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# Department of Veterans Affairs Electronic Health Modernization

## Request for Proposal Interoperability Review Report



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# VA EHRM RFP Interoperability Review Report

January 31, 2018

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## Executive Summary

This Review Report presents responses to three requests from the Department of Veterans Affairs (VA) to MITRE related to the topic of interoperability within the VA Electronic Health Record Modernization Request for Proposal:

- I. Conduct an external Interoperability Review Panel to review the interoperability language in the existing Request for Proposal (RFP),
- II. Engage an independent and unbiased legal expert to identify the specific changes to the RFP language necessary to implement the recommendations from the Interoperability Review Panel, and
- III. Visit the University of Pittsburgh Medical Center to understand the existing operational multi-vendor solution and interoperability solutions for applicability and scalability to the VA.

### I. Interoperability Review Panel

In support of the Secretary of Veterans Affairs, David J. Shulkin, M.D., The MITRE Corporation convened and hosted a VA Electronic Health Record Modernization (EHRM) Request for Proposal (RFP) Interoperability Review Panel on January 5, 2018, at MITRE's McLean headquarters. The invited external senior electronic health record (EHR) interoperability subject matter experts (the Panel) reviewed the interoperability language in the existing RFP and developed joint suggestions and recommendations for VA to consider for incorporation to support the successful execution of a new commercial EHR contract with industry. The Panel affirmed that the primary goal should be seamless Veteran-centric healthcare achieved through true EHR interoperability. Achieving this goal rests on three overarching principles that should be supported by interoperability language in the RFP: 1) free and open access to data, 2) an ecosystem that provides fair access to third parties by creating a level playing field, and 3) a seamless Veteran and health provider (clinician) experience. Four categories of recommendations from the Panel (the first three to the interoperability language in the RFP, and the fourth for future VA contracts) will enable VA to realize this goal on the basis of the underlying principles: 1) commit to full VA-Department of Defense (DoD) interoperability, 2) leverage current and future standards, 3) commit to open, standards-based application programming interfaces (APIs), and 4) use Care in the Community contracts to foster interoperability.

For the first category (commit to full VA-DoD interoperability), the Panel agreed that the Determination and Findings signed by Secretary Shulkin on June 1, 2017, represented the correct approach to interoperability within VA and between VA and DoD. The Panel strongly endorsed the proposed VA "API Gateway" language. The most important specific recommendations included:

- Define the degree of interoperability the solution will provide, ranging from basic file sharing to fully interchangeable, integrated and functionally identical patient records.

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Suggest that the Contractor conduct an annual Interoperability Self-Assessment against current and future standards that shall be specified by the VA; and

- The contract language should include the following elements:
  - performance measures to hold Cerner accountable for reducing the administrative burden in clinician workflow with the objective of increasing efficiency,
  - ability for bulk data export based on standards, with no proprietary formats (e.g., Flat FHIR [Fast Healthcare Interoperability Resources]), and
  - “push” capability to insert patient data back into the VA EHR / Cerner database.

For the second category (leverage current and future standards), the following specific recommendations were among the most important:

- Require that Cerner implement all standards as defined by VA, current and future,
- Engage Cerner as an advocate of the VA and DoD position in all relevant standards-making bodies, and
- Ensure that VA and Veterans have complete access to data.

For the third category (commit to open, standards-based APIs), the Panel voiced the following recommendations:

- Establish clear publishing and access service requirements,
- Provide a VA application platform that supports APIs from third party providers with no barrier to entry, and
- Require implementation of clinical decision support (CDS) Hooks to invoke decision support from within a clinician's EHR workflow.

The body of this report contains multiple additional specific recommendations.

## **II. Recommendations for RFP Changes**

MITRE engaged Morrison & Foerster, LLP as the independent and unbiased legal expert to identify the specific changes to the RFP language necessary to implement the recommendations from the Interoperability Review Panel. Appendix C presents all recommended changes to the RFP.

## **III. Observations from University of Pittsburgh Medical Center Site Visit**

A delegation from VA and MITRE traveled to Pittsburgh, Pennsylvania, on January 19, 2018, for a meeting with representatives from University of Pittsburgh Medical Center (UPMC) Enterprises to discuss aspects of EHR interoperability that UPMC has successfully implemented over the past several years. The report includes an overview of those practices.

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#### **IV. Closing Thoughts and Suggested Next Steps**

The Panelists noted that VA cannot achieve true future EHR interoperability through the Cerner RFP alone, or through technology alone. The state of practice today shares only a small portion of available patient data. For VA to succeed in the future, multiple other components must be present and aligned: innovation, policy, standards, customer buy-in, and legislation, to name a few.

The following next steps are recommended for VA consideration:

1. Complete the RFP revisions, conduct appropriate negotiations with the Contractor expeditiously, and complete the contract process as planned. Stand firm during negotiations to maximize ease of access to data and data models for building third party APIs, applications, and services for future community innovations.
2. Continue to work with other federal government agencies and departments with similar interoperability interests and concerns, including, but not limited to, the White House, DoD, Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), and other parts of the Department of Health and Human Services, to align approaches to EHR interoperability and the development and support of standards government-wide.
3. Support future innovation approaches, including concepts such as an Interoperability Laboratory and outreach to the broader innovation ecosystem (major medical centers, academia, traditional and non-traditional healthcare providers, startups, individual entrepreneurs, others). It is critical to align the innovations planned in VA's Digital Veterans Platform to the VA EHR innovation efforts to ensure consistent continuous improvements to clinician and Veteran health experiences.
4. Create an External Review Panel to provide expert continuous guidance, review, and feedback over the course of the implementation, to help capture best practices from the expert community going forward. Conduct ongoing demonstrations of end-to-end Veteran use cases requiring data sharing across organizational boundaries to validate improvements in Veteran healthcare and reduction of burden for healthcare providers. VA and Contractor will ensure that Federal Advisory Committee Act (FACA) guidelines are followed in leveraging any external review panels.

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## **Background**

The Department of Veterans Affairs (VA) plans to establish seamless care for Veterans throughout the health care provider market. Seamless care requires interoperability between the Department of Defense (DoD), VA, VA affiliates, community partners, electronic health record (EHR) providers, healthcare providers, and vendors. VA directed The MITRE Corporation to independently review the capability of Cerner's proposed EHR solution to seamlessly transmit health records between EHR systems supporting healthcare providers who both use and contribute patient data to a Veteran's health record, to include Veterans Choice Program (VCP) community-care service providers and VA affiliates. This Review Report presents responses to three requests:

- I. Conduct an external Interoperability Review Panel to review the interoperability language in the existing Request for Proposal (RFP),
- II. Engage an independent and unbiased legal expert to identify the specific changes to the RFP language necessary to implement the recommendations from the Interoperability Review Panel, and
- III. Visit the University of Pittsburgh Medical Center to understand the existing operational multi-vendor solution and interoperability solutions for applicability and scalability to VA.

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# **I. Interoperability Review Panel**

## **Introduction**

In support of the Secretary of Veterans Affairs, David J. Shulkin, M.D., MITRE convened and hosted a VA Electronic Health Record Modernization (EHRM) Request for Proposal (RFP) Interoperability Review Panel on January 5, 2018, at MITRE's McLean, VA headquarters. MITRE invited external senior EHR interoperability subject matter experts (hereafter referred to as Panelists) to review the interoperability language in the existing RFP and to develop joint suggestions and recommendations for VA to consider incorporating into the RFP to support the successful execution of a new commercial EHR contract with industry. Eleven Panelists took part in person, and several senior government executives observed the process (see Appendix A for the full list of participants).

## **Goal**

The Interoperability Review Panel sought to provide Secretary Shulkin and his senior leadership team with insights into key best practices and guidance from national experts regarding EHR interoperability. The Panel evaluated the corresponding language in the draft RFP based on successful business transformations and implementations of a new commercial EHR system across a distributed hospital and provider network. This section of the report summarizes the outcome of the Panel: expert recommendations that will inform VA's interoperability contract language. The document also provides actionable and specific best practice recommendations and rationales to enable successful acquisition and implementation of EHR interoperability.

## **Methodology/Approach**

The first part of the session, which lasted for five hours, was conducted as a fish-bowl exercise and was guided by Chatham House Rule. The Panelists sat at a center table, with VA and other government observers sitting at surrounding tables. The second part, which lasted two hours, consisted of a summary debrief to the Secretary and senior VA leadership. The Secretary could ask questions and engage with the Panel throughout the second session. MITRE moderated the session to elicit inputs from all Panelists and to drive alignment toward consensus in the recommendations.

The agenda for the first portion of the session was structured to elicit inputs from all Panelists, with notes captured on-screen as redlines to the RFP interoperability language to ensure recommendations accurately reflected the Panelists' contributions. Subsequently, in a facilitated discussion, the Panelists grouped their recommendations into specific categories in real time. The second portion, as noted, provided opportunities for the Secretary to discuss the recommendations in additional detail.

This section of the report summarizes the discussion that took place. It highlights actionable changes to the interoperability language contained in the RFP and additional recommendations and lessons learned that can enable interoperability of the VA EHRM solution. Text boxes

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throughout the report present direct quotations from Panelists. To ensure participant confidentiality, MITRE has destroyed the transcript and event recording used to develop this report.

## Topic Area: VA Definition of Interoperability

*The key to modernization is creating greater interoperability with Governmental partners, including DoD, in a way that focuses efforts in support of the Veteran's journey, beginning with their military service. We will partner with others to ensure Veterans can get their benefits, care, and services consistently, easily, and with excellent customer service, no matter where they are throughout their lives. VA will work with local communities, and with other Federal, State, Tribal, and Local Government entities to ensure Veterans get what they need. VA will also continue to leverage the private sector where appropriate and needed to deliver the very best outcomes for Veterans.*

– draft VA 2018–2024 Strategic Plan

## Enable data sharing, interoperability, and agility through data standardization

VA needs to allow data sharing among various business applications, such as appointment scheduling and business intelligence, as well as ensure transportability of information between sites. Panelists advised VA to leverage and support the best-in-class innovation currently in use within the VA culture. VA must also enable interoperability as the Department integrates the EHR into other supporting systems, both within the VA network and with external health service providers. Agility is necessary for adoption of future innovative technologies and/or if VA wants to upgrade or change the EHR approach. The Panelists cautioned that the current EHR technology is already 20 years old and, as with all industries and information technology (IT) solutions, many possibly disruptive technologies exist on the horizon.

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*"It really optimizes transportability of best practices, because if you are trying to transfer best practices from one site to another and you have the same system where the best practice is going to land, then it is much easier."*

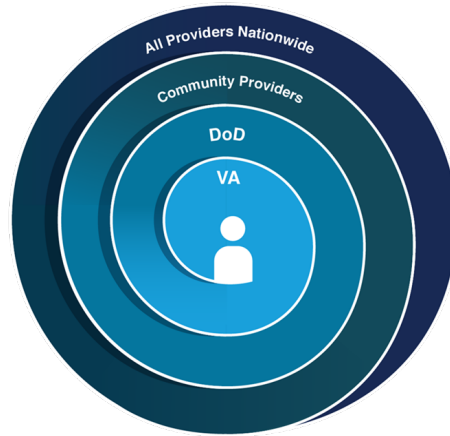
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The session began with a discussion on interoperability as currently defined by VA (Figure 1). Prior to establishing a roadmap to inform a nationwide plan to advance health data interoperability, VA must first ensure system-wide interoperability across the Department. Throughout the Review Panel session, the Panelists described and referred to this concept as "Level 1 Interoperability" throughout the Review Panel session; it includes migration of Veteran data from ~130 instances of the Veterans Health Information Systems and Technology Architecture (VistA) to one VA platform.

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**Figure 1. VA Definition of EHR Interoperability**

“Level 2 Interoperability,” as described in the Panel discussion, addresses the ability for VA to leverage the same Cerner platform used by DoD to ensure seamless care from active service to Veteran status. Once this capability is implemented, the clinical data transformation will allow a true longitudinal view of a Veteran’s record as he or she transitions from DoD to VA for care and other critical services such as benefit adjudication.

“Level 3 Interoperability” will allow both VA and DoD to take an important step toward transforming electronic patient data exchange on a national scale. With the utilization of community healthcare providers via the VA Community of Care initiative and DoD’s Tricare network providers, VA has the opportunity to drive interoperability between DoD and VA as well as with the extensive network of healthcare providers that serve our Nation’s Veterans, active duty service members, and their beneficiaries.

True nationwide EHR interoperability for the entire United States is the ultimate goal, and the Panelists agreed that VA and DoD could reach this goal if the three aforementioned levels of interoperability are achieved. Here, VA has the opportunity to drive clinical transformation and instantiation of a complete EHR for all patients at the national level.

### **Topic Area: Commit to Full VA-DoD Interoperability**

The Panel focused primarily on reviewing the interoperability language within the RFP for the Cerner contract. However as described in Interoperability Levels 1 and 2, the commitment to the seamless integration of VA and DoD health data represents the foundation required to realize interoperability with private sector

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“You really have to get the basics done first. Let's just make absolutely sure that the interoperability between DoD and VA [is achieved].”

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healthcare providers.<sup>1</sup> It is important to note that the interoperability levels can be addressed simultaneously and should not be separated, as they must be integrated to efficiently achieve the larger future data sharing ecosystem.

### **Specify the expectations for interoperability between DoD and VA**

During discussions about the expectation that Cerner will provide a single EHR solution to be shared by both DoD and VA, the Panel raised concerns about the lack of specificity in the contract language. Current interoperability data standards address a subset of the Veteran's clinical record and VA has the opportunity to ensure Cerner provides interoperability of all discrete data, at a minimum, between VA and DoD. Adopting the same platform would increase seamless sharing, but the Panel stated that VA should take additional action to ensure that such sharing is realized. The DoD and VA systems should use proprietary database-to-database interoperability if necessary, to maximize interoperability between those two systems. These systems should be configured to meet the distinct needs of each while being connected to each other in a native database-to-database method as necessary, leveraging open interoperability standards wherever possible. As a result, clinicians should experience no differences when they move from a VA system to a DoD system. These data should also be computable, or be made computable according to a specific schedule. VA should consider adding language to the RFP that specifically defines the degree of interoperability the solution will provide, ranging from basic file sharing to fully interchangeable, integrated and functionally identical patient records.

The Panelists also stated that, for VA and DoD collectively, the contractual language should include the following requirements:

- Performance measures to hold Cerner accountable for reducing the administrative burden in clinician workflow with the objective of increasing efficiency
- Capability for bulk data export based on standards, with no proprietary formats (e.g., Flat FHIR [Fast Healthcare Interoperability Resources])
- “Push” capability to insert new patient data back into the VA EHR / Cerner database.

### **Pivot the RFP to be Veteran-centric and not system-centric**

The Panelists discussed the impact of EHR implementations on clinician workflow, describing the issue as one of approaching the implementation as an IT system implementation rather than the preferred Veteran- or clinician-centric implementation. The current RFP appears to be written in a system-centric way rather than leveraging use-cases to describe the Veteran or clinician experience or workflow to characterize the requirement. The Panelists recommended that VA incorporate use-cases to characterize requirements and amend the RFP language to emphasize the Veteran-centric objectives. In addition, Panelists noted that VA should recognize that EHRs do not currently maximize efficient clinical workflow, and that VA specify that the

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<sup>1</sup> Healthcare providers is used to refer to community based physicians/specialist and hospitals.

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solution present clinicians with relevant information where needed with a minimum number of “clicks to find.”

## **Topic Area: Leverage Current and Future Standards**

The integrated EHR platform that DoD and VA are implementing provides the opportunity to significantly influence interoperability standards across the healthcare community, addressing gaps and competition among current standards. The Panel recognized that commercial health systems and technologies would realize only limited business value from making data portable between them, but this would lower the barrier to patient movement among healthcare providers.

### **Engage Cerner as an advocate of the VA and DoD position in all relevant standards-making bodies**

The Panel recommended increased VA presence and leadership in national health IT standards-making activities, in coordination with the DoD. Additionally, VA should encourage Cerner to serve as an active advocate of the VA-DoD position and to participate actively in the development and/or evaluation of new standards, policy directives, operating procedures, processes, etc. As an integrated voting bloc, VA, DoD, and Cerner will have the potential to act as a strong driver of national standards. Panelists understood that VA is not currently active in the FHIR community or in the Health Level Seven International (HL7) Argonaut Project.

In addition, Panelists identified a need for standards to exchange patient-reported outcome data for integration into the clinician’s workflow. The current RFP language seemingly puts the burden on Cerner for the development of standards, and the Panel recommended that VA take a more active position. This will ensure that VA will participate and drive implementation when standards mature. Where standards are immature, VA must participate in efforts to accelerate standardization.

### **Require Cerner to implement all standards as defined by VA, current and future**

Because it is unclear where health IT is heading in five years, the Panel strongly suggested VA include contract language to address possible future advancements in the form of standards as defined by VA. At a minimum, VA should seek maximum interoperability with community care organizations, using open interoperability standards wherever possible. This flexibility would ensure that VA does not rely on external stakeholders to determine the standards that VA would be required to accept. The Panel recommended that VA pay particular attention to specific categories of standards: real-time data read/write by care providers and Veterans; interoperability tools; seamless DoD and VA vision records; and principles for data normalization and structure. The Panel also recognized Cerner’s influence in ensuring that the CommonWell network interoperates at the highest possible levels with other networks including CareQuality—an influence that VA should continue to promote.

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## **VA must own its data; clear ownership and access are critical to success now and in the future**

The Panel highlighted an important recommendation regarding data rights that was discussed in the prior VA EHRM Listening Forum on September 7, 2017. The Panel recommended that VA define who has what rights from the perspectives of data ownership, access, and sharing (e.g., VA owns the data and all data products vs. community care providers own the patient data vs. each Veteran owns all of his or her data). Determining the authoritative data source for the various elements of a Veteran's health record is an important Veteran-centric component of interoperability, the longitudinal record, and seamless access to data.

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“So, what you need is clear access and clear ownership of your information...you need to have absolutely, undisputed, clear ownership and ability to move the data to any place you want to use it and use it in any way you want to use it when you get there. And not have them [Cerner] be able to say no, that's our data or hinder you in any way or have an unreasonable charge to get it.”

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VA should define an enterprise-wide policy for all VA data. A suitable policy would include, but not be limited to, EHRM-specific data, and should be issued by the VA Central Office (VACO) or Veterans Health Administration (VHA). VA must have clear ownership of and access to all the information in the EHR and be able to move that information (into new systems or among systems) as needed, now and in the future. Owning the data ensures that it is available regardless of vendor or system. VA must include this in the Cerner contract. Technology innovations occur rapidly in the 21<sup>st</sup> century, and VA must have full ability to move its data to future systems.

Panelists also recommended that VA publish its data model, for instance to the National Library of Medicine, to further promote commercial interoperability investments. Lastly, Panelists encouraged VA to leverage its investment in the Open Source Electronic Health Record Alliance (OSEHRA) by providing seed money to develop open source connectors between Cerner and Epic, which would encourage other vendors to join in the effort.

## **Topic Area: Commit to Open, Standards-Based APIs**

A significant technology enabler of seamless interoperability among the community of Veteran healthcare providers is the use of Application Programming Interfaces (APIs). These software intermediaries allow disparate EHR applications to communicate with each other and exchange data using standard, defined forms. The Panel emphasized the need for VA to create an environment that would minimize additional costs to community providers in order to interoperate with VA. VA can accomplish this by requiring the new EHR system to expose APIs that support bi-directional data transactions. The Panel further recommended that VA make a commitment to open, standards-based APIs, including the SMART on FHIR/Argonaut APIs, to facilitate the ready and efficient exchange of data with partners providing care in the community and to support open clinical workflow.

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## **Establish clear publishing and access service requirements**

The Panel recognized that data access requirements differ depending on who provides or accesses that data.

Therefore, the Panel recommended that VA be more specific in defining each level of data publishing and access service that is specific to (1) Veteran access (e.g., use of vets.gov); (2) VA clinician access; (3) partner access; and (4) Health Information Exchange (HIE) access. The RFP should include a clear description of identity and access management requirements, including user population types and the association of specific application permissions with particular roles/positions.

Machine-to-machine access is also critical for efficient sharing of information. The Panel recommended that VA ensure that all significant data stored in the software be accessible through APIs with no requirement for creation of custom applications to specifically access VA data. From a forward-looking perspective, VA should require that the EHR system support the ability to access data elements using open standards-based interfaces, and include the ability to interface with legacy data, patient-generated data, and third-party data that resides outside the EHR system. In addition, Cerner should provide the required utility services to support intermediary or peer-to-peer services (e.g., support Veteran-directed or Veteran-mediated requests, data exchange, and ingestion of data from non-VA providers).

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“The Contractor should provide all of the data that is currently being provided in the Contractor's patient portal to the consumer via an open standards-based API gateway. The Contractor should also provide all of the reporting data required by federal law to the Veteran via an open standards based API framework, accessible via any application or third-party data store of the Veteran's choice, that's number one.”

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## **Provide a VA application platform that supports APIs from third-party providers with no barrier to entry**

Currently vets.gov serves as a portal to Veteran services. The Panel recommended that VA consider using such a portal to connect any third-party application to the EHR solution without requiring fees or vendor permissions. VA should have full

authority to connect any third-party application through one of the standard open APIs conformant with the vendor's API without pre-registering the application with the vendor. This is a very important authority to have in terms of the ability to innovate rapidly, without constraints.

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“The API Gateway document is awesome ... world class and future looking.”

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The Panelists also reviewed the proposed VA “API Gateway” language provided during the API discussion to anchor the dialogue and concurred that this requirement is fundamental to supporting interoperability. The Panel strongly endorsed the “API Gateway” language. Specifically, the Panelists recommended that VA include a requirement that VA have full authority to connect any third-party application to the Cerner system without requiring prior approval by Cerner. Furthermore, VA should ensure that developers of third-party applications connecting to the VA system via the open standard and VA-defined APIs continue to own their

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intellectual property (IP). From a usability perspective, the Panel also recommended that VA be able to establish the connectivity business rules, such as the ability for applications to remain connected for a reasonable time frame (e.g., 1 year) and to receive automatic notification about patient information updates.

### **Require implementation of Clinical Decision Service (CDS) Hooks to invoke decision support from within a clinician's EHR workflow**

EHRs are essential to efficient delivery of high-quality care, as they provide the clinician with essential decision data at the time required. However, current EHR systems approach workflow from an IT system perspective rather than a clinician's perspective. The latter workflow should, of course, be paramount in the VA EHR implementation, and should also leverage a recent innovation called CDS Hooks. This technology provides the clinician with context-driven decision support and capability by enabling the EHR to trigger third-party services at key events that include ordering medication and opening a patient face sheet. For example, when the VA clinician begins to prescribe medication, a CDS Hook can call an external service that presents the clinician with the list of medications already prescribed to the patient by clinicians outside VA. The Panelists strongly recommended that VA require Cerner to implement and use CDS Hooks within the clinician workflow.

### **Topic Area: Use Community Care Contracts to Foster Interoperability**

The new EHR system must be able to communicate with other EHR systems (e.g., Epic, AllScripts, etc.) within the care community. It is critical that VA ensure the Cerner EHR system remain robust for future interoperability with new products. Cerner must commit itself to supporting other forms of interoperability, such as a presentation layer that is common to other systems (e.g., the App store model). The Panel recommended that prior to execution of the Community Care Act contract VA require third-party providers (and Cerner competitors) to commit to supporting the contract as early adopters.

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"Innovations going forward are going to come from multiple directions. And having those interfaces, and going with a general interoperability approach that doesn't fork off from what's happening in the rest of the healthcare system, will allow the Veterans to benefit from technology whether that's coming from Google, from a new company, from an innovative shop within VA -- you end up creating a market with good prices, high value."

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### **Veterans must be able to access and download a computable form of their health data**

Panelists noted that access to data represents the biggest problem today. VA must clearly direct Cerner to expose data so it can be used by third parties. In the contract and in conversations with Cerner and third parties, VA must require specifics regarding how Veterans and providers will

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access and share their data. In addition, VA must require that any agreements leave the door open for future standards and technologies.

Panelists believed that VA could achieve this by invoking the principle that the data belongs to the Veteran, rather than by citing specific technologies and standards (given how rapidly they are evolving). Veterans must be able to invoke their right of access to data to support data exchange across all providers (e.g., pull data through an API on their smartphone and push it to their community care provider), now and in the future. Keeping pace with this requirement will drive continual innovation by Cerner and all providers.

### **VA must own the API layer**

Cerner ownership of the API layer (across every customer) poses a real threat to achieving interoperability, speed of innovation, and cost efficiency throughout the network of community care providers. Panelists stated that it is of utmost importance that VA include specific language stipulating that VA and Veterans be able to use third-party applications without having to register them with Cerner. VA must control the API key, not Cerner.

Additionally, VA should require that Cerner provide access to MPages, a developer toolkit, and a programming interface that will enable innovators and third parties to develop APIs.

### **Require that community care contracts include VA EHR standards to support bi-directional data sharing**

Panelists agreed that requiring the support and collaboration of community care providers and participating actively in health IT standards bodies would give VA the opportunity to advance the “national” standard for data sharing—closing any gaps and inconsistencies among federal, industry, and inter-industry standards. VA must require every provider in the chain of a Veteran’s care to support the same standards for data interoperability in order to ensure seamless, best possible care for Veterans. This includes the requirement that all providers and third-party applications, in exchange for using the VA-provided API gateway, provide bi-directional health information back to VA that can be used for context-driven clinical decisions and informatics.

### **Change the data exchange consent model from “opt in” to “opt out”**

To encourage seamless interoperability across all entities providing care to Veterans, the consent model for exchanging data between healthcare providers must be modified to follow an opt-out rather than an opt-in policy, which limits participant numbers. This would allow Veterans to invoke their individual right of access under the Health Information Portability and Accountability Act (HIPAA) to move their data as needed. Many states have already adopted an opt-out consent policy as part of their HIE.<sup>2</sup> VA can achieve this by aligning its policy to an opt-

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<sup>2</sup> See [https://www.healthit.gov/sites/default/files/State%20HIE%20Opt-In%20vs%20Opt-Out%20Policy%20Research\\_09-30-16\\_Final.pdf](https://www.healthit.gov/sites/default/files/State%20HIE%20Opt-In%20vs%20Opt-Out%20Policy%20Research_09-30-16_Final.pdf)

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out model, supported by the new VA proposed rule<sup>3</sup> to allow HIEs to collect a Veteran's consent and electronically attest to the consent to VA in order to obtain the required EHR.

## **Topic Area: Additional Contract Changes**

In addition to the recommendations in the prior sections, the Panelists encouraged VA to add further definitions and clarity in the following areas:

- Require Cerner to provide VA with full read and partial write access to all data elements within the EHR, at VA's sole discretion.
- Require Cerner to make the VA data model, standards, and other similar interoperability changes available in all other non-VA Cerner instances of its EHR platform.
- Clearly define "enabling security framework" so that users know if this means a specific security framework such as those provided by the National Institute of Standards and Technology (NIST), HITRUST, etc.
- Amend "national Common Trust Framework" to specifically refer to the intended source. The Panelists suggested that VA replace this wording with "Trusted Exchange Framework and Common Agreement (TEFCA)" as specified in the 21<sup>st</sup> Century Cures Act.
- Amend RFP Performance Work Statement (PWS) Section 5.10.4(i) to clarify if the "provider collaboration via secure e-mail using Direct standards" is limited to the Direct protocols and just the Cerner platform.
- Incorporate the model RFP language necessary for Cerner to support the API and SMART on FHIR platform and SMART-enabled applications, as described in Appendix B.

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<sup>3</sup> See <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-00758.pdf>

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## **II. Recommendations for RFP Changes**

MITRE engaged Morrison & Foerster, LLP, as the independent and unbiased legal expert to identify the specific changes to the RFP language necessary to implement the recommendations made by the Interoperability Review Panel. MITRE provided Morrison & Foerster, LLP, with the summary recommendations and a copy of the RFP.<sup>4</sup> In addition, MITRE collected specific ideas for contract language from the Panel. Appendix C presents all recommended RFP changes.

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<sup>4</sup> *Performance Work Statement for the VA Electronic Health Record Modernization System*, Final Version 1.7, Amendment 03, December 4, 2017, Department of Veterans Affairs. File name: 001 - VA EHRM IDIQ PWS (Amended 12.04.2017) - Copy.docx

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### **III. Observations from University of Pennsylvania Medical Center Site Visit**

A delegation from VA and MITRE traveled to Pittsburgh, Pennsylvania, on January 19, 2018, for a meeting with representatives of UPMC Enterprises to discuss aspects of EHR interoperability that UPMC has successfully implemented over the past several years. The VA team, led by John Windom, included Dr. Ashwini Zenooz, (b) (6), John Short, and (b) (6). The MITRE group included Richard Byrne, Jay Schnitzer, (b) (6), and (b) (6). The hosts at UPMC included Dr. Rasu Shrestha, C. Talbot Heppenstall, Jr., Ed McAllister, Dr. Robert Bart, Adam Berger, Diane Michalec, Phyllis Szymanski, and Dr. Amy Urban, as well as additional staff.

The meeting was broken into four parts. Following introductions, Session 1 described the structure of UPMC. Session 2 covered UPMC's last decade of interoperability, and Session 3 centered on the road ahead for UPMC and industry.

Dr. Rasu Shrestha began the meeting by making the introductions and setting the agenda. He stated that UPMC's approach had followed a best-of-breed strategy, as opposed to a best-of-suite strategy, with the intention of failing fast and succeeding often. The overall UPMC structure has four parts: provider services, insurance services, international activities, and enterprises.

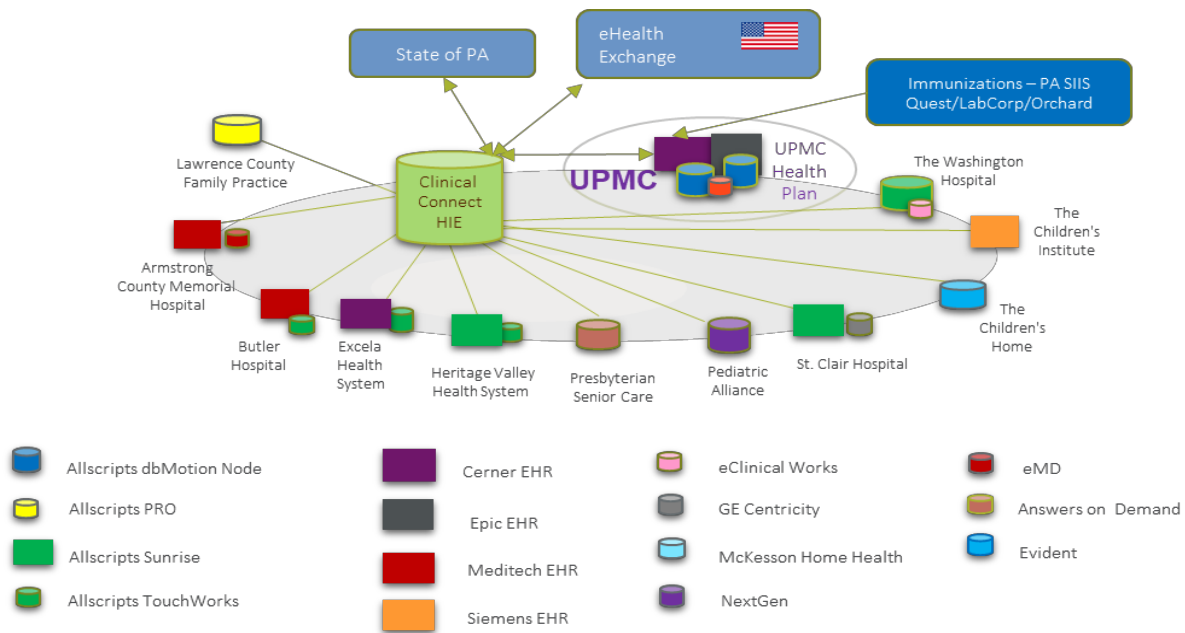
During the discussion of interoperability, the UPMC team described its approach to interoperability, called Connected Healthcare, which is based on the commercial product dbMotion of AllScripts. UPMC has created an entity titled ClinicalConnect HIE (CCHIE) that uses HL7. ClinicalConnect exists as a separate 501c(3) company, of which UPMC is a member. CCHIE contains 90 live interfaces. This HIE went live in June 2012; its members consist of 10 hospitals. It competes with three other HIEs in Pennsylvania. The repository contains data on 8.3 million patients, and, in terms of patient consent, CCHIE uses an opt-out model. It currently has connections to four EHRs: Cerner (two versions), Epic, and Varian. Data available within CCHIE spans allergies, clinical documents, diagnosis, encounters, immunizations, labs, medications, problems, and procedures. Much of this data is in the form of documents (Continuity of Care Document (HITSP C32 CCD format, including problems, allergies, and medications); unstructured clinical documents (HITSP C62 format); Consolidated Clinical Document Architecture (C-CDA CCD, including problems, allergies, medications, immunizations, procedures, and insurance); and HL7 Interface (ADT: encounters, documents, imaging documents, and labs only).

At the point of care dbMotion allows multiple views for the CCHIE: 1) a clinical view, 2) a newer view titled EHR agent, and 3) a Cerner MPage integration view. The next phase of the UPMC work in this regard will consist of integration with CommonWell. Figure 2 shows the architecture of the system. Figure 3 depicts the data feeds.

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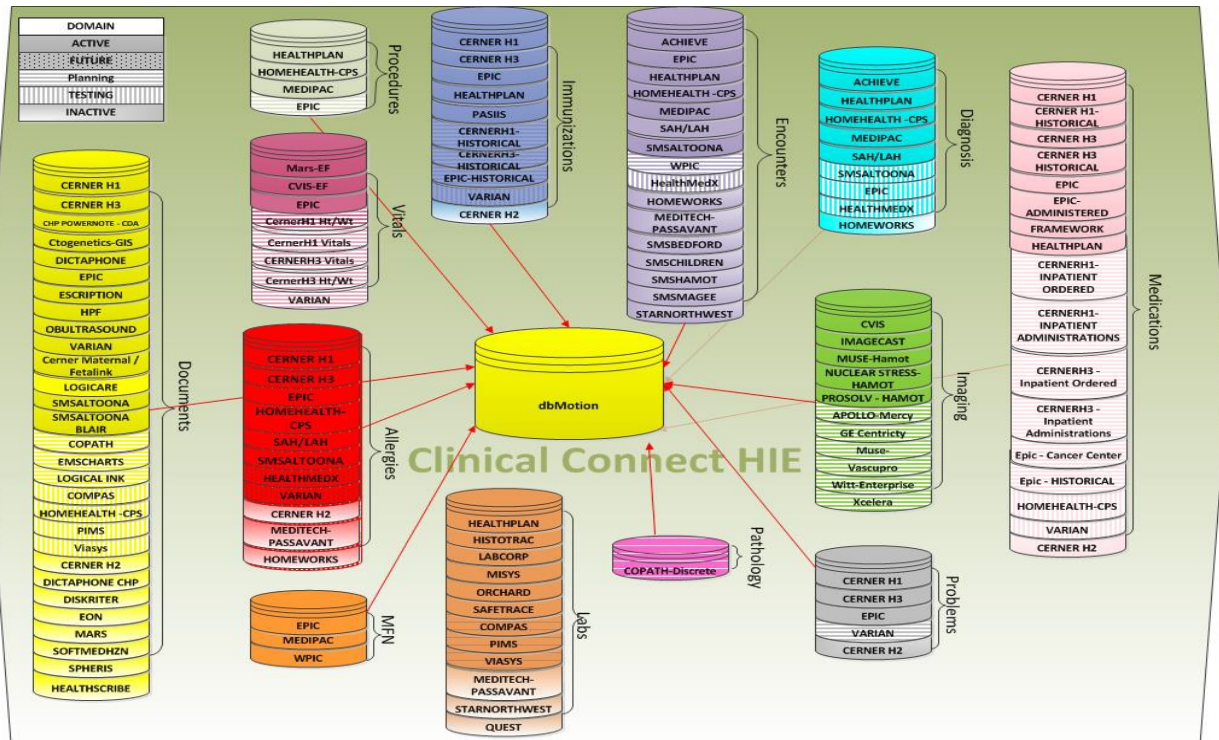
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Source: From UPMC Enterprises, used with permission, for VA use only

**Figure 2. ClinicalConnect (Western Pennsylvania) Health Information Exchange**



Source: From UPMC Enterprises, used with permission, for VA use only

**Figure 3. Interoperability Data Integration**

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When asked whether UPMC, or anyone else in the country, has a point-to-point Cerner-to-Epic interoperability solution that does not use an HIE, UPMC representatives responded “No.” Furthermore, UPMC representatives noted that about 10 percent of the total available individual patient data is currently transferred with UPMC’s interoperability system. This is complicated by an ongoing data explosion that doubles the amount of data in UPMC’s system about every 18 months.

Following the presentations and lunch, MITRE Chief Technology Officer Jay Schnitzer saw a live demonstration of CCHIE by Dr. Amy Urban and Dr. Rasu Shrestha. The live demonstration confirmed that all of the documents listed above are visible with equal fidelity and a very similar format from both the UPMC end and the community provider end and perspective. The system requires clinicians to know and understand where documents can be found, and sometimes requires multiple mouse clicks, but all documents can be accessed from the same EHR entry page with one single log in. Additionally, some data elements, including vital signs and labs, can be viewed in the form of graphs as a function of time, including data elements from multiple sources.

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## IV. Closing Thoughts and Suggested Next Steps

The Panelists noted that VA cannot achieve true future EHR interoperability through the Cerner RFP alone, or through technology alone. The state of practice today shares only a small portion of available patient data. For VA to succeed in the future, multiple other components must be present and aligned: innovation, policy, standards, customer buy-in, and legislation, to name a few.

The following next steps are recommended for VA consideration:

1. Complete the RFP revisions, conduct appropriate negotiations with the Contractor expeditiously, and complete the Contract process as planned. Stand firm during negotiations to maximize ease of access to data and data models for building third-party APIs, applications, and services for future community innovations.
2. Work with other federal government agencies and departments with similar interoperability interests and concerns, including, but not limited to, the White House, DoD, Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), and other parts of the Department of Health and Human Services, to align approaches to EHR interoperability and the development and support of standards government-wide.
3. Support future innovation approaches, including concepts such as an Interoperability Laboratory and outreach to the broader innovation ecosystem (major medical centers, academia, traditional and non-traditional healthcare providers, startups, individual entrepreneurs, others). It is critical to align the innovations planned in VA's Digital Veterans Platform to the VA EHR innovation efforts to ensure consistent, continuous improvements to clinician and Veteran health experiences.
4. Create an External Review Panel to provide continuous expert guidance, review, and feedback over the course of the implementation and help capture best practices from the expert community going forward. Conduct ongoing demonstrations of end-to-end Veteran use cases that require data sharing across organizational boundaries to validate improvements in Veteran healthcare and reduce burdens on healthcare providers. VA and Contractor will ensure that Federal Advisory Committee Act (FACA) guidelines are followed in leveraging any external review panels.

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## Appendix A: Interoperability Review Forum Participants

Panelists	Title	Organization
Aneesh Chopra	President	CareJourney, former United States Chief Technology Officer
Charles E. (Chuck) Christian	Vice President, Technology and Engagement	Indiana Health Information Exchange
Ryan Howells	Principal	Leavitt Partners, LLC
Andrew Karson, MD	Director, Clinical Decision Support	Massachusetts General Hospital
Chris Klomp	Chief Executive Officer	Collective Medical Technologies, Inc.
Kenneth Mandl, MD	Professor, Biomedical Informatics Director, Computational Health Informatics	Harvard Medical School Boston Children's Hospital
Frank Opelka, MD	Medical Director, Quality and Health Policy	American College of Surgeons
Peter Pronovost, MD, PhD	Director, Armstrong Institute for Patient Safety and Quality Senior Vice President, Patient Safety and Quality	Johns Hopkins University
Christopher J. (Cris) Ross	Chief Information Officer	The Mayo Clinic
Carla Smith	Executive Vice President	The Healthcare Information and Management Systems Society
Paul R. Sutton, MD, PhD	Professor, Biomedical Informatics and Medical Education Associate Medical Director, Inpatient IT Systems, UW Medicine IT Services	University of Washington

VA Participants	Title	Organization
David J. Shulkin, M.D.	Secretary	Department of Veterans Affairs
Carolyn Clancy	Executive in Charge, Veterans Health Administration	Department of Veterans Affairs
Bill James	Acting Assistant Secretary, Office of Information & Technology	Department of Veterans Affairs
John Windom	Program Executive for EHRM and Special Advisor to the Under Secretary for Health	Department of Veterans Affairs
Dr. Ashwini Zenooz	Chief Medical Officer, EHRM; Deputy, Office of Deputy Under Secretary for Health Policy & Services, VHA	Department of Veterans Affairs
John Short	Chief Technology Officer, EHRM; Executive Director of Information Technology System Modernization	Department of Veterans Affairs
(b) (6)	Portfolio Lead: Project Transition and VA Integration, VA Center for Innovation	Department of Veterans Affairs
Camilo Sandoval	Senior White House Advisor, VHA	Department of Veterans Affairs
(b) (6)	Senior Advisor to the Secretary on Strategic Partnerships	Department of Veterans Affairs
(b) (6)	Contracts	Department of Veterans Affairs
Kyle Sheetz	White House Fellow	Department of Veterans Affairs

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Other Federal Government Participants	Title	Organization
(b) (6)	Senior Advisor, Office of Administration	The Centers for Medicare & Medicaid Services
Chris Liddell	Assistant to the President for Strategic Initiatives	The White House, Office of American Innovation
*Bruce Moskowitz, M.D.	Internist	External Expert Participant
Shannon Sartan	Director, Digital Services	The Centers for Medicare & Medicaid Services
Dr. Lauren Thompson	Director	DoD/VA Interagency Program Office
Jon White	Deputy National Coordinator for Mental Health	The United States Department of Health and Human Services/The Office of the National Coordinator for Health Information Technology

\*Upon review of this document on October 6, 2018, Fred Mingo, OEHRM FOIA Officer noticed that Dr. Bruce Moskowitz was incorrectly identified and should not be under the entry column "Other Federal Government Participants."

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## Appendix B: RFP Language for Purchasing Extensible Health IT

From <https://smarthealthit.org/2017/08/draft-model-rfp-language-for-purchasing-extensible-health-it/>, as of January 15, 2018.

SMART Platform ([www.smarthealthit.org](http://www.smarthealthit.org)) is a project that lays the groundwork for a more flexible approach to sourcing health information technology tools. Like Apple and Android's app stores, SMART provides the means for developers to create and for health systems and providers to easily deploy third-party applications in tandem with their existing electronic health record, data warehouse, or health information exchange platforms.

To deploy SMART-enabled applications, health systems must ensure that their existing health information technology infrastructure supports the SMART on FHIR API. The SMART on FHIR starter set detailed below lists the minimum requirements for supporting the API and SMART-enabled applications. You may wish to augment this list of minimum requirements with suggestions from the Add-On Functionality listed depending on the types of applications your organization wishes to deploy.

This document is intended as a resource for providers and health systems as they draft Request for Proposals (RFPs) and negotiate with their HIT vendors for added functionality. It has multiple authors from across the SMART team and its advisors. Feedback is welcome.

The vendor must support the SMART on FHIR platform, a vendor agnostic API that allows third-party developers to build external apps and services that integrate with the vended product.

At a minimum, the vendor product should include the following components in order to support SMART on FHIR and SMART-enabled applications:

### Data Access

- Provide automated, standards-based, read-only access through the FHIR API and FHIR data models (resources) to:
  - a well-defined set of real-time discrete data (including support for the API parameters and resources described in the Argonaut Implementation Guide)
  - free-text clinical notes

### Data Manipulation

- Write structured data from third-party apps back to the organization's EHR and, where relevant, a data warehouse, using the FHIR REST API to communicate data including:
  - free-text clinical notes

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## Standards-Based App Authorization

- Protect data and identity endpoints with standards-based authorization mechanisms (including the OAuth2 profiles described in the Argonaut Implementation Guide).
- Provide access to data endpoints with an approach that does not require user intervention subsequent to the initial setup such as the method described in the draft SMART Backend Services Profile (<http://docs.smarthealthit.org/authorization/backend-services/>) Provide capability to restrict this access to a specified set of patients (roster).
- Enable Health System to connect any third-party app of their choice that is conformant with the API without pre-registering the app with HIT Vendor.
- Enable patients to connect any third-party app of their choice that is conformant with the API without pre-registering the app with HIT Vendor through the OAuth Dynamic Registration protocol.
- Provide OAuth refresh tokens with a duration of one year to patient and provider facing apps that support the SMART Client Secret profile.

## Identity Management

- Act as a standards-based Identity Provider using OpenID Connect. This ensures that users can authenticate to plug-in apps using single-sign-in via their existing EHR or patient portal credentials.
- Act as a standards-based relying party to a customer-selected Identity Provider using OpenID Connect. This ensures that users can sign into the EHR or patient portal using an external, hospital-supplied single-sign-on account.

## Workflow

- Support standards-based embedding of external application UI (HTML5). This ensures that app developers can build Web apps, and these apps can run directly inside of the EHR.
- Support the launch of external applications in the clinician's workflow (this is not limited to the EHR and should include non-EHR integrated tools such as smart phones and tablets). For example, a clinician that has opted to use a third-party-developed native iPad app to visualize a patient's BMI over time can seamlessly use the application alongside the EHR via single-sign-on.
- Support notifications to and from running applications. For example, an embedded app can notify the EHR when the user is "done" with it.

## Add-On Functionality

The provider organization may also want to consider the following additions to its RFP depending on the types of applications it wishes to develop and run in the future.

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## **Bulk Data Export**

- Provide automated access to bulk export of data (complete representation of all data in the MU Common Clinical data set as well as free text notes) using a method like the SMART Flat FHIR draft proposal (<http://docs.smarthealthit.org/flat-fhir>)

## **Data Manipulation**

- Write structured data from third-party apps back to the organization's EHR and, where relevant, a data warehouse, using the FHIR REST API to communicate data including:
  - medication prescriptions
  - lab and diagnostic imaging orders
- Support the dependent transactions necessary to ensure that actions completed by third-party applications using the API are valid in the EHR and data warehouse.

## **Context-Specific Service Hooks**

- Support the ability to call an external standards-based service in specific workflow steps, through the CDS Hooks specification, including:
  - opening a patient record
  - new prescriptions
  - new lab orders
  - new imaging studies

## **Intellectual Property**

The IP of any app integrated through the SMART on FHIR API belongs to the author and not the vendor.

## **Custom SMART on FHIR Extension to a Proprietary API**

Should a vendor neglect to provide SMART on FHIR natively, the client has the right to provide a custom extension to the vendor's API. The ownership of the IP for the custom extension is negotiable between the client and the vendor, but the ownership of the app using the custom extension belongs to its author.

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## Appendix C: Recommended RFP Interoperability Language Changes

The table below captures the recommended changes to the VA EHRM RFP.

Item No.	Independent External Review Recommendations	EHRM RFP Section(s) Affected and Additional Comments	MITRE Recommended Change(s) to the EHRM RFP	VA Adjudication
<b>Commit to Full VA-DoD Interoperability</b>				
1	Define specific capability performance requirement and mechanisms to hold Cerner accountable for reducing the administrative burden in clinician workflow with the objective of increasing efficiency.	<p>The IDIQ RFP PWS Section 5.1.11 speaks to overall EHRM value and performance management monitoring, measurement and reporting. Performance metrics will be defined and enforced at the task order level, since, for example, hosting metrics will be significantly different from deployment metrics.</p> <p>The RFP Section 8.6 refers to the use of Quality Assurance Surveillance Plans (QASP), which will include Functional and Non-Functional Key Performance Indicators (KPIs). The QASP will evolve as the EHRM solution and technology matures and is intended to establish Contractor accountability to what VA requires and values.</p>	None.	Concur.

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Item No.	Independent External Review Recommendations	EHRM RFP Section(s) Affected and Additional Comments	MITRE Recommended Change(s) to the EHRM RFP	VA Adjudication
2	Define specifically the <i>span</i> of providers who can properly interface with VA under a proposed solution (the number of community providers who would be able to interface with VA under a solution as a function of cost to the provider).	RFP Section 5.2.1(j) states that “The EHRM solution shall support access via tablet or mobile device as adjudicated by joint governance. Platform specifics will be identified by VA at a TO level.”  Section 5.10.4 states that "The Contractor is required to collaborate with VA affiliates, community partners, EHR providers, healthcare providers, and vendors to advance seamless care throughout the healthcare market.”	Suggest amending the language in RFP Section 5.2.1(j) to: “Support broad access via tablet or mobile devices and pursue technology to reduce the burden to the clinicians (e.g., providing third-party provide access to information using light-weight portals and support for future generation mobile devices). Platform specifics shall be adjudicated by joint governance and incorporated by VA at a TO level.”	Concur. Will negotiate with Cerner for inclusion of language.
3	Define the <i>degree</i> of interoperability the solution provides (ranging from basic file sharing to fully interchangeable, integrated and functionally identical patient records).	RFP Section 5.10.4 speaks to interoperability and provides sufficient breadth to introduce any additional information exchange requirements in the future, at the sole discretion of VA.  Requirements Traceability Matrix (RTM) VA-FR-31 discusses specifics of data management, types of data to be exchanged, and methods of communication.	Suggest adding to RFP Section 5.10.5: "m) The Contractor shall conduct an annual Interoperability Self-Assessment against standards that shall be specified by VA, such as those promulgated by HIMSS or future standards to be identified by VA.”	Concur. Will negotiate with Cerner for inclusion.

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Item No.	Independent External Review Recommendations	EHRM RFP Section(s) Affected and Additional Comments	MITRE Recommended Change(s) to the EHRM RFP	VA Adjudication
4	Pivot the RFP to be Veteran-centric and NOT system-centric. Be mindful that lessons learned are that many EHRs do not currently maximize efficient clinical workflow, so build that in (e.g., using CDS Hooks) and present information where needed with minimum "clicks to find" to reduce clinician burden.	<p>RFP Section 5.2.1 speaks to the EHR application supporting workflows.</p> <p>Section 5.5.1 Workflow development and normalization addresses configuration of workflows to meet VA requirements.</p> <p>Section 5.5.7 Organizational Change Management discusses optimizing workflows for each clinical role.</p> <p>Section 8.6 refers to the use of Quality Assurance Surveillance Plans (QASP) which provides active, continuous measurement against the extensive performance requirements captured in Appendices A-1 and A-2: EHRM Key Performance Indicators to ensure a Veteran-centric approach.</p> <p>RTM section VA-FR-33 requires adoption, development and maintenance of metrics to assess timeliness and quality of healthcare delivery to the patient population.</p> <p>The current RFP language can be clarified to specifically refer to the improvement on Veteran-centric delivery.</p>	<p>Suggest adding to RFP Section 5.5.1: “k) Provide an understanding of how all workflows will impact VA care coordination and management processes (e.g., incorporating community information) to improve Veteran-centric delivery.”</p> <p>Also add to Section 5.5.1: “l) Configure workflows to incorporate all community data at the discrete level in support of clinical decision support, care management, disease management. The clinical workflow within the EHR should not require users to visit additional screens to view externally sourced data.”</p> <p>See Item 29 for specific recommendations on CDS Hooks.</p>	Concur. Will negotiate with Cerner for inclusion.
5	Require Cerner support end-to-end use cases with major external stakeholders involved.	RFP Section 5.2.1 speaks to the EHR application supporting workflows. The Contractor can only be held responsible for elements of the end-to-end use case that reside within their system.	Suggest adding to RFP Section 5.2.1: “Testing conducted under the Test and Evaluation Program Plan may include specific workflows to inform a demonstration of end-to-end clinical use cases involving external stakeholders.”	Concur. Will negotiate with Cerner for inclusion.

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Item No.	Independent External Review Recommendations	EHRM RFP Section(s) Affected and Additional Comments	MITRE Recommended Change(s) to the EHRM RFP	VA Adjudication
6	Develop detailed data flow requirements between Cerner and all other vendors, be specific using clinical workflow or Veteran/patient-centric use cases.	Detailed data flow requirements should not be part of the RFP as it will result in the limitation of functionality to the specific data flows specified. They will be part of the Test and Evaluation Plan (TEP), where data flows can be added or modified. However, RFP Section 5.5.1 does not indicate that the external community data and end-to-end workflows will be considered in the configuration of standard EHRM workflows.	Suggest adding to RFP Section 5.5.1: “j) The Contractor shall enable configuration of the application that supports external community data without requiring the clinician to go to special screens to see and use external data.”	Concur. Will negotiate with Cerner for inclusion.
7	Specifically define the machine-data readability expectations to ensure interoperability between legacy, community care providers, and Cerner (e.g., notes fields).	RTM VA-FR-31 Requires the ability "to manage data structures that are standardized, accessible and editable." Specific requirements are to be incorporated into Task Orders, according to the structure of the contract.	See Item #34 for recommended changes to incorporate the SMART on FHIR and SMART-enabled applications.  See Item # 49 for recommended changes to incorporate sharing of the EHRM data model and to improve the amount of computable data shared with community care providers.  Suggest VA obtain a description from the Contractor that describes the current baseline of shareable data elements that are computable.	Concur. Will request information from Cerner.
8	Document the DoD-VA EHR Exchange Framework - it can serve as a starting point for the National model.	This is information that should be included as part of acquisition baseline developed by EHRM Program Management Office technical activities.	None.	Concur.
9	Require ability for bulk data export.	RFP Section 5.10.4(g) requires the Contractor to provide a software solution for multilateral standards-based ingestion, normalization, storage and exporting of Health Information Exchange acquired Veteran health information.	None.	Concur.

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Item No.	Independent External Review Recommendations	EHRM RFP Section(s) Affected and Additional Comments	MITRE Recommended Change(s) to the EHRM RFP	VA Adjudication
10	Require "push" capability to send data back in to VA EHR / Cerner database.	RFP Section 5.10.4(g) requires the Contractor to provide a software solution for multilateral standards-based ingestion, normalization, storage and exporting of Health Information Exchange acquired Veteran health information.	None.	Concur.

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Item No.	Independent External Review Recommendations	EHRM RFP Section(s) Affected and Additional Comments	MITRE Recommended Change(s) to the EHRM RFP	VA Adjudication
11	Require that VA drive and own the analytical algorithms and not rely on Cerner. Require that VA health organizations be involved in building the logic models with the community and the vendor.	<p>RFP Section 5.1.5 requires the Contractor provide requirements development support but does not include who is responsible for coordinating the community input on the logic models.</p> <p>RFP Section 5.1.7 requires the Contractor support data management but does not state that VA shall provide the analytical algorithms.</p> <p>RFP Section 5.5.1(e) requires the Contractor support robust semantic modeling for the information associated with the workflows. Further detail to achieve this recommendation is also detailed in the Functional Requirement documentation, specifically VA-FR-31. VA should lead and own the analytical algorithms as it is in the best interest of the health community. By owning the algorithms, VA will take the lead on coordinating the effort, but the Contractor will actually develop the algorithms.</p>	<p>Suggest adding to RFP Section 5.1.5: "While the Contractor shall provide such support, VA reserves the right to take the lead on coordinating input from the user and provider communities. VA may, at its discretion, incorporate analytics from other entities, and include them in its future Digital Veterans Platform, with which the EHR must be fully compatible and interoperable."</p> <p>Suggest adding to RFP Section 5.1.7(b): "based on community and VA coordinated analytic algorithms."</p> <p>Suggest adding to RFP Section 5.5.1(e): "VA and its agents shall have unlimited rights to all resulting models and algorithms."</p> <p>Suggest adding to RFP Section 5.5.1(f): "which modeling shall be based on analytical algorithms and data models (1) developed by the Contractor, (2) co-developed by the Contractor in coordination with VA health organizations and the community, (3) developed by VA health organizations, or (4) provided by third-party developers. VA and its agents shall have unlimited rights to all algorithms and logic models incorporated in the EHRM solution, and intellectual property rights will be handled in accordance with § H.2 of the Contract "VA EHRM IP License Agreement" on a Task Order basis."</p>	Concur. Will negotiate with Cerner for inclusion.

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Item No.	Independent External Review Recommendations	EHRM RFP Section(s) Affected and Additional Comments	MITRE Recommended Change(s) to the EHRM RFP	VA Adjudication
12	Enhance the data quality management requirements to ensure Cerner is responsible for maintaining and resolving data quality issues.	RFP Section 5.1.8 Requires the Contractor to be responsible for data migration, but RFP Section 5.1.7 does not include a requirement for the Contractor to manage data quality internal to its systems.	Suggest adding to RFP Section 5.1.7: "j) Maintain backward compatibility of the EHRM solution in such way as to maintain the quality of the data, to ensure that, once captured, the Government has access to and computational use of the data regardless of the evolution of the EHRM or age of the data k) Identify data quality issues found in data sourced from systems beyond its operational remit, applying the same validations and quality standards to incoming external data that it performs for data originated natively within the EHRM solution. Where the principle of seamless care requires that EHRM accept data that does not meet its internal data quality standards, Contractor shall implement the solution so that any incoming data that does not meet EHRM data quality standards be clearly flagged as such and provide both process and user interface to allow incorrect or missing data to be remedied if possible."	Concur.
13	Define the common identity and access management approach Cerner and others will adopt (e.g., using the Vets.gov identity as the coordinating identity).	RFP Section 5.5.2 describes the required approach to identity and access management across population types and roles. DoD/VA are aligning their efforts to address this going forward.	None.	Concur.
14	Adopt the DoD approach to data and system security.	RFP Section 5.4: Information System Authorization, Testing and Continuous Monitoring describes the security approach for the shared DoD/VA authorization boundary. Joint DoD/VA Strategy will be executed.	None.	Concur.

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15	Share the VA's security approach to medical and endpoint security with DoD for opportunity to leverage and harmonize.	RFP Section 5.4: Information System Authorization, Testing and Continuous Monitoring describes the security approach for the shared DoD/VA authorization boundary. Joint DoD/VA Strategy will be executed.	None.	Concur.
16	Require Cerner to make the VA data model, standards, and other similar interoperability changes available in all other non-VA Cerner instances of its EHR platform.	RFP Section 5.10.4.1 requires opportunity for agreed upon Contractor proprietary information/data model extension points (e.g., ingestion and record APIs) to be provided to both international and national standards designating organizations, however, this does not include providing the capability to other Cerner users, which would extend Cerner interoperability across the community.	Suggest adding to RFP Section 5.10.4.1: "The Contractor shall provide VA access and usage rights into any underlying proprietary terminology/code systems for the purpose of enhancing national standards to address any gaps identified in the EHRM solution. The Contractor shall also make the interoperability capabilities and product enhancements developed under this contract available to non-VA Cerner clients."	Concur. Will negotiate with Cerner for inclusion of language.
17	Clearly define "enabling security framework." Does this mean a specific security framework such as NIST, HITRUST, etc.	VA Requirements Traceability Matrix Non-Functional requirements provides the security requirements to include Access Management, Identity Management, and Information Assurance/Security. RFP Sections 5.4 Information System Authorization, Testing and Continuous Monitoring and 5.5.2 Identity and Access Management provide additional clarification on the security requirements.	None.	Concur.

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<b>Leverage Current and Future Standards</b>				
18	Specifically describe what and how you can read, write, and reconcile re: health data.	Requirement VA-FR-31 describes data management requirements: standardized data and coding terminology systems; use of government endorsed messaging and content standards for interoperability; management of data elements from various entry points etc. The current requirement does not provide understanding of which data elements are being exchanged and the degree of interoperability/ computability supported.	Suggest adding to RFP 5.10.4(m): “The annual assessment will report on the state of each data element (e.g., which are supported in what capacities and in which formats). This will help assure standards implementation consistency and assure standards compliance with evolving national standards.”	Concur. Will negotiate with Cerner for inclusion of language.
19	Define who has what rights from a data sharing perspective, impacting APIs (e.g., VA owns the data + all data products vs. Community care provider owns their treatment info on patient vs. patient owns all their own data.)	Requirement VA-FR-31 and RFP Section 5.1.7 describe data management requirements (including syndication).  Section 5.5.4 requires “all, significant data stored in the software is accessible through API’s” however clarification is needed to ensure access to all data originating from alternate VA-designated authoritative sources.	Suggest adding to RFP 5.5.4: “l) Provide standards-based API access (e.g., FHIR) to all patient data from the VA-designated authoritative data sources for the patient’s record within the Contractor’s product suite.”	Concur. Will negotiate with Cerner for inclusion of language.
20	Identify the authoritative source for the various elements of a Veteran's health record.	RFP Section 5.1.4 requires the Contractor to provide support in the development and/or evaluation of new Standards, Policy Directives, Operating Procedures, Processes, etc.  Broader recommendation beyond the scope of the EHRM RFP is for VA to define the authoritative source policy for all VA data. This is not an EHRM specific policy and should be issued by VACO or VHA.	Suggest adding to RFP 5.5.4: “j) assist VA in defining and establishing the authoritative data sources associated with each data element in the EHR (e.g., where it is available and who has access to the information).”	Concur with the language for 5.5.4.

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21	Increase the VA presence and leadership role in standards-making bodies (e.g., Argonaut).	Increasing VA presence and leadership roles in standards-making bodies is an entirely separate recommendation that is not related to the IDIQ.	None.	Concur.
22	Include requirement for Cerner to support VA as an advocate to VA position on all relevant standards-making bodies.	RFP Section 5.1.4 requires Contractor support in the development and/or evaluation of new standards, policy directives, operating procedures, processes and/or assessments on their impacts when implemented.	None.	Concur.
23	Require Cerner to implement all standards as defined by VA.	Requirements Traceability Matrix VA-NJ-177 defines interoperability data standards and specifically cites support of the health data standards identified in the VA-DoD Health Information Technical Standards Profile and by the VA-DoD Interagency Clinical Informatics board.	None.	Concur.
24	Clarify the intended reference in the phrase “national Common Trust Framework.” Does this refer to the Trusted Exchange Framework and Common Agreement (TEFCA) specified in the 21st Century Cures Act?	RFP Section 5.10.4(h) refers imprecisely to the "national Common Trust Framework."	Suggest replacing the phrase in RFP Section 5.10.4 h) "national Common Trust Framework" with “Trusted Exchange Framework and Common Agreement (TEFCA).”	Concur. Will negotiate with Cerner for inclusion of language.
25	Clarify if the “provider collaboration via secure e-mail using Direct standards” is limited to the Direct protocols and just the Cerner platform.	RFP Section 5.10.4(i) requires the Contractor, by IOC, to "provide a capability for provider collaboration via secure e-mail using Direct standards within a Cerner Millennium EHR workflow context."	Suggest adding to RFP Section 5.10.4(i): "the ONC Direct protocol or future VA-designated standard."	Concur. Will negotiate with Cerner for inclusion of language.

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<b>Commit to Open, Standards-Based APIs</b>				
26	Be specific about the VA publishing / access service requirements.	RFP Section 5.5.4 includes requirements that all significant data stored in the software is accessible through API's with no requirement for creation of custom applications to specifically access VA data. RTM VA-NF-7 requires the system to support the ability to access data elements using open standard-based interfaces including legacy data. Clarification is needed to ensure the intention to pursue standards-based APIs.	Suggest adding to RFP Section 5.5.4 – “standards-based” in front of APIs.	Concur. Will negotiate with Cerner for inclusion of language.
27	Define in the contract the VA publishing / access services specifically for (1) Veteran access services (e.g., vets.gov), (2) VA clinician access services, (3) Partner access services, and (4) HIE access service.	RFP Section 5.5.2 describes identity and access management requirements including user population types and the association of specific application permissions tied to roles/positions. RTM VA-NF-6 through 48 describe specific access services required.	None.	Concur.
28	Ensure external API developers can host their apps on an app platform that is NOT controlled by Cerner (and therefore does not require Cerner licensing and approval).	RFP Section 5.1.8(d) requires the contractor analyze and propose a way forward for the capability for external apps to use HealthIntent as a data source.  Section 5.5.4 requires the contractor to support data exchanges via the API gateway.  Section 5.10.4.2 requires the contractor to work in good faith to integrate the EHRM with the Digital Veterans Platform API gateway.	Suggest replacing the second sentence in 5.10.4.2: “The Contractor shall integrate the EHRM to interoperate with DVP or future state VA platform.”	Concur. Will negotiate with Cerner for inclusion of language.

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29	Include requirement for Cerner to provide CDS Hooks to support open clinician workflow.	RFP Section 5.8 requires the contractor provision robust data analysis toolsets that allow, among other things, analytics and Clinical Decision Support (CDS).  VA-NF-T26 requires "integration with Cerner via standards-based interfaces (including but not necessarily limited to support for FHIR APIs and/or OMG CDS API/ HL7 CDS APIs (e.g., CDS Hooks)".	None.	Concur.
30	Specify the required utility services to support intermediary or peer-to-peer services; e.g., support Veteran-directed or Veteran-mediated request, exchange, and ingestion from non-VA providers (via APIs where available).	RFP Section 5.10.4(c) requires "the Contractor shall provide a software solution enabling VA to release and consume, via on-demand access, a Veteran's complete longitudinal health record to and from DoD and connected community partners. The longitudinal record solution shall support Provider-to-Provider record sharing, as well as Provider-Veteran-Provider sharing (Veteran mediated record sharing), including appropriate consent management."	Suggest adding ", regardless of which EHR they use" after "connected community partners...to and from DoD and connected community partners, regardless of which EHR they use."	Concur. Will negotiate with Cerner for inclusion of language.
31	Require that VA has full authority to connect any VA-approved, secure third-party app with the Cerner system, without Cerner approval.	RFP Section 5.7.1 requires the contractor provide on-site integration for devices connecting to the Contractor system. VA is fully responsible for the security of its systems and protection of its data.	Suggest adding to 5.7.1b: "including via the Digital Veterans Platform...support for VA-approved third-party apps connecting to the Contractor system, including via the Digital Veterans Platform."  Suggest adding to 5.7.1 – "(g) Permit and approve connecting all VA approved secure apps without additional fees or licensing."	Concur. Will negotiate with Cerner for inclusion of language.

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32	Ensure the API developers retain their IP rights when their API is used to connect to the Cerner interface.	<p>RFP Section 5.5.4 sets forth requirements with respect to APIs, including paragraph (e), which provides for the provision and maintenance of a Developer Portal.</p> <p>Section 5.10 generally promotes innovation while 5.10.4.2 requires the Contractor to support the Digital Veterans Platform (DVP) API gateway which is intended to provide a neutral application platform for third party APIs.</p> <p>Additional language is required to promote innovation in the creation of third party applications by removing derivative or cascading intellectual property restrictions/ constraints.</p>	Suggest adding to RFP 5.5.4(e): " and provide policies and procedures for the use of the Developer Portal(s) and APIs that promote innovative third-party API development" and "Third party API developers shall retain their IP rights when their API is used to connect to the Cerner interface, and there will be no derivative IP ownership when third parties consume Cerner terminology through open APIs."	Concur. Will negotiate with Cerner for inclusion of language.
33	Require the ability for 3rd party apps to remain connected to the Cerner system and receive automatic notification on updates (e.g., vaccination). Allow the app to connect without being cut off in accordance with VA security requirements.	RFP Section 5.7.1 requires the contractor provide on-site integration for devices connecting to the Contractor system.	<p>Suggest adding to RFP Section 5.7.1(b): "support for third-party apps connecting to the Contractor system."</p> <p>Suggest adding the following new paragraphs (ii) and (iii) to RFP Section 5.7.1(b): "ii. Provide ability for third-party apps to remain connected to the Contractor system in accordance with VA security requirements and receive automatic notification on updates; and iii. Allow the app to remain connected without interruption lasting longer than a certain period of time to be approved by the Government."</p>	Concur. Will negotiate with Cerner for inclusion of language.

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34	Incorporate the model RFP language necessary for Cerner to support the API and SMART on FHIR platform and SMART-enabled applications.	RFP Section 5.10.4 and the Requirements Traceability Matrix refer to SMART and FHIR based applications but do not incorporate all elements of the suggested functionality such as the support for standards-based embedding of external application UI (HTML5).	Suggest adding to RFP Section 5.10.4: "In addition, the software and services shall support the VA designated standards, such as SMART on FHIR and SMART-enabled applications, or published standard at the time."	Concur. Will negotiate with Cerner for inclusion of language.
<b>Use Community Care Contracts to Foster Interoperability</b>				
35	Before the contract is signed, get Care Act providers and Cerner competitors to commit to support the contract as early adopters.	Pre-contractual activity and pertains to future strategic discussions to drive interoperability in the marketplace.	None.	Concur.
36	Require publication of the EHRM /Cerner clinical data model in the National Library of Medicine (following the Kaiser example).	RFP Section 5.10.4.1 states: In support of the interoperability objectives under this Section, agreed upon Contractor proprietary information/data model extension points (e.g., ingestion and record APIs) may be provided to both international and national standards designating organizations as described and set forth in an applicable Task Order.	None.	Concur.
37	Require the Veteran to be able to invoke their right of access to data as the intermediary to support data exchange (e.g., pull through their API on phone and push to their community care provider).	RFP Section 5.7.1 requires support to Veterans ensuring they can effectively navigate the HealtheLife patient portal and Wellness programs to effectively manage their health.	Suggest adding to RFP Section 5.7.1(c): "using mobile apps, thin-client and thick-client solutions" and "Veterans shall be able to enable sharing of their health data with their community care providers in accordance with all VA-designated national standards."	Concur. Will negotiate with Cerner for inclusion of language.

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38	Require Cerner and the Community Care provider applications provide bi-directional health information in exchange for using the VA-provided API gateway.	RFP Sections 5.10.1, .2, and .3 require support for innovation and other development activities.  Section 5.10.4(c) requires "a software solution enabling VA to release and consume, via on-demand access, a Veteran's complete longitudinal health record to and from DoD and connected community partners."  VA-NF-61, -63, and -65 requires bi-directional interface in support of Pharmacy. This requirement can be fulfilled by a flat file and does not require the data to be computable.	Suggest adding to RFP Section 5.10.4(c): "The bi-directional health information exchange shall maximize use of discrete data that supports context-driven clinical decisions and informatics."	Concur. Will negotiate with Cerner for inclusion of language.
39	Shift VA policy enabled by the Choice Care Act from "Opt-In" to "Opt-Out" such that the starting assumption is that data can be shared unless the Veteran "opts out."	Review and revise VA policy.	None.	Concur.
<b>Other</b>				
40	Analyze and understand the operational cost to VA to implement and operate under the proposed solution.	Analysis of cost information is not part of a IDIQ contract. It will be done as part of the standard PMO processes.	None.	Concur.

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41	Incorporate requirement that subsequent updates and improvements to the Cerner solution is part of the baseline contract (and cost).	RFP Section 5.2.3 Software Maintenance requires: The Contractor shall provide its commercial support and maintenance services described in its End User License Agreement. Leveraging Contractor's best practices and agreed upon upgrade schedule between DoD and VA, software maintenance includes all releases of the software such as major releases, minor releases, maintenance releases.	None.	Concur.
42	Address the differences between federal and state privacy laws - policy that Federal laws take precedence over state laws.	Federal and state privacy laws can only be addressed through legislation.	None.	Concur.
43	Ensure VA has no gag order: Require Cerner to allow open, public sharing/reporting (e.g., screen shots) on issues or errors with the EHR solution (e.g., if there is a known anomaly, that anomaly and its work-around is shared with the Cerner user community).	RFP Section 5.3.3 - System Quality and Performance Measures and Monitoring is appropriate to capture this requirement.  There is no explicit contractual language requiring the contractor to disclose issues or efforts, nor is there language explicitly preserving the right of VA to share such information.	Suggest adding to RFP Section 5.3.3: "Contractor is responsible for reporting all issues or errors associated with the EHR solution and acknowledges and agrees that errors shall not be considered confidential, proprietary or trade secrets, and accordingly, shall be releasable to VA or its agents. VA retains the right to share any issue, error or resolution approach."	Concur. Will negotiate with Cerner for inclusion of language.
44	Define the way ahead for 3rd party apps (sunset, rebuild and transition) during the Cerner transition.	This should be evaluated in congruence with the legacy transition plans (pivot plans) of existing systems to Cerner.	None.	Concur.
45	Emphasize the need and resource commitment to achieve clinician consensus, change management, and culture.	RFP Section 5.5.7 Organizational Change Management includes a detailed approach to clinician consensus, change management and culture change.	None.	Concur.

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46	Develop a roadmap for all EHR vendors that specifies how Veterans and providers access and share their data and get that data from A to B. This is not limited to the Cerner solution, but includes legacy and community care systems.	These tasks are not part of the IDIQ and will be addressed via Data Migration Plan and Data Management Strategy across VA.	None.	Concur.
47	Require ability for VA to innovate using the Cerner solution, including support to a Veteran Interoperability Partnership Lab.	<p>RFP Section 5.10: Innovation and Enhancements includes an innovation process, categories and development activities to enable VA innovation activities using the Cerner solution. The language is sufficiently broad to support issuance of a Task Order requiring the Contractor to support interoperability activities including a Veteran Interoperability Partnership Lab.</p> <p>MITRE recommends this lab be independently managed and used to support 3rd party innovators, demonstrate interoperability solutions, validate the effectiveness of interoperability solutions in an end-to-end clinical use case context, and serve as a reference architecture to allow 3rd party stakeholders to exercise innovations.</p>	None.	Concur.

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48	Understand how Cerner will manage data quality, including provenance, error bounds, data looping, security, etc.	<p>The RFP Section 8.6 refers to the use of Quality Assurance Surveillance Plans (QASP), which is intended to establish Contractor accountability to what VA requires and values.</p> <p>VA-NF-T46 requires “The system shall support provenance (chain of custody or ownership) and pedigree (processing history how the data was produced or incorporated) and enable identification, collection, and production of data according to source, custody and ownership and display of data in business, logical, legal or physical models.”</p>	None.	Concur.

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49	<p>Understand how Cerner will provide VA with access to the data model, share data for analytics freely to 3<sup>rd</sup> parties, increase the amount of computable data exchanged with 3<sup>rd</sup> parties.</p> <p>Panelists acknowledged this recommendation is a stretch goal.</p>	<p>RFP Section 5.8 address the support to business intelligence and data analytics. Section 5.10.4.1 supports the sharing of Contractor proprietary information/data model extension points (e.g., ingestion and record APIs) with both international and national standards designating organizations. However, current language does not require access to the EHRM data model, supporting understanding of and therefore increase the exchange of computable data with community care providers.</p>	<p>Suggest adding to RFP Section 5.8: “h) Provide VA EHRM data model, underpinning terminology model, tables, definitions, and examples of fully populated Veteran data files. Provide documentation or software that is used for quality checks and that illustrate what data elements are computable.”</p> <p>Suggest adding to Section 5.10.4.1: “n) The Contractor shall support Knowledge Interoperability by supporting the extension of clinical content assets such as terminologies, clinical decision support rules, order sets, etc. This includes the ability to curate, extend, and share that knowledge with clinical partners. This fosters rapid adoption from industry best practices, e.g., clinical professional societies.”</p> <p>Suggest VA obtain a price from the Contractor to provide a report explain the steps involved in accessing the data model, including producing an example data file, and demonstrating how much of the data is computable; provide cost estimates for outside parties to access the data via this mechanism.</p>	Concur.

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50	Understand how the Cerner EHRM solution will improve Veteran and clinician experiences.	<p>RFP Section 5.2.1 describes the EHR application, however does not specifically focus priorities on the Veteran and clinician experience as captured in end-to-end use cases.</p> <p>Section 8.6 refers to the Quality Assurance Surveillance Plans, which include Functional and Non-Functional Key Performance Indicators (KPIs). These KPIs will reflect VA priorities which include improvement of both Veteran and clinician experiences.</p>	Suggest adding to RFP Section 5.2.1.1: “k) Provide for the ability to measure the EHRM performance that contributes to any end-to-end use case, thereby capturing its impact on improving a Veteran and clinician experience.”	Concur.

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## Appendix D: Acronyms

API	Application Programming Interface
CCHIE	ClinicalConnect Health Information Exchange
CDS	Clinical Decision Service
DoD	Department of Defense
EHR	Electronic Health Record
EHRM	Electronic Health Record Modernization
FHIR	Fast Healthcare Interoperability Resources
HIE	Health Information Exchange
HL7	Health Level Seven International
IP	Intellectual Property
IT	Information Technology
PWS	Performance Work Statement
RFP	Request for Proposal
UPMC	University of Pittsburgh Medical Center
VA	Department of Veterans Affairs
VACO	VA Central Office
VHA	Veterans Health Administration

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