

ENCLOSURE 3
APPENDIX B

EHR AND PHR STANDARDS AND REQUIREMENTS

The minimum standards listed below are applicable to the individual parts of the County's proposed EHR system. As Counties implement specific parts of an EHR, they must assure compliance with all minimum standards related to the implemented part of the EHR. PHR Projects may also have applicable standards as noted below.

If the project includes an EHR or PHR, the following Standards and Requirements are applicable to the Project Proposal and MUST be evaluated.

No EHR/PHR = Appendix B Not Applicable

Please determine whether or not the EHR project(s) MEET the following criteria.

For the "Move Towards" functionality, the County may include information, but this is not a required item. See Appendix B for "Move Towards" details.

1. Functional Standards

County projects **MUST MOVE TOWARDS** an Integrated Information Systems Infrastructure. The foundation for an Integrated Information Systems Infrastructure is a comprehensive Electronic Health Record (EHR) system, which is a secure, real-time, point-of-care, client-centric, information resource for service providers. The applicable functional requirements a comprehensive EHR **MUST** meet are outlined in the **CCHIT Functionality Criteria 2007 (www.CCHIT.org)**. A summary of the attributes of a comprehensive EHR is **Definitional Model Version. 1.1.) (www.HIMSS.org)**.

Functional Standards that Must be met

1.1 Does the Project include components of a comprehensive EHR? If Yes, does it specifically:

- Provide secure, reliable, real-time access to client health record information where and when it is needed to support care.
- Function as a centralized and integrated information resource for clinicians during the provision of client care.
- Assist with the work of planning and delivering evidence-based care to individuals and groups of clients.
- Capture data used for continuous quality improvement, utilization review, risk management, resource planning, and performance measurement.
- Support clinical applications such as computerized order entry and decision support tools.
- Summarize via electronic prescribing, prescribed medications from all providers for quality management, coordination of care and for uses in the Personal Health Record.
- Provide compatibility with scheduling, billing and reporting applications as well as personal health record technologies.
- Capture and report California mental health specific cost reporting and performance outcome data.

Yes (Complete)
 No (Info Needed)
 N/A

1.2 If this is a comprehensive EHR, then does it meet the CCHIT Functionality Criteria 2007 (www.CCHIT.org)?

- Yes (Complete)
 No (Info Needed)
 N/A

User-Friendly Interface Standard

The EHR Project MUST Meet the Following

- Provide a useful and easy to understand interface, making it easy for clinicians and administrative personnel to operate.
- Address competency and literacy in the use of technology
- Comply with current Americans with Disabilities Act (ADA), Section 508 of the Rehabilitation Act requirements. Section 508 requires that individuals with disabilities, including Federal employees, have access to and use of information and data that is comparable to those without disabilities. To learn more about the regulations governing the accessibility of Federal electronic information, please see www.hhs.gov/Accessibility.html.
- Address cultural and language issues to facilitate access and sharing of data. Many cultures do not support the idea of sharing client information. Others share information and decision making on health matters at the level of the extended family or larger group. Counties must ensure that language translation using technology supports cultural competency and linguistic objectives.

1.3 Is there a User-Friendly Interface? Specifically does it:

- Provide ease of operations for the clinician?
- Comply with American Disability Act (ADA), Section 508 of the Rehabilitation Act requirements?
- Address cultural competency and language issues?

- Yes (Complete)
 No (Info Needed)
 N/A

The EHR Project MUST MOVE TOWARDS the Following

- Be Internet-based, available from any standard web browser, so that consumers or family members may access their PHRs.
- Be able to transmit an approved form of a Continuity of Care Record as applicable.
- Provide ability of the client and family to communicate with the clinician and service provider, especially in the multi-lingual environment.

Vendor Commitment Standard

The EHR Project vendor **MUST** meet Current Industry and Government Standards. At a minimum, the technology must Support Current Basic Standards and the Vendor must provide a Written Agreement to Continually Upgrade the Technology to Meet Future Standards as they become available.

The Vendor **MUST**

1.4 Do the Vendors proposed for the project:

- Include implementation plans that meet minimum staffing criteria for planning, implementation, conversion/migration, oversight, risk management and quality assurance of the technology.
- Specify how their product meets or is planning to address all State and federal regulations including but not limited to HIPAA Regulations.
- Provide the necessary plan for the product to have application interfaces as necessary to meet California mental health reporting and claiming requirements.
- Meet the CCHIT behavioral health criteria within One Year of the availability of final CCHIT behavioral health certification criteria.

Yes (Complete)
 No (Info Needed)
 N/A

2. Connectivity and Language (Interoperability) Standards

In addition to the functional requirements, the EHR Project must address the ability of the system to transfer data outside the County clinic. There are two types of data transfer: messaging and record exchange. Messaging is necessary when data is transferred between different systems with different data standards. Messaging requires the use of standardized protocols such as Health Level 7 (HL7). Health Level 7 (www.hl7.org) is one of several [American National Standards Institute](http://www.nist.gov) (ANSI) -accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level 7's domain is clinical and administrative data. The format and method of data distribution should be standardized wherever possible. Record exchange can occur where data is transferred between two systems that share a common structural design. Detailed requirements are shown below:

Connectivity Standard

The EHR Project **MUST MOVE TOWARDS** the Following

- Be compatible with modern Local- and Wide-Area Network technology supporting Internet and intranet communication.
- Be distributed, with "ownership" of the data remaining at both the sending and the receiving ends.
- Use standard protocols that include:
- Extensible Markup Language (XML), a markup language for documents containing structured information (www.XML.com).
- Simple Object Access Protocol (SOAP) - a protocol for exchanging XML-based messages over computer networks, normally using HTTP. (See the World Wide Web Consortium (W3C) at www.w3.org.)

- Security Assertion Markup Language (SAML) - an XML document standard for exchanging Authentication and Authorization data between an identity provider and a service provider. (See the Organization for the Advancement of Structural Information Standards (OASIS) at www.oasis-open.org.)
- Web Services used for Application Programming Interfaces.
- Message-Oriented Middleware (or software that connects two or more software applications so that they can exchange data).
- Other fully-documented and highly-supported Application Programming Interfaces as applicable and developed over time.

2.1 Does the EHR Project meet the following:

Use Industry-Standard Coding and Classification Systems, such as International Classification of Disease ICD-9 and Current Procedural Terminology (CPT)?

- Yes (Complete)
 No (Info Needed)
 N/A

2.2 Can it capture and report California Department of Mental Health cost and performance outcome data?

- Yes (Complete)
 No (Info Needed)
 N/A

Language Standard

The EHR Project **MUST** use Industry-Standard Coding and Classification Systems Such As

- International Classification of Diseases (ICD-9).
- Common Procedural Terminology (CPT) or the various nursing terminologies, which set up hierarchical models for specific descriptions of diagnoses, procedures, activities, etc.

The EHR Project **MUST** be Able to Capture and Report

- California specific cost reporting and performance outcome data.

Additionally, the EHR Project **MUST MOVE TOWARDS**

- Standardized clinical nomenclature within structured messages (reference terminologies such as SNOMED (Standardized Nomenclature of Medicine).
- HL7 2.X (with vendor commitment to migrate to HL7 RIM).
- Logical Observation Identifiers Names and Codes (LOINC) as applicable.
- Having a cross-mapping of terms from one formal terminology or classification to another consistent with federal, state and DMH standard languages.

3. Client Access, Security and Privacy Standards

Technology solutions must also address the need for client access and security. The system must support the ethical and legal use of personal information, in accordance with established privacy principles and frameworks, which may be culturally or ethnically specific. The basis of the relationship between service provider and clients and family is the delivery of high quality care with the highest respect for client self-reliance. This can only be achieved with the knowledge that information is secure and confidential. Detailed requirements are shown below.

Privacy

Government Compliance Standard

The EHR Project MUST be continuously updated to comply with current Federal and State Laws.

These include but are not limited to:

- The United States Department of Health and Human Services (DHHS) Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations.
- The Information Practices Act of 1977 (Civil Code 1798 et. seq.).
- The patient confidentiality provisions of section 5328 of the Welfare and Institutions Code.
- The Confidentiality of Medical Information Act (Civ. Code 56 et seq.).
- The right to privacy under Article 1, Section 1 of the California Constitution.
- All applicable privileges and rules of professional responsibility.
- Any other applicable State and Federal Laws and Regulations.
- All California rules and regulations pertaining to the privacy and security of mental health and substance abuse information.

Vendor proposals for technology solutions must specify how their product meets or plans to address all State and Federal Laws including, but not limited to, HIPAA regulations, Clinical Laboratory Improvement Amendments (CLIA), 42 CFR9 (Code of Federal Regulations), Information Practices Act (IPA), California Medical Information Act (CMIA), California Family Code 6920-6929, Title VI of the Civil Rights Act, and the Patient's Access to Health Records Act.

Privacy Standard

The EHR Project MUST support the application of prevailing California privacy and confidentiality rules. The technology solution must support the restricting of components or sections of the system to authorized users and/or purposes. This restriction should include restrictions at the level of reading, writing, amendment, verification, and transmission or disclosure of data and records.

- Support privacy and confidentiality restrictions at the level of both data sets and discrete data attributes.
- Support recording of informed consent for the creation of a client record.

Client Access

The EHR Project MUST

- Address competency and literacy in the use of technology.
- Comply with current Americans with Disabilities Act (ADA), Section 508 of the Rehabilitation Act requirements. Section 508 requires that individuals with disabilities, including Federal employees, have access to and use of information and data that is comparable to those without disabilities. To learn more about the regulations governing the accessibility of Federal electronic information, please see: www.hhs.gov/Accessibility.html.
- Address cultural and language issues to facilitate access and sharing of data. Many cultures do not support the idea of sharing client information. Others share information and decision making on health matters at the level of the extended family or larger group. Counties must ensure that language translation using technology supports cultural competency and linguistic objectives.

Security

The EHR Project **MUST** follow the security criteria outlined in the CCHIT Ambulatory Security Criteria 2007, as applicable. The criteria includes Access Control, Audit, and Authentication. The general security standards are noted in the sample from International Standards Organization (www.iso.org) which is listed below:

- ISO 17799 – Code of Practice for information security.
- ISO 27799 – Security Management in health using ISO 17799.
- ISO/CD TS 21298 – Health informatics functional and structural roles.
- ISO/TS 21091:2005 – Directory services for security, communications and identification of professionals and clients.
- ISO/TS 17090-1:2002 – Health informatics – Public Key infrastructure.
- ISO 26000 – Standard on Social responsibility (In development – 2008).

A sample from ASTM International originally known as the American Society for Testing and Materials (www.astm.org) is listed below. (All of the following standards are American National Standards Institute (ANSI) approved.)

- E1762-95(2003) – Standard guide for electronic authentication of healthcare information.
- E1985-98(2003) – Standard guide for user authentication and authorization.
- E1986-98(2005) – Standard guide for information access privileges to health information.
- E1869-04 – Standard guide for confidentiality, privacy, access and data security principles for health care including EHRs.
- E1988-98 – Standard guide for training of persons who have access to health information.
- E2147-01 – Standard specification for audit and disclosure logs for use in health information systems.

Access Control Standard

The EHR **MUST** support measures to Define, Attach, Modify, and Remove Access Rights to the Whole System and/or Sections.

- Support measures to define, attach, modify and remove access rights for classes of users.
- Support measures to enable and restrict access to the whole and/or sections of the technology solution in accordance with prevailing consent and access rules.
- Support measures to separately control authority to add to and/or modify the technology solution from the control of authority to access the technology solution.
- Support measures to ensure the integrity of data stored in and transferred to and from other systems.

Auditing Standard

The EHR **MUST** Support Recording of an Audit Trail of Access To, and/or Modifications of, Data.

- Support recording of the nature of each access and/or modification.
- Support audit capability sufficient to track accountability for each step or task in the clinical or operational processes recorded in the record including but not limited to the standards for e-signature auditing.

Authentication Standard

The EHR **MUST** support Two-Factor Authentication and work toward meeting the Evolving Standards for Authentication as they become available.

3.1 Does the EHR Project demonstrate compliance with:

- Current Federal and State Laws?
- Prevailing Privacy and Confidentiality Rules?
- Security criteria outlined in the CCHIT Ambulatory Security Criteria 2007?

- Yes (Complete)
- No (Info Needed)
- N/A