



CALIFORNIA DEPARTMENT OF

Mental Health

1600 9th Street, Sacramento, CA 95814
(916) 654-2309

December 4, 2008

DMH LETTER NO.: 08-10

TO: LOCAL MENTAL HEALTH DIRECTORS
LOCAL MENTAL HEALTH PROGRAM CHIEFS
LOCAL MENTAL HEALTH ADMINISTRATORS
COUNTY ADMINISTRATIVE OFFICERS
CHAIRPERSONS, LOCAL MENTAL HEALTH BOARDS

SUBJECT: ELECTRONIC SIGNATURES AND ELECTRONICALLY SIGNED RECORDS

The increased use of electronic health records and electronic methods of signing them has prompted the State of California Department of Mental Health (DMH) to issue standards regarding the use of electronic signatures in records reviewed by its auditors.

In addition to the addressees, this letter should be reviewed by all appropriate county staff in areas including, but not limited to, compliance, audit, clinical, quality improvement, fiscal, and information technology. Topics covered in this letter include:

- Definitions of an electronic signature and an electronically signed record
- Standards for an electronic signature used in an electronically signed record
- Information security considerations
- Obtaining consumer signatures
- Health Insurance Portability and Accountability Act (HIPAA) compliance
- DMH audit requirements for electronically signed records

Electronic Signature – Definition

Federal law¹ defines an electronic signature as “an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.”

¹ 15 USC § 7006

Under California law², a digital signature is defined as "an electronic identifier, created by computer, intended by the party using it to have the same force and effect as the use of a manual signature."

Electronically Signed Record – Definition

For the purposes of these standards, an electronically signed record is a financial, program, or medical record that (1) is required to be signed under California or Federal law, California or Federal regulation, or organizational policy or procedure, and (2) may be requested during an audit by a DMH auditor or a DMH audit contractor.

Standards for Electronic Signatures in Electronically Signed Records

DMH approves the use of electronic signatures in electronically signed records as equivalent to a manual signature affixed by hand for financial, program, and medical records audit purposes. This approval extends to all electronically signed records requiring signature under the California Code of Regulations, Title 9, Division 1. The electronic signature should meet the following requirements:

1. The electronic signature mechanism is a) unique to the signer, b) under the signer's sole control, c) capable of being verified, and d) linked to the data so that, if the data are changed, the signature is invalidated³.
2. Computer systems that utilize electronic signatures comply with the following Certification Commission for Healthcare Information Technology (CCHIT) certification criteria⁴ or equivalent: *Security: Access Control, Security: Audit, and Security: Authentication*.
3. Counties maintain an Electronic Signature Agreement (example attached) for the terms of use of an electronic signature signed by both the individual requesting electronic signature authorization and the county mental health director or his/her designee.
4. County mental health directors complete a County Mental Health Director's Electronic Signature Certification form (example attached), certifying that electronic systems used by the county's mental health operations, including contract provider systems, meet the standards.

² California Government Code Section 16.5 (d)

³ California Government Code Section 16.5 (a) and California Code of Regulations Section 22002

⁴ http://www.cchit.org/files/Ambulatory_Domain/CCHIT_Ambulatory_SECURITY_Criteria_2007_Final_16Mar07.pdf

5. The signed Electronic Signature Certification and signed Electronic Signature Agreements from county employees and contract providers, or copies thereof, are available to the DMH auditor at the time of an audit.

Under these standards, Mental Health Plans (MHPs) may set additional restrictions or requirements beyond what is presented in this Information Notice, provided those restrictions or requirements meet the minimum requirements stated above and are consistent with applicable state and federal laws and regulations. MHPs are responsible for identifying laws and regulations that may apply to restrictions or requirements they set.

Information Security Considerations

The Department's standards do not require encryption of the data in the electronically signed record for compliance. However, counties are still responsible for taking appropriate security measures to safeguard the contents of all electronic records and complying with Welfare and Institutions Code section 5328, the Confidentiality of Medical Information Act⁵, California Government Code section 6254, and all other applicable federal and state laws and regulations.

Obtaining Consumer Signatures

In many situations, the mental health consumer, or his/her representative, must acknowledge his/her willingness to participate in and accept the treatment plan. In paper-based systems, the consumer, or his/her representative, physically signs a document to that effect. As an alternative to paper, it is proposed that MHPs use any of the following approaches: 1) scanning paper consent documents, treatment plans or other medical record documents containing consumer signatures, 2) capturing signature images from a signature pad, 3) recording biometric information, such as a fingerprint using a fingerprint scanner, or 4) entering authenticating information known only to the consumer or authorized representative, such as a password or personal identification number (PIN). If a signature is unavailable, an electronically signed explanation must be provided by the county mental health director or his/her designee.

Health Insurance Portability and Accountability Act (HIPAA) Compliance

In addition to complying with the standards in this letter for electronic signatures and electronically signed records, MHPs and providers that manage consumer mental health

⁵ California Civil Code section 56 et seq.

information should be in full compliance with all applicable HIPAA security standards⁶. Upon future publication of HIPAA electronic signature regulations, MHPs will be required to be in full compliance within the timelines and other requirements established by the federal government.

DMH Audit Requirements for Electronically Signed Records

Electronic records and electronically signed records may replace paper-based records for purposes of a DMH audit. Counties and contract providers should conform to the standards for electronic signatures in electronically signed records set forth in this Information Notice. When DMH conducts audits and reviews, counties and contract providers should make available the following upon arrival of DMH staff at the audit site:

- Physical access to electronic health record systems
- Adequate computer access to the electronic health records needed for the audit review
- System or network access to electronic records such as user IDs and passwords
- Access to printers and capability to print necessary documents
- Technical assistance as requested
- Scanned documents, if needed, that are readable and complete

⁶ http://www.cms.hhs.gov/SecurityStandard/02_Regulations.asp

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If you have questions or need additional information regarding electronic records or electronically signed records requirements, please contact Denise Blair at (916) 651-3084.

Sincerely,

Original signed by

STEPHEN W. MAYBERG, Ph.D.
Director

Enclosures

cc: Denise Blair, CIO, Information Technology, DMH
Stan Bajorin, DD, Administrative Services, DMH
Carolyn Michaels, Acting DD, Program Compliance, DMH
Gigi Smith, CIO, Information Technology, ADP

Letterhead or Header Identifying Legal Entity

LEGAL ENTITY ELECTRONIC SIGNATURE CERTIFICATION

I certify that the electronic signatures affixed to the electronic mental health records on the computer systems employed by the above named Legal Entity meet or exceed all of the standards, information security considerations, regulations and laws applicable to them and comply with the California Department of Mental Health Letter No.: 08-10 dated December 4, 2008 regarding Electronic Signatures and Electronically Signed Records. Furthermore, in accord with DMH Letter No.: 08-10, I certify that the above named Legal Entity maintains Electronic Signature Agreements for all individuals utilizing an electronic signature, which minimally includes all Rendering Providers.

I further certify that the original of this document is maintained, either electronically or in paper version, by the Legal Entity and an electronic version was submitted to the Los Angeles County, Department of Mental Health at ecertify@dmh.lacounty.gov.

Signature of Legal Entity Director

Date

Printed Name of Legal Entity Director

Date

LEGAL ENTITY ELECTRONIC SIGNATURE AGREEMENT

This Agreement governs the rights, duties, and responsibilities of (Legal Entity Individual Name) in the use of an electronic signature in (Legal Entity Name). The undersigned (I) understands that this Agreement describes my obligations to protect my electronic signature, and to notify appropriate authorities if it is stolen, lost, compromised, unaccounted for, or destroyed. I agree to the following terms and conditions:

I agree that my electronic signature will be valid for one year from the date of issuance or earlier if it is revoked or terminated per the terms of this Agreement. I will be notified and given the opportunity to renew my electronic signature each year prior to its expiration. The terms of this Agreement shall apply to each such renewal.

I will use my electronic signature to establish my identity and sign electronic documents and forms. I am solely responsible for protecting my electronic signature. If I suspect or discover that my electronic signature has been stolen, lost, used by an unauthorized party, or otherwise compromised, then I will immediately notify the (Legal Entity Security/Privacy Officer) and request that my electronic signature be revoked. I will then immediately cease all use of my electronic signature. I agree to keep my electronic signature secret and secure by taking reasonable security measures to prevent it from being lost, modified or otherwise compromised, and to prevent unauthorized disclosure of, access to, or use of it or any media on which information about it is stored.

I will immediately request that my electronic signature be revoked if I discover or suspect that it has been or is in danger of being lost, disclosed, compromised or subjected to unauthorized use in any way. I understand that I may also request revocation at any time for any other reason.

If I have requested that my electronic signature be revoked, or I am notified that someone has requested that my electronic signature be suspended or revoked, and I suspect or discover that it has been or may be compromised or subjected to unauthorized use in any way, I will immediately cease using my electronic signature. I will also immediately cease using my electronic signature upon termination of my contract, employment or termination of this Agreement.

I further agree that, for the purposes of authorizing and authenticating electronic health records, my electronic signature has the full force and effect of a signature affixed by hand to a paper document.

Requestor Signature

Date

Requestor Printed Name

Approver Signature

Date

Approver Printed Name

Approver Title