed to substantiate a service. We believe that clear statement also should be given to the benefits of reducing downstream burden on claims processing and on post payment audit to strengthen the business case for authorization. However, all of this starts with transparent and consistent statement by payers of documentation requirements, and with a consistent application of same to the authorization of service.

*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*

Beyond the comments on recommendation 1, we strongly support advancement of interoperability standards and specifications to advance the use of electronic prior authorization and for electronic submission of medical documentation. We appreciate and support the focus that CMS is demonstrating through the Da Vinci project to identify opportunities to streamline the authorization process building on data already available through the expanding set of FHIR based service APIs being deployed through EHRs, thus reducing administrative overhead and reducing re-documentation requirements.

We caution against a regulatory regime that prescriptively locks in the use of a given standard or version of standard that can only be updated or replaced by further regulation. We observe that the standards proposals contained in the [original](#) claims attachment NPRM were quickly outdated and outmoded such that they were never adopted. We do think that some of the realities the rule tried to contend with still prevail which are that not all providers have implemented systems that are fully capable of transacting in a given specified standard, and that an onboarding strategy may be needed. We do not believe the industry is yet at a place where a singular standard may be possible for enabling claims attachments or clinical documentation submissions for prior authorization across all venues of care and across all use cases. The reality is that different provider venues are at different places depending on the level of their HIT adoption, and an onboarding approach that evolves towards use of standards and specifications needs to be defined in any future rulemaking. The original proposed rule allowed for human and

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machine-readable formats to be used for claims attachments, and since the rule categorically covers all types of providers, it seems wise to retain that element as part of an onboarding strategy. Additionally, as requirements and capabilities evolve, new versions or alternative standards should not be hindered by regulatory constraints to deploy them as soon as they have demonstrated to be viable improvements. Any rulemaking should encourage progression towards standard based transacting, but we encourage the HHS Office for Civil Rights (OCR), ONC and CMS to develop an approach that does not prescribe a single basis of standard but leverages market supported approaches to documentation submission over time that may converge towards a normalized use of common standards that serve broad use. Rather, any standards referenced in any regulation should represent a minimum floor that enables a minimum level of interoperability, while allowing for capabilities that have emerged before a next regulatory update may occur. We therefore encourage efforts like the Documentation Requirements Lookup Service to better support requirements discovery and submission, and we encourage the use case approach to prove out feasible capabilities providers, payers and suppliers can use.

We observe that use of standardized templates for documenting assessment, medical justification or substantiation of service should focus more on the content than the human readable form per se given that their use needs to be compatible with the clinical documentation capabilities of many HIT systems in use. This presents opportunity for the use of APIs (such as is being tested by the DaVinci project) to support collection of the relevant data which could bypass the need for standard data collection templates and instead focus on the data requirements for the service at hand. The focus can be on what data is needed and not on what templates should be used. Further, we believe it problematic to think that HIT systems in use by providers should be required to incorporate use of payer defined data collection templates to be completed for a given service or procedure authorization instance. They may be useful for reference but not for ongoing use as the collection and presentation of the data content required can be better optimized when considered in context of the overall documentation requirements to be supported by their HIT. Providers would prefer their requirements supported within documentation capabilities already in use. The utility of such templates could be to support initial reference configuration for new documentation requirements or changed requirements to ensure the relevant data is available, not to inform specific documentation formats and flow of a given service or procedure for individual patients at time of service or ongoing data collection for a given service.

We also caution introducing any requirements of having to complete additional documentation not already recorded as a part of the clinical process in place at a provider or a supplier. The core business for clinicians is in providing healthcare for patients. The interactions of providers with the EMR should always support and be subordinate to this mission. Data collection requirements for regulatory, research, billing, and quality needs should always be judged against the frame that they can be captured naturally and organically as part of clinical workflows. Well-designed and well-thought out measures should support the inherent workflow of clinical care and not just be met by clerical or data collection activities. User-centered design is critical to making this realistically possible. The specification of any data collection requirements should be grounded in clinical workflow for original service documentation, and not as an adjunct or extracurricular recording of additional information not already recorded in the original clinical workflow. We reiterate that the opportunity exists to move towards API based accesses to already available data so that the need for templates can be made irrelevant, while at the same time considering a "burden ratio" comparing essential clinical data collection with all other

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documentation requirements imposed on clinicians aiming for a near zero burden ration (simplified: all other documentation requirements / essential clinical data collection).

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

We support providing for incentives to encourage adoption of standardized documentation and to automate authorization processing to reduce post payment audit burden. We urge focusing incentives to spur adoption of new standards based on FHIR based service APIs to support authorization use cases that can achieve workflow simplification and more efficient payer/provider interaction. In other words, there should be no need for a person on the payer side to review documentation manually, and responses to providers would come back in a similar fashion to an eligibility check. Further, one wonders if steps could be taken to manage authorization like how medical necessity verification for Medicare often is supported. While medical necessity verification depends on published sets of rules that form the basis for applying the verification requirements in provider scheduling and ordering processes to support Advance Beneficiary Notification processes, we wonder if something similar should be considered for authorization that allow the simpler cases to be processed in an automated fashion which could reduce the burden on providers and payers, and incentives designed accordingly to support its adoption. Cases that require a subjective review but are submitted electronically should also be processed faster if based on standard authorization requirements for the payer resulting in a quicker response.

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

We understand CMS is focusing on Durable Medical Equipment (DME) as an initial pilot use case for the Documentation Requirement Lookup Service (DRLS). An additional suggestion for a pilot area is Oncology where standard regimens are published and there appears to be opportunity for a consistent approach to authorization. The complexity and cost related to treatment types and medications leave health care providers searching for better ways to manage these time-sensitive courses of action to minimize the financial burden on patients.

*Recommendation 5: Coordinate efforts to advance new standard approaches supporting prior authorization*

We support ONC, OCR and CMS working to advance the cause of promoting new standards-based approaches for both authorization and for claims attachments. As reflected in our comments on Recommendation 2, we do not believe that prescription of exclusive standards is best done by reference through regulations as this constrains the need for progress, particularly at this stage of emerging new standards and technologies, such as FHIR based service APIs. Any endorsement of standards should reflect a floor of minimum support, not an exclusive requirement to only be able to use that standard. Additionally, there will be an onboarding reality necessary to be reconciled with depending on the level of HIT adoption in place, and the capabilities for supporting use of standards-based documentation present in trading partner systems. The role of regulation should be to encourage convergence towards



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standards-based approaches over time. We encourage regulators to advance the use of such approaches for claims attachments as they do so for prior authorization.

## **Health IT Usability and the User Experience**

### **Guiding Points for Health IT Usability and the User Experience**

In framing the strategies for burden reduction for health IT usability and the user experience, we offer the following as guiding principles:

- EHR use should promote and support safe and effective patient care
- Patient information presentation should be clear and unambiguous
- User interface design should demonstrably follow minimum design process standards
- User interface design should support clear navigable pathways
- EHRs/HIT should have internal consistency of design for such things as
  - Common iconography to represent levels of danger or harm
  - Common vocabulary to describe severity of alerts
  - Common locations for commit/cancel/review/sign operations
  - Navigation of clinical workflow for common tasks and application behaviors
- EHRs/HIT should consider usability to include support for a meaningful par between users with accessibility challenges and those without
- Cross-HIT harmonization should be patient safety driven only sparingly using prescriptive, national level standards/regulations to mandate such harmonization.

Cerner applies human factors methodology to help inform smart design decisions to enhance the user's overall experience. We accomplish this by evaluating our designs against common heuristics, onsite clinician workflow shadowing, iterative research, and design feedback from clinicians, and formative / summative usability testing. Usability research includes iterative, verification usability testing with a broad selection of users starting early in the design phase as well as validation testing to evaluate overall system usability. Participants are selected based on clinical specialty/persona, age, familiarity with Cerner, and EHR experience. Each study has a mix of participants from varying organizations. By its very nature, usability research requires end-user engagement to achieve. Furthermore, as identified with Safety-enhanced design regulations (e.g., [170.315 \(g\)\(3\)](#)), these activities should be performed with practicing end-users of the EHR and strongly encourage ONC and CMS to continue to promote such design processes. We do recognize that this ideal state is often complicated by logistics and resources in achieving an ideal engagement level from all our end-users. Inherent in this engagement is the availability and willingness of the end-users themselves to participate in research to improve the applications. Cerner finds that this is a larger barrier than it may seem in successfully and regularly engaging in usability research with our clients. We encourage ONC and CMS to encourage the user community to actively participate in these activities as they have demonstrated to provide substantive contributions to improve usability and design.

**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.*

We believe that EHR vendors should embrace a user-centered design (UCD) process that calls for them to work directly with their provider clients and include them in the development process. It is significant in the design of an application, that the vendor needs to account for both the role of the user as well as the environment in which the user works to inform methods used to explore the users and their workflow; there is no “one size fits all” approach to EHR development.

During the process of development of an application, in person site visits and iterative usability testing provide clinical perspectives and verification of the specific clinical tasks being explored. In person visits allow for observing and interviewing multiple health-care providers and nurses along with managers and directors in various departments. Such engagements are invaluable for providing feedback from interviews, usage metrics, and on-site observation data to focus on the system’s overall usability. Elemental metrics should be included such as identifying the critical path steps within the software that are required for completing a task, documenting of errors in use, user comments, and feedback regarding existing “pain points.”

Enabling data analytics across applications and sharing the findings with participant client organizations to look for patterns of usage can help determine use variations across venues of care, user roles, and other factors. This concept of Human-Data Interaction (HDI) completes the loop for a vendor to be a design-driven organization; utilizing person-to-person interaction, research and design in the initial stages of development to maximize the intended user experience and to support the constant monitoring of the usage of applications in production thereafter to ensure that they are being used effectively and efficiently at scale. Data without context has a diminished value, and it is imperative that vendors maintain human interaction in this process to support going from finding a perceived problem with data scientists, to repeating the research process in-person with end users to find out directly how and why things are not going as expected.

We strongly believe a process like this should be followed by all EHR developers to ensure that they are focusing on the end user in the design of their applications. The recent move by the European Union to introduce CE Marking as a requirement for software applications is a good example of a step to make sure that medical software is tested as thoroughly as medical devices, as both have the same potential of risk to a patient if they were badly designed.

However, we also strongly believe that specific design patterns should not be subject to standardization and specifically regulation, barring some very specific patient safety related guidance, as user communities, settings, and capability requirements may yield different workflow and user interaction design. One size does not fit all in this space, where we should note that the iOS experience would not have been possible with UI design philosophies enshrined through standards and regulations. Only in well understood situations where patient safety can only be addressed through common UI design should design pattern standardization be contemplated.

*Recommendation 2: Improve clinical decision support usability*

We believe that with Clinical Decision Support there is a need to optimize alert processing and feedback given that the proliferation of alerts that exist within a healthcare environment has created a situation



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where end users have become desensitized to many alerts. Alerts are often regarded as more of a nuisance than their intended use of being a helpful guide and warning if a potential error or safety event is about to occur.

In support of such optimization, some targeted standardization that impacts patient safety should be considered. We recommend that a cross-industry strategy could be employed to address the following:

- Apply a standard set of rules for alert severity levels that follow solid, accessible, human factors principles that should be easily recognizable regardless of software developer
- Work to create a standard nomenclature for alerts enabling clear, consistent instructions and next steps for users to follow and be able to action.

As a best practice, vendors, in collaboration with their clients, should pursue harmonizing clinical decision support approaches from a user interface standpoint enabling consistent deployment of clinical decision support triggers and variables where desirable. Today, there is variance in the triggers that are coded into alert systems, such as the correct temperature of a patient, with a similar situation occurring with medication alerts, with variance in the dosage of a drug that should alert the end user. This makes things difficult from a data analysis standpoint, as each implementing provider may have their own unique set of rules, with the efficiency of said alerts only being measurable on a site by site basis.

- Definition of best practice alert variables and triggers that can be used as the starting point for provider implementations yet allowing for essential site specific variations would improve on not only data analysis across larger provider/patient populations thus improving on identifying opportunities to improve on patient care.

We recommend utilizing data, research and design to assess audit alerts for their effectiveness and find ways to reduce the number of pop-up interruptions that end users face. Rather than eliminate lower severity notifications, we should be looking at ways to incorporate them into the user interface in other ways. Similarly, we propose better utilization of data in the field of patient safety to record safety events across the industry in a non-punitive manner. If this can be done at scale, then it would be the beginnings of the “black box” concept adopted by airlines long ago to be able to accurately see where and how safety events are happening at scale and to address those problems universally. Patient safety events are not just a usability issue and there are many factors at play such as:

- Hardware
- Interoperability
- Training
- Communication
- Configuration
- Provider Policies and Process
- Regulations
- Staffing

Any or all these variables may affect a patient safety event; if there is a way to be able to capture the outcomes of these events at scale, then there would be a very good chance that through data that one would be able to see commonalities in events that could be shared broadly.

We re-emphasize the need to balance appropriateness of standards vs. evolving best practice guidelines and suggest that standards be focused on patient safety objectives that otherwise cannot be improved upon.

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*Recommendation 3: Improve clinical documentation functionality*

We recommend several actions to consider for improvement of clinical documentation:

- Continue to promote use of standard nomenclature to promote efficiency of documentation of what is elemental and necessary for documenting services in the medical interests of the patient care less beholden to billing requirements. Volume is a problem over value as evidenced in our own research where we have noticed two major variables that contribute to the documentation burden that our end users face.
  - The amount of documentation that gets written up on the patient can vary massively, with the clinician sometimes writing a detailed written narrative about the patient and their various problems, with other clinicians writing a very short summary. This creates a wide variance in the total amount of words that need to be written.
  - The second variable is the actual typing speed of the clinician which with transcription dependent methods is a significant burden in their use; consider a relatively small two page note at 1,000 words.
    - At 40wpm – This will take ~25 minutes to type
    - At 80wpm – This will take ~12.5 minutes to type
    - Compare this to conversational voice speed at 120 wpm, which would drop the time down 8.5 minutes to complete the note.
- We appreciate the focus in current regulatory developments to moderate the information that must exist in the clinical note, but we encourage attention also be paid to provide guidance at scale as to what is useful to both the clinician in authoring the note as well as to the person that will go on to read it. Best practice guidance should be developed considering what needs to be written and in what order to bring some order to the structure of the note. The focus should be about what is useful and meaningful from a healthcare standpoint that needs to be included.
- We encourage the continued review of requirements to identify documentation that burdens clinicians stemming from the regulatory requirements that exist today and challenge if they are necessary to establishing the efficacy and need for the service. We also encourage the continued challenge of whether it is also appropriate for the physician to be the person bearing the bulk of the responsibility of that workload. Recognizing the contributions that other clinicians and clinical support staff can make to clinical documentation and rationalizing the ability to make use of that documentation to reduce redundancy of entry are important design points to consider when developing regulations.
- Much in the same vein as regulatory burden, the amount of documentation work that needs to be done to assist with billing is something that is contributing heavily to not only documentation size, but the time required to complete the work. While we recognize that providing supporting documentation is essential to support their being billed, we encourage continued challenge to documentation being focused on what readily available from essential clinical documentation vs. what is additionally required specifically to substantiate billing. Particularly as healthcare adapts from fee-for-service to value-based care, this is an ideal opportunity to evaluate documentation holistically establishing essential documentation requirements and eliminate

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any redundant or extraneous documentation that is not needed anymore to justify performance of a service.

*Recommendation 4: Improve Presentation of Clinical Data Within EHRs*

We support the recommendation in principle but recommend that ONC and CMS defer on the specifics to EHR vendors working with their user community how they need to improve the applicable user interface actions for internal consistency within their EHRs, and to make specific design decisions specific to their UIs. We recommend ONC and CMS focus on working to reduce the burden of clinical documentation to focus on what is essential to assuring accurate rendering of the patient's story and to support what is necessary for treatment and care coordination. We remind ONC to be mindful the challenges vendors need to address when solving for meaningful information presentation:

- While the day to day processes of healthcare and for task automation for hospital based or ambulatory care may seem linear, the needs for access and many interactions beyond direct patient care is not. Presenting timely, meaningful and contemporary information of significance (e.g. to non-linear use cases) is challenging and should be given careful thought.
- The draft report observes that developers must move beyond the encounter or episode focus to truly address presentation at the person level or in longitude, and not just in the context of or limited to an encounter or episode. While acknowledging this, this also connotes a responsibility for developing guidance on how to address it in appropriate contexts while not losing the context of the encounter or episode when meaningful. There is a fundamental need to emphasize both contexts are important for their own sake but should not be expected of an EHR that only supports an episode or encounter view. This may require new forms of HIT (or at least views of patient information in the same EHR) to support population health and a longitudinal perspective.

We also observe that ONC needs to find a place in all this conversation to address accessibility as a dimension of presentation and use that needs equal treatment as any of the concerns raised by this report. This report seems to be oriented to addressing the needs of "normal" users who do not operate with any physical or cognitive disability. We assert that for clinical users accessibility remains a relevant consideration and should be accounted for in the user centered design process. as patient safety risk can also be impacted having deployed poorly accessible systems.

**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*

We agree that harmonization of certain design patterns across EHRs can benefit usability for users interacting with multiple EHRs. However, we suggest that many opportunities to harmonize do not require regulatory driven standards, rather continuous evolution of experiences and best practices. Collaboration across the vendor and user community show more promise of improvement than development and introduction of prescriptive standards that have a substantial risk to create solutions

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that cannot easily adapt to new learnings. It is not inherently “bad” to present flexibility in user interactions

*Recommendation 2: Promote and improve user interface design standards specific to health care delivery*

As indicated earlier, we agree that there is a need to harmonize the user experience across EHRs in areas where there is substantial patient safety risk when systems behave differently. We submit though that progress is best based on continuous learning and improvement that use principles and best practice guidance rather than prescriptive standards such as those developed for interoperability (where common data definitions are critical to any high-fidelity data exchange without loss of meaning). Such prescriptive standards should be reserved for use cases where patient safety risks can only be improved on when everybody uses the same design pattern. By way of comparison, similarities observed in similar situations in car and aeronautic development demonstrate the limited application of prescriptive standards, rather collective learning on how to best prevent incidents.

*Recommendation 3: Improve internal consistency within health IT products*

HIT vendors should use design principles and approaches that address definition of the effective use, appearance, behavior, and technical usage of the user interface elements that provide the framework for their applications. The purpose of these principles and approaches is to develop consistent, extensible, technically sound, and visually appealing designs which lead to intuitive and efficient applications.

In our own experience, we have set about to provide an internal process for consistency across our applications to create a single user experience. Through dedicated usability teams, we have been working to create a library of reusable components that will allow us to create a consistent look, feel and behavior across our application sets. The goal is to create an ecosystem of these components that have all been thoroughly researched against all known industry experiences, design principles and best practice, as well as validated with the end user to ensure applicability to their interaction needs.

Provision must be made for dealing with the reality of legacy applications while addressing new development as existing capabilities cannot can only be incrementally changed. Consideration must also be given as to the tolerance for variances between older and newer parts of the application set while working on their replacement. While working towards solid design principles and a clear set of best practice guidance to utilize across applications, HIT vendors will continue to need to involve the end user in the design of applications and further, once an application is complete, be involved in the validation that it is working as intended. Only by taking this approach at scale across a vendor’s applications with the help of end users will vendors be able to really improve upon HIT usability.

*Recommendation 4: Promote proper integration of the physical environment with EHR use*

We appreciate the recognition of the physical environment where the EHR is being accessed. We suggest addressing both the devices used to interact with the EHR, as well as the actual physical environment where the user is as they have a need to interact with the EHR.

As various devices with different form factors are enabling users to interact with the full EHR or targeted subsets, we believe that consistency of design patterns across devices is maintained wherever possible

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or are consistent across the same class of devices. Similar design approaches and processes should be involved as discussed earlier using the same considerations as to when standards vs. best practice guidance and continuous learning is appropriate.

Another element that Cerner is actively investigating (and would encourage other vendors to consider) is how to allow the clinician as end user to have more “face time” with their patients taking advantage of the physical environment they are in and use of various device classes to gather and present the relevant data. Both investigating utilization of technologies within the EHR to promote direct face to face contact with the patient without the disruption of requiring transcription based technology use (such as the use of video, voice, AI/ML, VR and AR to help support the clinician), and opportunities to look at the design and layout of rooms to maximize the engagement with the patient are essential ingredients to improve on usability objectives for EHRs.

We believe the patient needs to be included in this process too and that a more circular (patient/provider interacting) technological relationship needs to be encouraged to grow between the clinician and the patient that goes beyond the active face to face encounter. Whether it be general health and wellness or specific treatment focuses, a better understanding of what is needed to promote patient/provider engagement including how to help patients better navigate their financial health, health IT vendors need to be taking a more holistic “bigger picture” view to healthcare to match to the value based environment that is growing in importance where longitude and person centeredness are important contexts of interaction between patients (persons) and providers.

There are many factors in play that can affect the overall usability of a HIT, and we believe that overall alignment to “getting current and staying current” is an important overarching principle to follow. Whether the issue is getting providers current on contemporary versions of software that embody improvements in usability or encouraging HIT vendors to adopt principles of user centered design that are contemporary to user need, there is a need to remain current. We do not believe this a matter that ONC or CMS should prescribe but encourage as best practices. HIT vendors should consider recommended practices for use in their HIT that have been fine-tuned to be the best user experience possible. Providers should be encouraged to be fully up to speed with their code base as possible so they can be aligned to vendor recommended practices and configuration requirements while being able to use more widely agreed to vocabularies and common catalogs. Vendor initiatives to drive provider adoption of recommended practices to move to optimum configuration would help significantly in not just improving the end user experience, but by also normalizing the code, vocabulary and usability experience an HIT vendor’s client base. This would inherently lower the variation substantially, allowing both clients and HIT vendors to concentrate on the most important issues affecting their applications to prioritize and focus on them.

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

*Recommendation 1: Standardize medication information within HIT*

While Cerner agrees in principle with goal behind many of the best practices available within the industry for medication display, we caution development of prescriptive standards to establish how data is presented. Depending on purpose, context, and user community, different display approaches and data sets may be appropriate. To make best use of a combined set of best practices, we would expect

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that any best practice guidelines would provide the opportunity for the design of medication displays to advance with the technology. Many of the existing guidelines present internationally are based on the traditional desktop display and do not consider the limited display space present on mobile form factors. This presents a challenge when trying to meet the goal of the guidelines and not just the safety spirit. Additionally, we would like to see more consideration for the safety implications behind the different types of medication displays. This will help any superset of best practices represent the intended goal of improving the safety around medications and not just provide a formulaic level of consistency that doesn't match the changes incurred with advances in medical treatment.

*Recommendation 2: Standardize order entry content within HIT*

We support the need for minimum data content requirements for valid orders, particularly in the medication prescription space, both in terms of order attributes and vocabulary used. The latter is of importance to establish a common catalog of orderable services/procedures/tests using a common vocabulary (e.g., LOINC). Common naming conventions (including full name and use of abbreviations) can substantially help promote consistent use and interpretation (e.g., in clinical decision support). This should be reinforced by interoperability standards and specifications for order communication. While we recognize variances across jurisdiction in what data may need to be included, collaboration is essential to establish a common superset where the same concept is not represented differently by jurisdiction. As care transcends jurisdictional borders due to both patient and data crossing those borders, data must be able to be consistently interpreted no matter where it was sourced and where it is accessed/used.

*Recommendation 3: Standardize results display conventions within HIT*

We caution development of prescriptive standards to establish how data is displayed. Depending on purpose, context, and user community, different display approaches and data sets may be appropriate. Rather we suggest focusing on best practices and principles that the industry collaborates on that can also quickly adjust to the latest learnings. For example, the Clinical Laboratory Improvements Act (CLIA) [regulations](#) identifies the data set that must be available for complete lab reporting, but does not prescribe the format other than that the source's format must be preserved. However, for a wide variety of purposes beyond the original report, different representations using graphs, columns, distributions, etc. may be used to visualize the data to best inform the user about the meaning of one or more data points.

**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*

We agree that engaging clinical end-users early in the acquisition and implementation processes (and beyond) is imperative for a successful EHR implementation. We add that it is important for organizations to include clinicians in defining the value to be achieved by implementation of new technologies and determine the best way to measure outcomes that align with their defined future state value objectives. Training is an important element and it can be large investment so we believe it is an imperative for providers to consider their options fully and ensure that as many variables that directly affect them have



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been identified and addressed first, to make sure that any investment made is addressing the correct issue and helping set up the end user for success.

Key processes should be reviewed, and baselines set for key performance indicators (KPIs), which should be monitored before and after the implementation. Ongoing measurement of KPIs will help determine where to focus efforts as the organizations continues to refine workflows, education end users, and roll out new enhancements. The initial implementation of a new EHR system (or implementation of additional products) is an event, but we believe that organizations should adopt a culture of continuous improvement, and this should be included in the budget each year.

For our part, Cerner includes "timers" within our code and exposes that information to key stakeholders to help them better understand the time a clinician is spending on different workflows (e.g. Documentation Time per Patient). This type of information is used post go-live to proactively identify clinicians that may need some additional focus in the form of additional training or "at-the-elbow" support. Cerner also believes that clinicians play a very important role in the governance structure for a successful implementation. Having a strong governance structure with stakeholders from many departments, including clinicians, and true executive buy-in will go a long way toward a successful initial implementation and ongoing optimization of the EHR system.

*Recommendation 2: Promote understanding of budget requirements for success*

We agree with this recommendation, and we support the need for providers implementing HIT to have a whole understanding of the longitudinal costs that go into not only original implementation but ongoing use including for workforce training, taking upgrades and managing continuous improvement efforts to optimize the use of HIT. However, any discussion of this with providers must also consider the need for continuous updates/upgrades, retraining and deployment to address regulatory requirements.

In the discussion of the issues behind this recommendation, and for the recommendation itself, it does not seem that ONC considers the burden caused by what have been recurrent and frequent needs for updates due to the very regulatory requirements that ONC and CMS are examining for burden reduction. Whether it is the need for updating electronic prescribing capabilities to meet NCPDP 2017071 adoption by January 1, 2020 or addressing the next generation of Promoting Interoperability measurement requirements or Inpatient Quality Reporting specification updates, we believe that proper rendering of the impacts of these requirements on upgrades, workforce training, testing and rollout need to be considered among the costs associated with provider burden from EHR use, and underscore the need for regulators to do a far better job accounting for the onboarding of new requirements that significantly impact EHR use. Greater consideration for this needs to be accounted for in the development of the regulatory proposals to begin with. For example, CMS originally proposed adoption for NCPDP 2017071 to be in effect by 1/1/19 when first proposed in early 2018. Similarly, the E/M documentation proposals were originally made to go into effect 1/1/19, and now have been more appropriately set for 1/1/21. We stand ready to help work with ONC, CMS and other federal regulatory agencies to have a better accounting for what it takes to accommodate these policy changes when they directly impact the use of HIT and require new development to meet them. This needs to be part of the burden calculus.

We also point out that the budget requirements for HIT adoption are more nuanced than the recommendation depicts. We urge ONC to broaden it better recognize the role that hosting and outsourcing play in a provider's/implementor's costs, and the effect that such deployment models may

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have on a provider's ability to keep current. Similarly, we urge that the recommendation give greater treatment to the effects of customization or addressing needs that often arise after the initial implementation. These include addressing ongoing needs related to external regulatory reporting requirements, measurement requirements and regulatory requirements such as are mentioned in the prior paragraph. This includes the effects of making other configuration decisions than what is recommended by the vendor. As we discuss in our comments under Recommendation 1 for Strategy 2 in the Public Health Reporting section of the report, a challenge that needs to be part of this discussion is the burden and budget challenge for addressing regulatory reporting and specialty registry specification requirements where there is not a common normative specification in use. Both for initial implementation, and for ongoing maintenance as specification updates occur, this is a significant operational challenge for HIT vendors and providers alike.

We suggest that ONC also consider how to scale this recommendation to deal with the size and capabilities of the provider. We work with many smaller community and rural hospitals as well as with small physician practices who often do not have dedicated training resources post conversion. We suggest that ONC champion ideas for vendors to develop alternative methods to deliver training by online means that afford better leverage for smaller providers.

*Recommendation 3: Optimize system log-on for end users to reduce burden*

We appreciate that this recommendation is focused on making log-on seamless for providers across applications, and from their initial point of access can navigate to any application without a need to log-on separately to each application. Emerging technologies and use of single sign-on approaches can reduce current friction. We believe that as these solutions prove their value that applications will rapidly adopt them. At the same time even a single log-on can be onerous when multi-factor authentication is required where the technologies are considered cumbersome, while recognizing the value they bring. Similarly, as new agreed to technologies emerge that can improve on this, e.g., biometric and proximity-based identification, applications can rapidly adopt them. We urge ONC and OCR to support adoption of standards that can serve as a minimum standard for supporting single sign on, and to consider developing guidance on how to balance these interests with other practices that present security and patient safety risks.

While a seamless, efficient single sign-on approach optimizes the log-in experience, it must be done with attention paid to mitigating risks of abandoned sessions because of lax time out policies defined primarily to minimize provider log-on. The same goes for guarding against session roaming that may be vulnerable to spoofing or hijacking if providers are not vigilant about their use. While we respect the need to be mindful of user convenience, we also have to be mindful of the amount of time a user can stay logged in without performing an action and timing out, as the longer they are away from their machine, the higher the potential chance of an error occurring when they return (especially if someone else uses the machine in the intervening time period). Any improvement to the log-on process likely needs to come with an equivalent level of training in both security and best practice for end-users and for organizations to find the appropriate balance between efficiency and safety.

*Recommendation 4: Continue to promote nationwide strategies that further the exchange of electronic health information to improve interoperability, usability and reduce burden*



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We strongly support this recommendation. We recommend ONC and CMS consider the following in implementing this recommendation. When it comes to topics such as health information exchange content, privacy and security of ePHI or quality reporting for regulatory reporting, standards and specifications of formats, data definitions, secure transport and communication requirements are essential and should be specific and clear to enable consistent interpretation of the data set at hand. As we have highlighted in responses to proposed rules and other strategy proposals, where the underlying standard is general and flexible (e.g., most of HL7's standards), the focus must be on use case specific implementation guides as those are sufficiently specific and unambiguous to promote consistent and predictable interoperability.

We also encourage that as this recommendation is applied across different types of providers and different types of HIT recognition is given to the need for an onboarding path to allow for difference in levels of adoption and capability that may arise. When we saw the initial proposals for the Trusted Exchange Framework Cooperative Agreement (TEFCA) especially when paired with potential coupling of interoperability requirements to CMS Conditions of Participation, we expressed concerns in public comment that any trusted exchange regime as well as any regulatory underpinnings for requiring interoperability need to be designed with onboarding in mind to account for differences in adoption, capability and in the form of what is to be exchanged (as per specified standards). Hospitals and physician practices have benefited from the EHR Incentive Program to drive adoption of interoperable HIT insofar as EHR certification required those capabilities to be present. However, venues such as for post-acute care, for behavioral health, for home health and for hospice have not so benefited. The available capital to many of these venues to invest in more functional HIT is often limited, and absent incentives for adoption, the HIT in use is more rudimentary and limited in function than what is used in hospitals and physician practices. We encourage ONC and CMS to assess if there is room in nationwide strategies to meet providers where they are, and to encourage their adoption to progress their capacity rather than adopt strategies that presume par level abilities across sectors of healthcare (at least for the near future) and that apply sanctions or compel removal from participation in nationwide trusted exchange over a lack of immediate capability or an inability to meet required levels of exchange as may be expected of those who have adopted CEHRT.

## **EHR Reporting**

### **Guiding Points for EHR Reporting**

In framing the strategies for burden reduction for EHR Reporting, we offer the following as guiding principles:

- Quality measures and performance measures should not require data capture that is not essential to patient care wherever possible
- Measure reporting should not necessitate post service abstraction for assuring data completion
- Measure development should be an open transparent process with allowance for “real-world testing” prior to their proposal for inclusion in federal rulemaking or program requirements

**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*

The focus of the recommendation seems specific to Eligible Clinicians who participate in the MACRA Quality Payment Program's (QPP) Merit based Incentive Payment System (MIPS). Our comments apply to both Promoting Interoperability in the MACRA QPP/MIPS domain and in its use as a program of the same name for Eligible Hospitals. Based on what we see of the 2019 Promoting Interoperability (PI) program policies adopted by rulemaking, we have several suggestions.

- Harmonize Medicaid EHR Incentive Program requirements and PI requirements for performance measurement to fully be the same.
- Develop value sets for the newly adopted opioid measures to improve consistency across HIT vendors so that each does not have to develop their own value set.
- Reduce inconsistencies across programs that seem purposeless such as varying reporting period lengths and timeframes in which measurement actions can be counted. There are also inconsistencies that accrue to attesting to the use of CEHRT or that require the use of CEHRT for program participation. This situation exists between the requirements for the Comprehensive Primary Care Plus medical home program for Medicare (full year) and the requirements of MACRA QPP (90 days). For the ease of managing provider burden both for the same type of provider (EC in the above case) and for those systems that face disparate reporting period requirements between EHs and ECs, harmonize them.
- Develop a standardized approach to calculating the number of opioid days as referred to by the new opioid measures adopted into PI such that the determination is not up to the HIT vendor but is a returned value supported by medication history interoperability.
- Standardize how (and where) providers are expected to verify the existence of an opioid treatment agreement and provide a specification basis for what constitutes as a "query of a treatment agreement" both for what applies to queries within the same EHR that is in use and external to the EHR if of an external source.

*Recommendation 2: Incentivize innovative uses of health IT and interoperability that reduce reporting burdens and provide greater value to physicians*

We support this recommendation. We encourage efforts supporting more efficient submission of quality measures data such as efforts CMS has made to use API based submission. We urge CMS to ensure such methods offer par level results to other existing submission methods but support their exploration and use. Also, rewarding innovation that reduces burdens allows providers, hospitals, health organizations, and vendors an incentive to focus time and resources in improving and facilitating reporting. Reducing burden by offering alternate pathways of program participation such as flexibility on submission or certification requirements would allow organizations to allocate resources to focus on improvements to future program requirements and show a value to the organization.

*Recommendation 3: Reduce burden of health IT measurement by continuing to improve current 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 should look to adopt an additional layer of objective/measure consideration between its newly adopted call for measures and the introduction of the measure into rulemaking. Currently the public has no chance to view or comment on an objective or measure until CMS publishes it in a notice of proposed rulemaking and once an objective or measure has been introduced into a notice of proposed rulemaking the ability to make changes to the measure are limited. Further, measures are adopted on occasion that seem provisional and experimental without a strong foundation of EHR use or supporting workflow that would be the basis of measurement performance. The opioid related measures adopted into Promoting Interoperability in the 2019 rule making cycle for both MACRA QPP/MIPS and for IPPS are cases in point. Commenters have a 60-day window in which to evaluate and comment on a potential measure, sometimes without even knowing what CEHRT functionality will be required to be used to meet the measure. This process severely limits the ability of stakeholders and the public to provide valuable comments. In addition, once CMS receives those comments it is limited in its options for the objective/measure. CMS essentially has one of three options: 1) adopt the objective/measure as is, or with minor changes; 2) finalize the objective/measure with more significant changes warranting additional comments from the public; or 3) decide not to finalize the objective/measure. The additional level of consideration also provides the industry additional time to prepare to meet the measure.

For quality measures, CMS contracts with the National Quality Forum (NQF) to make suggestions on which measures should be adopted. CMS does not have to only use measure recommended by NQF, however the process of running the measures through NQF provides value to CMS, to health care providers that will be required to meet the measure, to Health IT vendors that may be asked to provide functionality to meet the measure, and to other stakeholders. The NQF process allows stakeholders to dissect the measure, to review impacts to workflow, to analyze the value of the measure compared to potential disruption in workflow. It allows stakeholders to provide educated feedback on the measure and a potential timeline required for adoption of the measure.

CMS should look to adopt a process like the one it has with NQF to provide an additional feedback point for stakeholders. In the process of creating and adopting this process, CMS should ensure that its stakeholder group not only includes health care organizations and providers, but also Health IT vendors and developers that will be relied on to provide functionality to meet the measures.

We also suggest that ONC and CMS adopt some manner of “burden ratio” to determine what percentage of data required for measurement is captured beyond what is needed for patient care taken against the total set of data that is being collected. We suggest that the ratio should be less than 5% for a measure to be considered “non-burdensome”.

**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.*

We strongly favor this recommendation to the extent it can improve semantic interoperability for quality data. We encourage in this evaluation that ONC account for the prevalence of use of local codes and the amount of consolidation and possible variance of local codes that can impact semantic interoperability. For example, assessing the variability of meaning that can come from local code set

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values when mapped into standardized code set values is important to understanding the degree of “mistakes in data mapping” that may occur given that this is substantially up to the implementor/provider organization or HIT vendor to work out in implementation. We further encourage ONC to examine why local codes are used, and to determine if standard vocabularies can be used rather than local codes to eliminate mapping needs.

*Recommendation 2: Adopt additional data standards to make 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.*

We support the intent of this recommendation, and offer the following as considerations for its implementation:

- One challenge for this recommendation is to address the consolidation of data between EHRs or source systems when providers are migrating from a legacy system to a new EHR or to consolidate data from more than one source system into one external quality measure submission. We suggest that ONC and CMS consider collaborating with the industry to develop best practice guidance for dealing with data management between EHRs if one consolidated submission set is needed for submission. Guidance would be welcome focused on patient identity matching, semantic interoperability of reference information and consolidation of reporting data into one submission set. In a way, this represents a use case for information exchange but between legacy systems and newly adopted systems that involves significant customization for the sake of data convergence and reconciliation for external reporting purposes. It seems an issue left to the responsibility of individual HIT vendors and their clients to work out at present.
  - Specifically, we have seen specific use cases for clinicians reporting for MACRA/MIPS and the Comprehensive Primary Care Plus (CPC+) programs where clinicians have data resident in multiple EHRs that must be consolidated. [Current certification testing](#) focuses on import of QRDA Category 1 files for individual clinicians when most of our clients are reporting as a MIPS Group or CPC+ practice. The use of CPC+ practice address to identify the population group is also inconsistent when integrating data between EHRs and the HL7 QRDA Category 1 specification does not address the use of the CPC+ Practice ID. Since Category 1 files are not used for submission for the MIPS or CPC+ programs, there is little real world testing of integration and sharing of data between EHRs. There are also areas of concern when the HL7 specifications are not complete for the needs of CMS program requirements and specifications. CMS only published a Hospital QRDA Category 1 Implementation guide and a Clinician QRDA Category 3 Implementation guide – which leave some ambiguity when truly integrating QRDA Category 1 files between EHR systems. With the HL7 FHIR standards, there is opportunity to provide a tool to translate eCQM measure specification from QDM to FHIR as this model becomes a standard in the industry and would allow a more streamlined ingestion option for vendors.

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- The development of standards to help classify sensitive health information to support data segmentation remains a significant area of need. At present, there is a fundamental lack of normalized semantically interoperable understanding of what is “sensitive” particularly when that sensitivity is contextual. It seems that the determination of sensitivity is dependent on provider judgement. While standards development and reference implementations such as those created under the auspices of the Standards and Interoperability Framework several years ago addressed data segmentation once something was established to be sensitive, little tangible and implementable work has been done to address how to identify personal health information as “sensitive” in the first place. It may be that such can only be feasibly done as a matter of provider judgment and only feasibly implemented at the level of whole documents, episodes, encounters or patients such that everything shared within those contexts is marked as sensitive. However, this places the burden on the provider, and little progress has been made to address semantic interoperability based on data segmentation to address what is “sensitive” to begin with. That still seems left to the implementor/provider to determine or dependent on definition of implementation specific “blacklists”.

### **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.*

We support provision for “real-world testing” new measures that are to be electronic clinical quality measures (eCQMs) before they are proposed through rulemaking to assess how well they are supported by clinical workflow. Given the experience of data quality and data completeness of eCQMs to date, and feedback received from industry that such measures often require additional “check the box” or post coordination to assure data completion given specification requirements, more rigorous challenge is needed to evaluate if eCQMs truly can be a “by product of care”. Field testing should subject new measures to the same evaluation of “burden” as is applied to evaluate measures for retirement when it comes to data collection burden, documentation requirements asynchronous to care and determining if data collection truly is “seamless”.

### **Public Health Reporting**

#### **Guiding Points for Public Health Reporting**

In framing the strategies for burden reduction for public health reporting, we offer the following as guiding principles:

- EHRs and PDMP should have interoperable interactive health information exchange at the data element level for effective use of patient opioid history in clinical workflow to support opioid prescribing, use and treatment;
- Public health and specialty registries should make use of common standards and specifications whenever possible;

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- Consideration should be given to a “neutral convener” as a testing authority for those that do;
- Public health and specialty registry reporting requirements should be transparent and available to EHR vendors and their clients;
  - Data requirements that are typically only met by additional chart abstraction because of registry specific requirements should be known short of “discovery by experience;”
- Expectations of registries, providers, EHR/HIT vendors and 3<sup>rd</sup> party intermediaries should be fair and grounded in
  - What the limits on the use of the capabilities of CEHRT are to support registry submission requirements (particularly for use of the Data Export and QRDA generation capabilities).
  - Reasonable turnaround times for support of registry specific requirements.

**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.*

We strongly support this recommendation. The current state of the industry represents a lack of meaningful integration of PDMP with clinical workflow within EHRs. This means between the EHR and PDMP interactions are mostly passive and view only with little interoperability at the data level that enables the requester to integrate the PDMP data into their record. To the extent information is recorded from PDMP references, it is therefore primarily up to the provider/user to manually record information. Further, there is often limited consolidation of information available at the person level to provide a complete picture of a patient’s opioid use beyond one state or across a few states. We encourage advancement of truly interoperable PDMPs to enable a holistic view of a patient’s medication history across jurisdiction and in context of their overall medical record. This will also improve on the opportunities to provide clinical decision support taking more/all relevant data into consideration. We understand that this may take breaking down barriers that exist within a state for use of PDMP information beyond its historical purposes, and across states. We encourage exploration of this as a priority use case for the Trusted Exchange Framework under the 21<sup>st</sup> Century Cures Act, and to leverage the use of health information exchange under the TEF to enable cross state information compilation and consolidation to support provider inquiries into a patient’s medication history.

*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 as it is in line with a prescriber having a full understanding of the context for a patient’s history with controlled substances. This is a critical area of interoperability to



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support detection of possible “doctor shopping” and would help provide needed context to support Promoting Interoperability measurement requirements for the Verify Opioid Treatment Agreement measure denominator. We encourage the use of a standards based approach to making medication history available from PDMPs as not having standardized data available limits the EHR’s ability to consume and provide insights based on that history. This in turn limits the ability for the EHR to assist providers in assessing possible “doctor shopping” or similar situations where a new prescription may not be warranted or needed.

**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.*

We strongly support a public resource of the registry submission requirements of public health and specialty registries considering federal, federally funded, state and professional society registries that CMS and ONC may maintain or sponsor.

As is discussed in our comment on Recommendation 2, the level of effort to support registry level content requirements and lack of use of common standards for the same are among the most burdensome activities HIT vendors and their clients engage in to support Promoting Interoperability program participation. It also is a significant source for potential friction between HIT vendors, their clients, 3<sup>rd</sup> party vendors and intermediaries and the registries over issues of transparency of requirement, timeliness of support and the level of post coordination effort required to make up for incomplete data availability upon initial extraction from certified EHRs to have complete and accurate data submissions.

We recommend that ONC and CMS press for two strategies to alleviate burden for registry reporting:

1. There should be a required transparency of specifications available through such a resource for any public health or professional (private) entity that stands up a registry that is used by EHs or ECs as a basis to meet Promoting Interoperability requirements and/or where federal funding is involved in supporting the operations of the registry or the entity that sponsors it. We believe a public inventory should not only include reporting requirements but also clear statement of additional efforts necessary to provide for complete submissions post service abstraction of data to complete a submission set is reasonable to expect, identify supported submission formats that could be met by adopted standards and specifications, identify any material adaptations of standards or specifications or use of optional segments, data elements, extensions of code sets or other requirements that serve to represent additional development requirements beyond what a standard or specification indicates as required for conformance. This is an area that can benefit from transparency.

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Where federal funding is similarly involved, ONC and CMS should encourage adoption of use of normative standards and specifications for data content, vocabularies and submission formats so HIT vendors and their clients do not have to be subject to increased dependency on mapping, increased points of failure and manual abstraction of data to support registry 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.*

Since the adoption by CMS of options for the Public Health Reporting objective of Promoting Interoperability (Meaningful Use) to allow for specialty registry submissions, we have observed that HIT vendors and providers have struggled in their efforts to address the fact that while data must be electronically submitted from CEHRT, there has not been a specification or standard associated with any given 2014 Edition or 2015 Edition certification criteria that adequately provides support for these submissions. Certain registries and intermediary third parties have attempted to make use of the capabilities of CEHRT to for Data Portability or Export and for QRDA file generation under 170.314(b)(7) or 170.314(c)(1) and 170.315(b)(6) or 170.315(c)(1) to support such submissions. Provider expectations that these capabilities can be used “out of the box” become frustrated because these capabilities as certified lack abilities to support qualifying patients for submission or to meet data content requirements of submission to specialty registries because of incompleteness for what is required or require post coordination processes that are burdensome to fill out missing data to ensure data quality. The problem in short is that HIT vendors are placed in the situation to contend with registry specific data content submission requirements that necessitate custom development without the benefit of a standards-based format or specification.

Further, many providers have attempted to make use of 3<sup>rd</sup> party specialized registry technology vendors and 3<sup>rd</sup> party clearinghouses to leverage their relationships with specialty registry sponsors to provide data transformation services and data extraction support from source certified EHRs to ease support for submission. However, this still has required HIT vendors to develop custom extracts to meet proprietary format requirements that will meet all the data point requirements for the registries these 3<sup>rd</sup> parties support. The reason for this is two-fold. First, effort is involved to obtain registry specific requirements which often includes HIT vendors having to satisfy intellectual property concerns of registries sponsors (medical societies and professional organizations) to have full access to the necessary specifications and standards to avoid potential issues of data integrity and completeness. Second, as we have discussed leveraging capabilities of CEHRT for this purpose (HL7, CDA, or QRDA formats such as those mentioned earlier), it elicits the response from the 3<sup>rd</sup> party registries that these formats do not contain enough data or support patient qualification sufficient to meet their requirements. Notably there is not an ability to leverage the capabilities of CEHRT to include into such formats a way to submit:

- Charge and billing data
- Diagnostic reports and clinical notes
- Insurance
- Clinical information (scales and assessments, certain clinical documentation or results, certain medical/health histories)
- Gaps-in-care or health maintenance for preventative or condition management

These, and other, required data elements can be captured using other capabilities of CEHRT or that are integrated with CEHRT, but what we have experienced is many 3<sup>rd</sup> parties or registries can have their



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own proprietary formats in which to receive the data which can lead to specific development support based on where and to whom our clients are submitting.

We strongly favor CMS working within its own programs and ONC and CMS working with other federal agencies and with state agencies dependent on federal funding to press for adoption of common standards and specifications for public health and specialty registry reporting. We equally urge ONC and CMS to do far more to educate providers, state agencies and specialty/professional societies that operate registries to understand the limits of the capabilities of certification and to understand the limits of their use for meeting purposes of registry submission absent use of standards or specifications tested by certification. As mentioned in the comment on Recommendation 1, we argue in favor of a clearinghouse of registry specifications and processing requirements necessary to meet submission requirements. We believe education of high importance to help the market understand reasonable expectations and a fair measure of vendor responsiveness to meet what are proprietary specifications that necessitate custom development.

Adjunct to such an effort, We recommend ONC and CMS consider if they could work on providing an expanded support for semantic interoperability similar to their approach for a [Data Element Library](#) for common clinical data elements of interest for registry reporting. Further, ONC could consider such common clinical data elements as candidate for the U.S. Core Data for Interoperability once that is in place and operational.

We also advocate for ONC and CMS to support identifying one or more “neutral conveners” to be able to serve as testing entities for conformance testing to support public health or specialty registry submission testing where registries have adopted normative common standards and specifications that stand outside of the standards and specifications of ONC EHR certification. This helps serve to provide confidence to vendors, providers and registries alike to be give accord to the independent validation of conformance for registry submissions where no other certification process exists and could help relieve testing burdens from registries themselves in dealing with many distinct providers and their vendors from seeking to on board.

As we consider pending information blocking regulations, the last thing the industry needs is a spate of acrimony and spurious allegations of bad faith over vendor efforts that we believe substantially in good faith to try to help meet specialty registry requirements. We believe that ONC and CMS have a responsibility to help effect positive solutions to a situation spurred by the adoption of “use” requirements where there is no basis of specification or standard supported by certification.