



Health and Human Services Agency



California's Statewide Health Information Policy Manual (SHIPM)

Written and Produced by:

California Health and Human Services Agency (CHHS)

California Office of Health Information Integrity (CalOHII)

Health Information Policy and Standards Division

FINAL: June 25, 2015

Updated: September 1, 2016

Statewide Health Information Policy Manual

Dear SHIPM User:

I am delighted to welcome you to the California Statewide Health Information Policy Manual (SHIPM) user community.

This manual was developed and is maintained by the California Health and Human Services Agency's Office of Health Information Integrity (CalOHII). I particularly want to thank the dozens of state departments who generously provided subject matter expertise, rigorously reviewed drafts and provided review comments during the policy development process.

The SHIPM is an important tool that helps CalOHII fulfill its responsibility for providing statewide leadership, coordination, direction, and oversight of the Health Insurance Portability and Accountability Act (HIPAA) implementation and compliance, including the setting of statewide policy.

Our goal in providing this manual is to offer state departments a resource that:

- Provides departments guidance on how to protect patient privacy while promoting coordinated care,
- Promotes uniform interpretation and application of health information laws including those relating to security, patients' rights, and transactions and code sets, and
- Helps state entities avoid fines and sanctions resulting from unauthorized disclosures of health information.

State entities including all state departments, boards, commissions, programs, and other organizational units of the executive branch of state government that are required to comply with the Health Insurance Portability and Accountability Act (HIPAA) must comply with the California SHIPM policies.

For entities not defined by HIPAA as covered entities or business associates, the California SHIPM serves as guidance for voluntary compliance. These entities may find themselves impacted by HIPAA due to receipt, access, storage, transmission, disclosure, or usage of health information.

State entities are also responsible to know and comply with other legal requirements unique to each state entity and ensure that those provisions are included in the state entity's own policies and procedures, if not already addressed in the SHIPM.

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The manual provides direction to help staff working with health information become and remain compliant with HIPAA, as well as other state and federal privacy laws including, but not limited to, the Confidentiality of Medical Information Act (CMIA), the Information Practices Act (IPA), the Lanterman-Petris-Short Act (LPS), the Lanterman Developmental Disabilities Act, the California Penal Code, the California Health and Safety Code, the Patients Access to Health Records Act (PAHRA), the Genetic Information Nondiscrimination Act (GINA), the California State Administrative Manual (SAM), and the National Institute of Standards and Technology (NIST).

CalOHII, with our state department partners, has ensured vigorous legal review of each policy. Preemption analysis was built into the development and review of each policy. If departments impacted by HIPAA (and related laws) follow the SHIPM tenets to develop and manage department-specific policies and procedures, they will be in compliance with HIPAA, and the other state and federal laws referenced in the policies.

CalOHII will conduct future statutorily-required compliance reviews based on the policies in this manual. Each department impacted by HIPAA and related laws should ensure its internal policies and procedures align with the standards and requirements in the SHIPM. Entities outside of state service may also use SHIPM policies to assist with the difficult task of reconciling state and federal medical privacy and security laws.

Finally, we welcome your feedback on the manual. The SHIPM is intended to be a useful, living document that provides on-going guidance and support to HIPAA-impacted state departments. We expect it to be an ongoing, well-used and well-trusted resource. To ensure the SHIPM's ongoing effectiveness, please send any recommended changes to CalOHII for consideration at OHIcomments@ohi.ca.gov. Thank you in advance for your suggestions.

Sincerely,

Elaine Scordakis, MS
Assistant Director
California Office of Health Information Integrity

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How to Use this Manual

Legal Review

This manual is intended to be a guide for use by those implementing and maintaining department policies relating to health information. The vast majority of policies require no additional legal review prior to implementation and incorporation into each department's own policies and procedures. There are several exceptions noted below.

Due to their complex nature, the following policies contain language recommending additional review and interpretation by each department's legal department for guidance in implementation and maintenance of operational policies and procedures:

- Chapter 2: Privacy – Specially Protected Information – HIV/AIDS Information
- Chapter 2: Privacy – Specially Protected Information – Mental Health Records
- Chapter 2: Privacy – Specially Protected Information – Developmental Services Records
- Chapter 2: Privacy – Uses and Disclosures – Employers
- Chapter 3: Security – Administrative Safeguards – Verification of Identity
- Chapter 4: Administrative – Compliance – Consequences of Non-Compliance
- Chapter 4: Administrative - Business Associates
- Chapter 5: Patient Rights – Access
- Chapter 5: Patient Rights - Restriction of Self-Pay and Confidential Communication

How to Navigate this Document:

- Each policy is linked to the Table of Contents. Simply Click to go directly the policy from the Table of Contents.
- Definitions: Definitions associated with the SHIPM policies, are included in the last section of this document. The first time they are used in a policy, words and phrases that have SHIPM definitions are hyperlinked to the corresponding definition. The definitions will include the source, citation, and the majority are based on statute. However, definitions might differ from what is familiar because they may include elements of HIPAA, state, and other federal law.
 - All forms of the word are included under one definition (e.g., patient, patients, and patient's would all be listed under "patient" in the definitions)
- Attachments: Attachments to policies on the SHIPM webpage are included as separate documents.

Please see next page for navigation in Adobe Acrobat or Adobe Reader.

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How to Navigate the SHIPM Document in Adobe Acrobat or the free Adobe Reader:

- Please download the SHIPM Document and use either Adobe Acrobat XI or the [free Adobe Reader](#).

- To make navigation within the SHIPM document easier a table of contents is included that can be clicked and it will take you directly to the desired Policy.

- To return to the table of contents you will need to click  +  and you will be returned to the table of contents.

- Also within the SHIPM document are terms that linked to the definitions at the back of the document. To return to the policy you had clicked from you

will need to click  +  and you will be returned to previous location.

- To return to a previously clicked location use the  + .

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How to Interpret Lists of Items (numbered, lettered, or bulleted):

In the absence of any language to the contrary, assume that it is a list of “OR” items and that the direction applies to each of the items independently.

For example, in the following list, the reader must disclose for any of the following reasons.

Health information shall be disclosed under the following circumstances:

- a. By a court pursuant to an order of that court
- b. By a board, commission, or administrative agency pursuant to an investigative subpoena
- c. By a search warrant lawfully issued to a governmental law enforcement agency

In this example, the reader must disclose health information if requested by a court order OR a subpoena OR a search warrant.

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Topic Format:

The format of each chapter and section is consistent from topic to topic. The following summarizes how each policy topic is organized:

I. Purpose

This section briefly states why this policy has been included in the manual and its intended function.

II. Policy

This section contains a clear and explicit general policy statement. Most often, this policy language applies equally to all covered entities, inside or outside state service. Any provisions specific only to state entities are documented in this section.

III. Implementation Specifics

This section provides more specific details on implementing the policy. Occasionally, state entities have additional restrictions or responsibilities beyond those of non-state covered entities due to the Information Practices Act or other statutes. These details are identified in this section.

IV. References

This section lists legal citations upon which this policy is based. This includes not only HIPAA, CMIA, California IPA (CA IPA), California Health and Safety Code (CA Health and Safety Code), California Welfare and Institutions Code (CA Welfare and Institutions Code), but also the California State Administrative Manual (CA SAM), NIST, and other applicable rules.

V. Related Policies

This section identifies related policies, which may help clarify or amplify the current policy. Referenced policies are presented with the SHIPM chapter number and policy name (for example *SHIPM Chapter 4 – Policies and Procedures*).

VI. Attachments

This section lists any documents related to the policy.

Chapter 1 - Overview

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Chapter: 1 – Overview		
Section: 1.1.0 – CalOHII Authority		
1.1.1 – CalOHII Authority		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To summarize the authority and responsibilities of the California Office of Health Information Integrity (CalOHII) and ensure full and proper [implementation](#) and oversight of the federal Health Insurance Portability and Accountability Act (HIPAA) *and* related state and federal laws.

CalOHII's authority is the basis for this Policy Manual.

II. Policy

California law requires CalOHII to provide statewide leadership, coordination, policy formation, direction, and oversight for HIPAA implementation, including compliance. CalOHII must also exercise full authority over [state entities](#) to establish policy, provide direction, monitor progress, and report on implementation efforts. CalOHII's mandate to provide uniform implementation of HIPAA includes the authority to conduct preemption analyses and set policy based on the results of the analyses.

State entities are responsible for complying with the policies outlined in the California Statewide Health Information Policy Manual (SHIPM). State entities must cooperate with CalOHII's implementation and compliance efforts, provide documentation or information upon request in the format requested, and assist in periodic statewide assessments to determine which state entities are impacted by HIPAA. State entities must comply with the decisions of CalOHII's Director regarding implementation and compliance with HIPAA standards.

[CA Health and Safety Code §130303]

III. Implementation Specifics

A. CalOHII Statutory Authority. CalOHII is required to:

1. Specify tools, such as protocols for assessment and reporting.
2. Develop uniform policies and provide training on [privacy](#), [security](#), [patient rights](#), [transactions and code sets](#), and other matters related to HIPAA. These policies must be adopted and implemented by state entities. The policies are also intended to provide a clear understanding of law for state entities that have oversight of other

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impacted organizations (such as: state, county, and private-sector), so implementation and enforcement is consistent and accurate.

3. Provide ongoing evaluation of HIPAA implementation in California state departments and to refine plans, tools, and policies as required.
4. Develop standards for state and federal health information law compliance reviews of state departments.
5. Represent the State of California in HIPAA discussions with the federal Department of Health and Human Services and national and regional groups developing standards.
6. Monitor the HIPAA implementation activities of state entities and require these entities to report on their implementation activities.
7. Provide state entities with technical assistance.
8. Establish and maintain a public website to provide information in a clear, consistent format concerning state HIPAA implementation activities.
9. Provide the Department of Finance with recommendations on HIPAA implementation and compliance expenditures, including proposals submitted by state entities.
10. Conduct periodic assessments, at least once every three years, to determine whether staff positions established in the office and in other state entities to perform HIPAA compliance activities continue to be necessary or whether additional staff positions are required to complete these activities.
11. Review and approve contracts related to HIPAA to which a state entity is a party, prior to the contract's effective date (prior to execution signatures).
12. Review and approve all legislation that is related to administrative aspects of HIPAA, proposed by state entities and review all analyses and positions on HIPAA-related legislation being considered by either the Congress or the Legislature.
13. Ensure state departments claim federal funding for those activities that qualify.

[CA Health and Safety Code §130306]

- B. Preemption. CalOHII is responsible for leadership, coordination, direction, and oversight regarding HIPAA preemption analyses including determining which statutory requirements apply and setting policy based upon this determination. State entities impacted by HIPAA, at the direction of CalOHII, must assist in completing HIPAA preemption analyses.

[CA Health and Safety Code §130311.5]

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IV. References

CA Health and Safety Code §§130300-130317

V. Related Policies

SHIPM Chapter 2 – Privacy

SHIPM Chapter 3 – Security

SHIPM Chapter 4 – Administrative

SHIPM Chapter 5 – Patient Rights

VI. Attachments

None

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Chapter: 1 – Overview		
Section: 1.2.0 – State Agency Responsibility		
1.2.1 - State Agency Responsibility		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding [state entity](#) responsibilities, relating to the policies in the State Health Information Policy Manual (SHIPM).

II. Policy

State entities are required to comply with all SHIPM policies and to incorporate the provisions into their own policies and procedures.

III. Implementation Specifics

State entities are responsible to:

1. Know legal requirements unique to each state entity and ensure that those provisions are included in the state entity's own policies and procedures, if not already addressed in the SHIPM.
2. Incorporate the protections, provisions, and requirements of the SHIPM into the state entity's own policies and procedures.
[CA Health and Safety Code §130303, §130306, §130311, and §130313]
3. Establish procedures describing when to engage legal staff on activities related to specific SHIPM policies, particularly those policies that advise consulting legal counsel.
4. Provide [workforce](#) training on SHIPM policies as incorporated into individual state entity policies and procedures as appropriate based on the workforce member's role and responsibilities.
[CA Health and Safety Code §130311]
5. Provide feedback and comments to CalOHII regarding SHIPM policies, notices of proposed rule-making, other documents or activities related to HIPAA [implementation](#), compliance, and other state and federal [health information privacy](#) and [security](#) laws.
[CA Health and Safety Code §130306]

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6. Respond in a timely and complete manner to all activities undertaken to assess and ensure implementation and compliance with SHIPM policies. Responses shall include, but are not limited to:
 - a. Assisting in periodic statewide assessments
 - b. Assisting in and partnering with periodic compliance reviews
 - c. Providing documentation or information upon request in the format requested.

[CA Health and Safety Code §130306, and §130310]
7. Comply with the decisions of the CalOHII director in achieving compliance with state and federal health information privacy and security laws.

[CA Health and Safety Code §130311]

IV. References

CA Health and Safety Code:

- §130303
- §130306
- §130310
- §130311
- §130311.5
- §130313

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority
SHIPM Chapter 2 – Privacy
SHIPM Chapter 3 – Security
SHIPM Chapter 4 – Administrative
SHIPM Chapter 5 – Patient Rights

VI. Attachments

None

Chapter 2 – Privacy

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Chapter: 2 – Privacy		
Section: 2.1.0 – Authorizations		
2.1.1 – Authorizations		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To provide guidance regarding the circumstances when an [authorization](#) for the [use and disclosure](#) of [health information](#) is required from the [patient](#) and what must be included in the authorization.

II. Policy

Policies and procedures must be implemented and maintained which outline requirements for when a patient authorization is needed and what must be included.

[45 C.F.R §164.530(i)(1)]

III. Implementation Specifics

A. Health information can be used or disclosed without authorization for certain specific purposes (*see the “Related Policies” section for specifics*).

All other uses and disclosures of health information require prior authorization from the patient.

B. When an authorization is received, uses and disclosures of health information, for the purpose listed in the authorization, are permitted.

[45 C.F.R. §164.508]

C. The authorization must be written in plain language, and printed in 14-point font. This means that authorizations should be written at an appropriate grade level that most adults can understand.

[45 C.F.R. §164.508(c)(3); CA Civil Code §56.11(a)]

D. An authorization must include the following to be valid:

[45 C.F.R §164.508(c)]

1. A specific description of the health information to be disclosed.

[45 C.F.R §164.508(c)(1)(i)]

2. The types of information listed below must be expressly stated in authorizations:

a. [HIV/AIDS test results](#)

[CA Health and Safety Code §120980(g)]

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b. [Mental health records](#)

[CA Welfare and Institutions Code §4514(b) and (d), §5328; CA Health and Safety Code §123115(b)]

c. Genetic test results

[CA Civil Code §56.17; CA Health and Safety Code §124980(j)]

d. [Substance abuse treatment records](#)

[CA Health and Safety Code §11845.5(c)(4); 42 C.F.R Part 2 2.31]

If a [state entity](#) is unclear regarding what health information is covered by the authorization, it must clarify the request prior to disclosing any information.

3. The name or other specific identification of the person(s) or class of persons requesting the health information.

[45 C.F.R. §164.508(c)(1)(ii)]

4. The name or other specific identification of the person(s) or class of persons to whom the health information will be disclosed.

[45 C.F.R. §164.508(c)(1)(iii)]

5. The purpose for the use or disclosure.

a. If the patient initiates the authorization, the statement “at the request of the patient” or similar language that indicates the patient’s wishes is sufficient description of the purpose.

[45 C.F.R. §§164.508(c)(1)(ii) - (iv)]

b. When someone other than the patient initiates the authorization, the purpose for the use or disclosure of health information must be clear enough to limit use or disclosure to the extent necessary to accomplish the stated purpose.

[45 C.F.R. §164.502(b)(2)(iii)]

6. An expiration identified by a date or an event (e.g., end of hospitalization). When an authorization is signed by a parent, the expiration date of the authorization may be the date the minor reaches age 18.

[45 C.F.R. §164.508(c)(1)(v)]

7. Signature of the patient and date signed. If the authorization is signed by a [patient representative](#), a description of the representative's authority to act for the patient must also be provided.

[45 C.F.R. §164.508(c)(1)(vi)]

8. Statement that the patient has the right to modify or revoke the authorization in writing, directions on how the patient can do so, and exceptions to the right to revoke.

[45 C.F.R. §164.508(b)(5), and §164.508(c)(2)(i)(A)]

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9. Statement advising the patient of his/her right to receive a copy of the authorization.
[45 C.F.R. §164.508(c)(4)]

10. Statement that [treatment](#), [payment](#), enrollment, or eligibility for benefits cannot be conditioned upon patient authorization.

[45 C.F.R. §164.508(b)(4) and §164.508(c)(2)(ii)]

11. HIPAA required statement. Health information disclosed through the authorization may be subject to re-disclosure and is no longer protected if it is disclosed to anyone other than a [covered entity](#).

[45 C.F.R. §164.508(c)(2)(iii)]

Note related to D.11 above: This statement is required by HIPAA even though state entities may not further disclose health information unless through an exception or additional authorization.

[CA Civil Code §56.10, §56.11, §56.13, and §56.37]

E. Requirements for handling and processing authorizations.

1. Modification or revocation of authorizations. A patient may modify or revoke an authorization at any time in writing. Once notice is received, state entities are responsible for modifying or revoking the authorization based on the patient's request.

2. Compound authorizations. An authorization for use or disclosure of health information may not be combined with any other document to create a compound authorization.

[CA Civil Code §56.11(b)]

3. Defective (non-valid) authorizations. An authorization is not valid if the document has any of the following defects:

- a. The expiration date has passed
- b. The required elements have not been filled out completely
- c. The authorization is known by the state entity to have been revoked
- d. The authorization violates state or federal law on compound authorizations and/or the prohibition on conditioning of authorizations
- e. Any material information in the authorization is known by the state entity to be false.

[45 C.F.R. §164.508(b)(2)]

F. Documentation retention. A state entity must retain any authorization, modifications or revocations applied to authorizations for a minimum of six (6) years from date of request. [45 C.F.R. §164.508(b)(6)]

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IV. References

45 C.F.R.

- §§164.502(b) – (b)(2)(iii)
- §164.508
- §164.508(b)(2)
- §164.508(b)(6)
- §§164.508(c)(1) – (c)(3)
- §164.524(c)(3)
- §164.530(i)(1)

CA Civil Code

- §§56.10 –56.15
- §56.37

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Uses and Disclosures

SHIPM Chapter 2 – Minimum Necessary

VI. Attachments

Yes – Authorization for Release of Information (Template)

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.1 – Decedents		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the [privacy](#) rights of deceased [patients](#) (decedents) and the requirements to protect the decedent's [health information](#).

II. Policy

Health information of decedents must be protected by all the same safeguards as that of living persons.

Genetic information, HIV/AIDS related information, Mental Health records, Substance Abuse Treatment records, Developmental Service records and Psychotherapy notes are types of Specially Protected Information - see *SHIPM Chapter 2, Specially Protected Information*.

III. Implementation Specifics

A. [State entities](#) are responsible to:

1. Protect the health information of decedents in the same manner, and to the same extent, as required for the health information of living persons. However, the obligation to protect the health information of decedents is limited to a period of 50 years following the date of the patient's death. After that, the information about the decedent is no longer considered health information. *[45 C.F.R. §164.502(f)]*
2. Treat executors, administrators or other persons having the authority to act on behalf of decedents or their estates, as the decedents' [patient representative](#), and provide them [access](#) to the decedents' health information.

However, such access to health information must be limited to that which is relevant to the authority of each patient representative based on decision by the covered entry or business associate.

[45 C.F.R. §164.502(g)(4)]

3. Obtain an [authorization](#) from a patient representative of decedent for [uses or disclosures](#) of decedent's health information not otherwise permitted (see *below*).

[45 C.F.R. §164.502(g)(4)]

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B. Permitted disclosures of a decedent's health information:

1. To alert law enforcement to the death of the patient when there is a suspicion that death resulted from criminal conduct. [45 C.F.R. §164.512(f)(4)]
2. To coroners or medical examiners and funeral directors upon request. [45 C.F.R. §164.512(g); CA Civil Code §56.10(c)(13)]
3. For research that is solely on the health information of the decedent. [45 C.F.R. §164.512(i)(1)(iii)]
4. To organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye, or tissue donation and transplantation. [45 C.F.R. §164.512(h); CA Civil Code §56.10(c)(13)]

Exceptions to the permitted disclosures of decedent's health information. Please see *SHIPM Chapter 2, Specially Protected Information.*

IV. References

45 C.F.R.

- §164.502(f)
- §164.502(g)(4)
- §164.512(f)(4)
- §164.512(g)
- §164.512(h)
- §164.512(i)(1)(iii)
- §164.520(b)

CA Civil Code

- §56.10(b)(8)
- §56.10(c)(13)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Breach and Breach Notifications

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Organ Procurement

SHIPM Chapter 2 – Patient's (Personal) Representative

SHIPM Chapter 2 – Psychotherapy Notes

SHIPM Chapter 2 – Research

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SHIPM Chapter 2 – Required by Law and Required Disclosures

SHIPM Chapter 4 – Policies and Procedures

SHIPM Chapter 4 – Business Associates

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.2 – Employers		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the permitted circumstances and required notices that must be provided when [health information](#) is [disclosed](#) to an [employer](#) about a member of the employer's [workforce](#).

II. Policy

[Health care providers](#) may disclose the [minimum necessary](#) health information, with a valid [authorization](#) from the [patient](#), to an employer about a member of the employer's workforce, or to itself, as an employer for one of its workforce members.

[45 C.F.R. §164.512(b)(1)(v)]

III. Implementation Specifics

A. [State entities](#) are permitted to disclose health information to an employer about a member of the employer's workforce if one of the following conditions are met:

1. A valid authorization has been obtained from the workforce member (*see SHIPM Chapter 2, Authorizations*), or
2. For [payment](#) for [health care services](#). Health information may be disclosed:
 - a. To an employer that is not a state agency for payment purposes.
 - b. To a state agency, for payment purposes if the transfer is necessary for the other state entity to perform constitutional or statutory duties.

[CA Civil Code §56.10(c)]

There is an exception to these permitted disclosures for patients who self-pay for health care services (*see SHIPM Chapter 5, Restriction for Self-Pay and Confidential Communication*).

B. When required by law, the disclosure of health information is permitted for:

1. Occupational Safety and Health Administration (OSHA)/CalOSHA reporting
2. Public Health reporting
3. Workers' Compensation subpoena

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Consult with your legal counsel before developing policies and procedures, or disclosing health information in response to a Workers' Compensation subpoena.

[45 C.F.R. §164.512(b)(1)(v), and §164.512(l); CA Civil Code §56.10(c)(18), and §1798.24]

C. State entities are permitted to disclose health information *internally* about a member of the state entity's workforce, for the purpose of:

1. Reasonable accommodation and return to work laws
2. Workers' Compensation laws
3. OSHA/CalOSHA laws
4. Legal defense (*consult with your legal counsel*).

[CA Civil Code §56.30]

IV. References

45 C.F.R.

- §164.512(b)(1)(v)
- §164.512(l)

CA Civil Code

- §56.10(c)(2)
- §56.10(c)(18)
- §56.30
- §1798.24

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 5 – Restriction for Self-Pay and Confidential Communication

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.3 – Fundraising		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the circumstances under which [health information](#) may be [used or disclosed](#) for [fundraising](#) purposes.

II. Policy

A valid [authorization](#) must be obtained from the [patient](#) prior to using or disclosing health information for fundraising purposes.

III. Implementation Specifics

[State entities](#) cannot use or disclose health information for fundraising activities without obtaining a valid authorization from the patient.

[45 C.F.R. §164.514(f); CA Civil Code §1798.24]

IV. References

45 C.F.R. §164.514(f)

CA Civil Code §1798.24

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.4 – Health Oversight		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding uses or [disclosures](#) of [health information](#) for health oversight purposes.

II. Policy

Health information is permitted to be used by, and disclosed to government agencies that are legally authorized to conduct health oversight activities, if such activities are necessary for the appropriate operation and management of programs, and other functions involving the provision of health care or health care related services.

[45 C.F.R. §164.512(d); CA Civil Code §§56.10(c)(2) – (c)(7), §56.10(c)(14), and §1798.24; CA Health and Safety Code §1797.122]

III. Implementation Specifics

A. [State entities](#) are responsible to:

1. Understand what constitutes health oversight activities, and how to respond to requests for health information by other agencies for this purpose.
2. Limit disclosure of health information to the [minimum necessary](#) for the stated health oversight purpose.
3. Be prepared to address health information [privacy](#) concerns of other state entities when requesting health information.
4. Require reasonable evidence and/or legal authority in the forms listed below:
 - a. A written statement of identity on agency letterhead
 - b. An identification badge
 - c. Similar proof of official status, *or*
 - d. Written request provided on agency letterhead describing legal authority for release of health information.
5. Understand that [health oversight agency](#) representatives will be required to provide verification of both identity and authority when requesting health information for authorized oversight activities.

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- B. Permitted uses. A state entity that is also a health oversight agency may use health information (internally) for health oversight activities. [45 C.F.R. §164.512(d)(4)]
- C. Permitted disclosures. Health information may be disclosed to a health oversight agency, without an authorization, for authorized oversight activities (examples include, but are not limited to, audits, licensure or disciplinary actions).
[45 C.F.R. §164.512; CA Civil Code §56.10, and §§1798.24–1798.25; CA Health and Safety Code §1797.122]
- D. Exceptions to permitted disclosures to health oversight agencies. A health oversight activity *does not include* an investigation or other activity in which the [patient](#) is the subject of the investigation or activity, when it is not a direct result of, or directly related to:
1. The receipt of healthcare
 2. A claim for public benefits related to health
 3. Qualification for, or receipt of, public benefits or services when a patient’s health is vital to the claim for public benefits or services
 4. Reporting of child abuse, neglect, or domestic violence (see *SHIPM Chapter 2, Victims of Abuse, Neglect, or Domestic Violence*)
 5. [Payment](#) collection activities related to provision of healthcare (see *SHIPM Chapter 2, Treatment, Payment, and Health Care Operations*).
- [45 C.F.R. §164.512(d)]
- E. Temporary suspension of accounting of disclosures. Health oversight agencies may request a temporary suspension of a patient’s right to receive an accounting of disclosures. The temporary suspension must be made in writing, include the reason why the disclosure would impede the health oversight activities and indicate the time frame the suspension is required.
- For requests made orally, the patient’s right to an accounting will be suspended for no more than 30 days unless a written request is submitted during that timeframe.
[45 C.F.R. §164.528]
- F. Joint activities or investigations. If a health oversight activity is conducted in conjunction with a public benefits investigation (not related to health), the joint activity or investigation is considered a health oversight activity (e.g., Social Security Number fraud involving health [treatment](#) and other public benefits such as food stamps, housing vouchers, etc.). [45 C.F.R. §164.512(d)(3)]

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G. Notice of Privacy Practices. A state entity that is a [business associate](#), [health care clearinghouse](#), [health care plan](#), [health care provider](#), or [hybrid entity](#), must state in its Notice of Privacy Practices, if applicable, that it will disclose health information to health oversight agencies for health oversight purposes. Some entities are exempt see *SHIPM Chapter 5, Notice of Privacy Practices*). [45 C.F.R. §164.504(e)]

IV. References

45 C.F.R.

- §164.501
- §164.512
- §164.512(d)
- §§164.512(d)(3) – (4)
- §164.528

CA Civil Code

- §56.10
- §§1798.24 – 1798.28

CA Health and Safety Code §1797.122

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 - Law Enforcement

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 - Treatment, Payment and Health Care Operations (TPO)

SHIPM Chapter 2 - Victims of Abuse, Neglect or Domestic Violence

SHIPM Chapter 3 - Verification of Identity

SHIPM Chapter 4 – Business Associates

SHIPM Chapter 5 - Accounting of Disclosures

SHIPM Chapter 5 - Notice of Privacy Practices

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.5 – Judicial and Administrative Proceedings		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the permitted uses and [disclosures](#) of [health information](#) for purposes of administrative and judicial proceedings.

II. Policy

Health information shall be disclosed in the course of a judicial or administrative proceeding without a [patient authorization](#) if disclosure is compelled, such as in response to a court order, valid subpoena, or other compulsory legal process.

However, prior to disclosing the information, [state entities](#) are responsible for reasonably attempting to notify the patient who is the subject of the compelled information, if the notification is not prohibited by law.

Due to the nature, complexity, and sensitivity of this area, state entities should consult with their legal counsel before disclosing health information in response to subpoenas or when developing and implementing operational policies and procedures.

[45 C.F.R. §§164.512(e)(1) – (e)(2); CA Civil Code §1798.24]

III. Implementation Specifics

A. State entities shall disclose health information to the extent necessary, without an authorization, after reasonably attempting to notify the patient in writing. State entities are responsible for maintaining the notification documentation for a minimum of six (6) years.

B. Health information shall be disclosed under the following circumstances:

1. By a court pursuant to an order of that court.
2. By a party to a proceeding before a court or administrative agency, pursuant to a subpoena, notice to appear, or any provision authorizing discovery, in a proceeding before a court or administrative agency.

[CA Code of Civil Procedure §1987; CA Civil Code §1798.24(k)]

3. By a board, commission, or administrative agency pursuant to an investigative subpoena. *[CA Government Code §11180]*

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4. By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena, in a proceeding before an arbitrator or arbitration panel. *[CA Code of Civil Procedure §1282.6]*
5. By a search warrant lawfully issued to a governmental law enforcement agency.
6. By the patient or the [patient's representative](#). *[CA Health and Safety Code §123100]*
7. When responding to requests otherwise specifically required by law (see *SHIPM Chapter 2, Required by Law and Required Disclosures*).
8. When responding to an investigative subpoena issued by a law enforcement entity (see *SHIPM Chapter 2, Law Enforcement*).
[45 C.F.R. §§164.512(e)(1)(i) – (e)(1)(ii); CA Civil Code §56.10(b), and §1798.24]

IV. References

45 C.F.R. §164.512(e)

CA Civil Code

- §56.10(b)
- §56.29
- §1798.24

CA Code of Civil Procedure

- §1282.6
- §1987

CA Government Code §11180

CA Health and Safety Code §123100

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Uses and Disclosures - All

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.6 – Law Enforcement		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the requirements for [disclosure](#) of [health information](#) for law enforcement purposes.

II. Policy

Health information may be disclosed, without an [authorization](#) from the [patient](#), for law enforcement purposes to [law enforcement officials](#), provided certain conditions are met.

Due to the nature, complexity, and sensitivity of this area, [state entities](#) are encouraged to consult with their legal counsel before disclosing health information to law enforcement or developing and implementing operational policies and procedures.

III. Implementation Specifics

A. State entities are required to disclose health information to law enforcement officials as follows:

1. A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer.
[45 C.F.R. §164.512(f)(1)(ii)(A); CA Civil Code §56.10(b); CA Penal Code §§1543 - 1545]
2. A grand jury subpoena. *[45 C.F.R. §164.512(f)(1)(ii)(B)]*
3. An administrative request, including an administrative subpoena or summons; a civil or an authorized investigative demand; or similar process authorized under law provided that:
 - a. The information sought is relevant and material to a legitimate law enforcement inquiry
 - b. The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought
 - c. [De-identified](#) information could not reasonably be used
 - d. The request, or a separate document, indicates that the requirements (*Items #3, a-c above*) have been satisfied

[45 C.F.R. §164.512(f)(1)(ii)(C)]

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4. Identification and location purposes. State entities are permitted to disclose health information in response to a law enforcement official's written or oral requests for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person limited to the following information:
- a. Name and address
 - b. Date and place of birth
 - c. ABO blood type and Rh factor
 - d. Social Security Number
 - e. Type of injury
 - f. Date and time of [treatment](#)
 - g. Date and time of death (if applicable)
 - h. A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair, scars and tattoos

[45 C.F.R. §164.512(f)(2)(i)]

5. Victims of a crime. When not otherwise required by law, disclosure of health information in response to a law enforcement official's written or oral request for information about a patient who is or suspected to be the victim of a crime is permitted if:
- a. The patient agrees to the disclosure
 - b. The patient's agreement cannot be obtained because of incapacity or other emergency circumstances, provided that all of the following are met:
 - i. The law enforcement official represents that the information is needed to determine whether a violation of law by a person other than the victim has occurred, and that the information is not intended to be used against the victim,
 - ii. The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the patient is able to agree to the disclosure, *and*
 - iii. The disclosure is in the best interests of the patient as determined by the entity making the disclosure.
 - c. If it is suspected that the patient may be a victim of child abuse or neglect, elder abuse or neglect, or domestic violence (*please see SHIPM Chapter 2, Victims of Abuse, Neglect, or Domestic Violence*).

[45 C.F.R. §164.512(f)(3)]

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6. Decedents. Disclosure of health information to a law enforcement official about a patient who has died if there is suspicion that death may have resulted from criminal conduct (see *SHIPM Chapter 2, Decedents*).
[45 C.F.R. §164.512(f)(4)]
7. Crime on the premises. Disclosure of health information to a law enforcement official if there is a reasonable and honest belief that it constitutes evidence of criminal conduct. [45 C.F.R. §164.512(f)(5)]
8. During an emergency. If a state entity that is a covered [health care provider](#) is providing emergency health care in response to a medical emergency that is not on its own premises, then disclosure of health information is permitted to a law enforcement official if doing so appears necessary to alert the law enforcement official to:
 - a. The commission and nature of a crime
 - b. The location of such crime or of the victim(s) of such crime, *and*
 - c. The identity, description, and location of the perpetrator of such crime.

If the state entity believes that the medical emergency is the result of abuse, neglect, or domestic violence of the patient in need of emergency health care, see *SHIPM Chapter 2, Victims of Abuse, Neglect or Domestic Violence*.
[45 C.F.R. §164.512(f)(6)(i), and §164.512(f)(6)(ii)]

IV. References

45 C.F.R.

- §§164.512(f)(1)(ii)(A) – (f)(1)(ii)(C)
- §164.512(f)(2)(i)
- §§164.512(f)(3) – (f)(5)
- §§164.512(f)(6)(i) – (f)(6)(ii)

CA Civil Code

- §56.10(b)
- §1798.24

CA Penal Code §§1543 - 1545

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V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Judicial and Administrative Proceedings

SHIPM Chapter 2 – Required by Law and Required Disclosures

SHIPM Chapter 2 – Victims of Abuse, Neglect, or Domestic Violence

SHIPM Chapter 2 – Minimum Necessary

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.7 – Marketing		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

For guidance regarding the uses and [disclosures](#) of [health information](#) for [marketing](#) purposes.

II. Policy

[State entities](#) cannot use or disclose health information for marketing purposes.

[Enforcement agencies](#) are responsible for ensuring that health information obtained from state entities is not used or disclosed for marketing purposes, unless a valid, written [authorization](#) has been obtained from the [patient](#).

III. Implementation Specifics

- A. Policies and procedures. Enforcement entities are responsible for maintaining policies and procedures that outline the details and restrictions of marketing activities.

Though not required, it is a best practice to include this information in the state entity's notice of privacy practices (see SHIPM Chapter 5, Notice of Privacy Practices).

[45 C.F.R. §164.316(a)]

- B. Guidance to enforcement entities. Health information obtained from state entities may not be used or disclosed for marketing purposes without a valid, written authorization from the patient.

A valid authorization for marketing must contain the following information:

1. The fact that the state entity is receiving a financial benefit from a third party, if applicable.
2. Adequate descriptions of the intended purposes of the requested uses and disclosures and the scope of the authorization.
3. A clear statement that the patient may revoke the authorization at any time.

[45 C.F.R. §164.501, and §164.508(a)(3); CA Civil Code §§56.10-56.16]

4. It must also comply with the SHIPM Authorization Policy (see SHIPM Chapter 2, Authorizations). *[45 C.F.R. §164.508(a)(3); CA Civil Code §56.10(d)]*

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C. Exceptions to required authorizations. The following are exceptions and *do not* require an authorization, because they do not meet the definition of marketing:

1. Refill reminders, or other communications about a drug or biologic currently being prescribed to a patient. Federal law permits state entities to receive payment for these communications as long as the amounts received are reasonably related to the cost of creating the communication and include only the costs of labor, supplies, and postage to make the communication.

Examples include, but are not limited to:

- a. A pharmacy emails a patient of the need to refill their prescription
- b. A pharmacy sends a letter to a patient that the patient is running out of refills and to see their provider for renewal
- c. A pharmacy calls a patient to inform them medication is available for pickup

[42 U.S.C. §17936(a)]

2. General communications that are deemed necessary to promote health without promoting a particular provider's services or products.
3. Communications about government and government-sponsored programs (as long as they do not include a commercial component).

[45 C.F.R. §164.501, and §164.508(a)(3); CA Civil Code §56.10(d), and §56.11]

4. General communications necessary to ensure appropriate treatment for a patient.

Examples include but aren't limited to:

- a. A provider texts a patient to remind the patient to take prescribed medication
- b. A pharmacy calls a provider to inform the provider that the patient did not refill their medication so the provider can determine whether to provide counseling
- c. A lab contacts a provider to inform the provider that test results indicate low or non-existent levels of medication
- d. A provider reviews lab results indicating low or non-existent levels of medication and calls a patient for counseling

D. Business associates. If a [business associate](#) (BA) conducts marketing activities, the [business associate agreement](#) must explicitly limit the BA to only communications by the business associate using health information to those approved by, and on behalf of, the state entity. *[45 C.F.R. §164.508(a)(3)]*

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IV. References

42 U.S.C. §17936(a)

45 C.F.R.

- §164.316(a)
- §164.501
- §164.508(a)(3)

CA Civil Code §§56.10 – 56.16

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 - Authorizations

SHIPM Chapter 2 - Breach and Breach Notification

SHIPM Chapter 4 - Policies and Procedures

SHIPM Chapter 4 - Business Associates

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.8 – Opportunity to Agree or Object		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding a [patient's](#) opportunity to agree or object to certain uses or [disclosures](#) of his or her [health information](#).

II. Policy

Policies and procedures must be implemented and maintained to allow patients the opportunity to agree or object to specific uses and disclosures of their health information.

III. Implementation Specifics

[State entities](#) are responsible to inform the patient in advance, if practicable, about their opportunity to agree or object to uses or disclosures of their health information listed in this section.

- A. Patient's prior preference. If the state entity knows of a patient's prior expression of preference, the state entity must follow that expression. This may involve disclosing some portion of the patient's health information but not others, to comply with the patient's preferences.
- B. Uses and disclosures - with the patient present. If the patient is present for, or otherwise available prior to, a permitted use or disclosure and has the capacity to make health care decisions, the state entity may use or disclose the health information *if* it:
 - 1. Obtains the patient's agreement
 - 2. Provides the patient with the opportunity to object to the disclosure, and the patient does not express an objection.
 - 3. Reasonably infer from the circumstances, that the patient does not object to the disclosure

[45 C.F.R. §164.510(b)(2)]
- C. Uses and disclosures - when the patient is not present. If the patient is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the patient's incapacity or an emergency circumstance, the state entity may determine whether the disclosure is in the best interests of the patient and, if so, disclose the [minimum necessary](#) that is directly relevant to the person's or entity's

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involvement with the patient's care or [payment](#) related to the patient's health care or necessary for notification purposes.

A state entity may use its experience with common practice to make reasonable inferences of the patient's best interest in allowing a person to act on behalf of the patient to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of health information.

[45 C.F.R. §164.510(b)(3)]

D. Disclosure for facility directories. State entities are responsible for informing patients they may be included in a facility directory, how the directory may be used, and the persons to whom the state entity may disclose the health information in the directory. Any of the following may be used to maintain a directory of patients in a health care facility:

1. The patient's name
2. The patient's location in the facility
3. The patient's condition described in general terms that does not communicate specific health information about the patient
4. The patient's religious affiliation. If a patient provides such information, the state entity may release that information only to clergy members and not to other persons. A state entity must provide patients with the opportunity to prohibit or restrict some or all of these uses or disclosures.

[45 C.F.R. §164.510(a)(1)(ii), and §164.510(a)(2)]

5. In emergencies. Patients may not be able to object because they are incapacitated or receiving emergency treatment. If the opportunity to object cannot practicably be provided because of patient incapacitation or receipt of emergency [treatment](#), the state entity may use or disclose health information for the facility's directory, if such disclosure is either of the following:

- a. Consistent with a prior expressed preference of the patient, if any, that is known to the state entity
- b. It's in the patient's best interest as determined by the state entity.

The state entity must inform the patient and provide an opportunity to object to uses or disclosures for directory purposes when it becomes practicable to do so.

E. Involvement in the patient's care and for notification purposes. A state entity may disclose to a family member, other relative, close personal friend of the patient, or any other person *identified by the patient*, the health information directly relevant to such person's involvement with the patient's health care, or [payment](#) related to the patient's health care.

[45 C.F.R. §164.510(b)(1)(i)]

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1. A state entity may use or disclose health information to notify, or assist in the notification of (including identifying or locating), a family member, a representative of the patient, or another person responsible for the care of the patient of the patient's location, general condition, or death.

[45 C.F.R. §164.510(b)(1)(ii)]

2. If the patient is deceased, such uses or disclosures may be made unless doing so is inconsistent with any prior expressed preference of the patient that is known to the state entity. A power of attorney or other legal relationship to a patient is not necessary for these disclosures.

[45 C.F.R. §164.510(b)(5)]

3. State entities are not required to verify the identity of relatives or other persons involved in the patient's care. However, it is recommended that state entities confirm with the patient that he or she authorizes disclosing health information while the other person is present.

[45 C.F.R. §164.514(h)]

- F. For disaster relief purposes. A state entity may use or disclose health information to a public or private entity, authorized by law or its charter to assist in disaster relief efforts, to notify or assist in the notification of the patient's location, general condition, or death to any of the following persons:

1. A family member
2. A patient representative
3. Another person responsible for the patient's care.

[45 C.F.R. §164.510(b)(4)]

- G. Documentation retention. Patients may be informed of, and may agree or object to the proposed use or disclosure orally, but any prohibition or restriction by patients must be documented and maintained for at least six (6) years.

[45 C.F.R. §164.510]

IV. References

45 C.F.R.

- §164.508(a)(2)
- §164.510
- §164.514(h)

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V. Related Policies

- SHIPM Chapter 1 – CalOHII Authority
- SHIPM Chapter 2 – Public Health Activities
- SHIPM Chapter 2 – Required by Law and Required Disclosures
- SHIPM Chapter 2 – Research
- SHIPM Chapter 2 – Victims of Abuse, Neglect, or Domestic Violence
- SHIPM Chapter 2 – Mental Health Records
- SHIPM Chapter 2 – Minimum Necessary
- SHIPM Chapter 2 – Patient’s (Personal) Representatives
- SHIPM Chapter 3 – Verification of Identity
- SHIPM Chapter 4 – Waiver of Rights Related to HIPAA Compliant
- SHIPM Chapter 5 – Restriction for Self-Pay and Confidential Communication

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.9 – Organ Procurement		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the permitted uses and [disclosures](#) of [health information](#) for organ procurement purposes.

II. Policy

A [patient's](#) health information may be disclosed, without an [authorization](#), to a coroner, or organ or tissue banks, upon request, for the purpose of facilitating organ, eye, tissue donation or transplantation.

[45 C.F.R. §164.512(h); CA Civil Code §56.10(b)(8), §56.10(c)(13), and §1798.24(i)]

III. Implementation Specifics

A. [State entities](#) *must* disclose without delay health information of the deceased donor to a coroner upon request for either of the following:

1. for the purpose of organ or tissue donation
2. upon notification or investigation of imminent deaths that may involve organ or tissue donation

[CA Health and Safety Code §7151.15; CA Civil Code §56.10(b)(8)]

B. State entities may disclose health information to organ procurement or tissue bank organizations processing the tissue of a donor for transplantation into the body of another person. However, only the donor's information may be disclosed for the purpose of aiding the transplant.

[45 C.F.R. §164.512(h); CA Civil Code §56.10(b)(8), §56.10(c)(13), and §1798.24(i); CA Health and Safety Code §1644, and §§7181 – 7184.5]

C. State entities that are acute care hospitals, may disclose health information to next of kin of a deceased person to notify them of the option for organ donation.

[CA Health and Safety Code §7184]

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IV. References

45 C.F.R. §164.512(h)

CA Civil Code

- §56.10(b)(8)
- §56.10(c)(13)
- §1798.24(f)
- §1798.24(i)

CA Health and Safety Code

- §1644
- §7151.15
- §§7181 – 7184.5

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Decedents

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.10 – Public Health Activities		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding [disclosures](#) of [health information](#) to [public health authorities](#).

II. Policy

Health information *must* be disclosed to public health authorities, without a [patient's authorization](#), when required by law.

Health information *may* be disclosed for public health activities, without the patient's authorization, when the reason for the disclosure is related to the purpose for which the information was collected and under the circumstances outlined under "*Implementation Specifics*."

[45 C.F.R. §164.512(b); CA Civil Code §1798.24]

III. Implementation Specifics

A. [State entities](#) may disclose health information to public health authorities who are legally authorized to receive such reports to prevent or control disease, injury, or disability. This includes, but is not limited to, any of the following:

1. The reporting of a disease or injury
2. Reporting vital events, such as births or deaths
3. Conducting public health surveillance, investigations, or interventions

[45 C.F.R. §164.512(b)(1)(i); CA Civil Code §56.10(c), and §1798.24]

B. State entities that are public health authorities may use and disclose health information for public health purposes, if specifically authorized by law.

[45 C.F.R. §§164.512(b)(1-2); CA Civil Code §56.10(c)(14), and §1798.24]

C. Health information may be disclosed as needed to notify a person that (s)he has been exposed to a communicable disease, or is at risk of contracting or spreading a disease or condition, if the state entity is legally authorized to do so to prevent or control the spread of the disease.

[45 C.F.R. §164.512(b)(1)(iv)]

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D. Verification of identity. State entities are responsible for verifying public health authorities' status and identity (see *SHIPM Chapter 3, Verification of Identity*).
[45 C.F.R. §164.514(h)]

E. Minimum Necessary. State entities are responsible for reasonably limiting the health information disclosed for public health purposes to the [minimum necessary](#) to accomplish the intended purpose (see *SHIPM Chapter 2, Minimum Necessary*).

However, state entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to a patient's authorization or for disclosures that are required by law.

[45 C.F.R. §164.502(b)]

F. Accounting of disclosures. State entities are responsible to document, track and maintain information concerning disclosures of health information. This tracking must document what, when, why and to whom disclosures are made (see *SHIPM Chapter 5, Accounting of Disclosures*).

IV. References

45 C.F.R

- §164.501
- §164.502(b)
- §164.512(b)
- §164.512(b)(1)(i) - §164.512(b)(1)(iv)
- §164.512(b)(2)
- §164.514(h)(2)

CA Civil Code

- §56.10(c)
- §56.10(c)(14)
- §1798.24

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V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Victims of Abuse, Neglect, or Domestic Violence

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 3 – Verification of Identity

SHIPM Chapter 5 – Accounting of Disclosures

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.11 – Required by Law and Required Disclosures		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding required uses or [disclosures](#) of [health information](#), which are mandated by federal or state law.

II. Policy

Health information must be disclosed when required by state or federal law, and limited to the extent required by law.

III. Implementation Specifics

- A. [State entities](#) are responsible for identifying laws and regulations that require disclosures of health information, and limiting any uses or disclosures *only* to what is necessary to comply with the law.
- B. Prior to disclosure of health information, state entities are responsible to verify the identity and authority/credentials of the requestor (see *SHIPM Chapter 3, Verification of Identity*).
- C. For state entities that are [business associates](#), [health care clearinghouses](#), [health care plans](#), [health care providers](#), or [hybrid entities](#), disclosures are required under any of the following circumstances:
 1. When oversight requires health information to determine compliance with the Privacy Rule.
 2. By court order. *[CA Civil Code §56.10(b)(1)]*
 3. By a board, commission, or administrative agency for adjudication. *[CA Civil Code §56.10(b)(2)]*
 4. By a warrant, subpoena, or summons issued by the court. This includes a subpoena to produce evidence, a notice to appear which has been served, or any provision authorizing discovery in a proceeding before a court or administrative agency. *[CA Civil Code §56.10(b)(3)]*
 5. By a board, commission, or administrative agency pursuant to an investigative subpoena. *[CA Civil Code §56.10(b)(4)]*

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6. By an arbitrator or arbitration panel, to produce specific documentation, in a proceeding before an arbitrator or arbitration panel. *[CA Civil Code §56.10(b)(5)]*
 7. By a search warrant issued to a law enforcement agency.
[CA Civil Code §56.10(b)(6)]
 8. By the [patient](#) or the [patient's representative](#).
[45 C.F.R. §164.502(a)(2)(i); CA Civil Code §56.10(b)(7)]
 9. By a coroner, when requested in the course of an investigation by the coroner's office to identify a deceased person, determine cause of death, or other duties approved by law. *[CA Civil Code §56.10(b)(8)]*
 10. To the U.S. Department of Health and Human Services (HHS), when disclosure is required to investigate and determine a state entity's compliance with HIPAA, with disclosure limited to information pertinent to determine compliance.
[45 C.F.R. §164.502(a)(2)(ii)]
 11. When otherwise specifically required by law. *[CA Civil Code §56.10(b)(9)]*
- D. Special requirements. State entities are responsible to follow special procedures regarding the following disclosures:
1. about victims of abuse, neglect, or domestic violence
 2. for judicial/administrative proceedings/subpoena
 3. for law enforcement purposes
- See *SHIPM Chapter 2, Victims of Abuse, Neglect, or Domestic Violence; Judicial and Administrative Proceedings; and Law Enforcement*, regarding uses and disclosures for these required disclosures.
- E. Minimum necessary. When the law requires a use or disclosure, the HIPAA minimum necessary rule does not apply. However, a best practice is to limit uses and disclosures to the information requested that is relevant and material to the inquiry.

IV. References

45 C.F.R.

- §164.502
- §164.512
- §164.514

CA Civil Code

- §1798.24
- §56.10

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V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Victims of Abuse, Neglect or Domestic Violence

SHIPM Chapter 2 – Judicial and Administrative Proceedings

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Specially Protected Information

SHIPM Chapter 3 – Verification of Identity

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.12 – Research		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the permitted uses and [disclosures](#) of protected [health information](#) for [research](#) purposes.

II. Policy

A [patient's](#) health information may be disclosed without a patient [authorization](#) for purposes of research, under specific circumstances described below.

Due to the nature, complexity, and sensitivity of this area, [state entities](#) are advised to consult with their legal counsel before disclosing health information for research purposes or developing and implementing operational policies and procedures.

III. Implementation Specifics

A. Use and disclosure without patient authorization. State entities are permitted to disclose health information to the University of California, a nonprofit educational institution, or in the case of education-related data - another nonprofit entity, conducting scientific research, if the request is approved by either of the following:

1. By the California Health and Human Services Agency (CHHS) Committee for the Protection of Human Subjects
2. By a legally authorized [institutional review board \(IRB\)](#)
[45 C.F.R. §164.512(1)(A); CA Civil Code 1798.24(t)]

B. Use of [de-identified information](#). A patient's health information that has been de-identified may be used or disclosed for research purposes (*see SHIPM Chapter 2, De-identification*).

C. Use of a [limited data set](#). A patient's health information that is part of a limited data set may be used or disclosed for research purposes, if the [state entity](#) enters into a data use agreement with the recipient of the health information (*see list in SHIPM Chapter 2, De-identification*).

For this policy, a data use agreement is defined as an agreement entered into by a covered entity and a researcher, pursuant to which the covered entity may disclose a

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limited data set of health information to the researcher for research, public health, or health care operations.

[45 C.F.R. §164.514(e); CA Civil Code §1798.24(t)]

- D. Accounting of disclosures. Upon request by the patient, state entities are responsible for providing an accounting of disclosures related to research for the six (6) years prior to the request (see *SHIPM Chapter 5, Accounting of Disclosures*).

[45 C.F.R. §164.528]

IV. References

45 C.F.R.

- §164.508(c)
- §164.512(i)
- §164.514
- §164.528
- §164.532(c)

21 C.F.R. Parts 21, 50, and 56

CA Civil Code

- §56.10(c)(7)
- §1798.24(b)
- §1798.24(h)
- §1798.24(t)

CA Penal Code §3500

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – All policies

SHIPM Chapter 5 –Accounting of Disclosures

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.13 – Specialized Government Functions		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the permitted uses and [disclosures](#) of [health information](#) for specialized government functions.

II. Policy

Health information may be disclosed, without a [patient authorization](#), when the use or disclosure involves, or is related to, a specialized government function defined below.

III. Implementation Specifics

A. [State entities](#) are permitted to disclose health information, without patient authorization, for any of the following specialized government functions:

1. Correctional institutions and other law enforcement custodial situations. If the disclosure of health information is made to authorized correctional or law enforcement officials with lawful custody of the patient, *and* the health information is needed, according to the [law enforcement official](#) or representatives of the correctional institution, to do any of the following:
 - a. Provide healthcare to the patient
 - b. Ensure the health and safety of the patient or other inmates
 - c. Ensure the health and safety of officers, employees, or others at the correctional institution
 - d. Ensure the health and safety of individuals responsible for transporting or transferring of patient inmates from one institution, facility, or setting to another
 - e. Enforce the law on the premises of the correctional institution
 - f. Administer and maintain the safety, security, and good order of the correctional institution

[45 C.F.R. §164.501, §164.512(j), §164.512(k)(5), and §164.514(h); CA Civil Code §56.10(c)(14), and §§1798.24(d) – (f)]

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2. Government programs providing public benefits. Health information is permitted to be disclosed when the disclosure is related to the purpose for which the information was collected, *and* any of the following:
- The state entity is a [health care plan](#) that is a government program
 - The disclosure is to another entity administering a government program providing public benefits
 - The disclosure is required or expressly authorized by law, and
 - The disclosure is the sharing of eligibility or enrollment information
 - Is required for the maintenance of information in a single or combined data system accessible to both government agencies

[45 C.F.R. §§164.512(k)(1) - (k)(6), and §164.514(h); CA Civil Code §56.10, and §1798.24]

3. Government agencies administering a government program providing public benefits. Health information is permitted to be disclosed when the disclosure is related to the purpose for which the information was collected, *and* any of the following:

- The state entity is a [covered entity](#) administering a government program providing public benefits
- The disclosure is to another covered entity that is a government agency administering a government program providing public benefits
- Both programs serve the same or similar populations
- The disclosure is necessary to coordinate HIPAA [covered functions](#) of the programs, or to improve administration and management relating to the programs covered functions

[45 C.F.R. §§164.512(k)(1) - (k)(6), and §164.514(h); CA Civil Code §56.10, and §1798.24]

4. Military and veterans activities. Disclosure of health information of armed forces personnel is permitted, *if* upon separation or discharge from military service, disclosure is made by a component of the Departments of Defense or Homeland Security to provide information to the Department of Veterans Affairs (DVA) to determine eligibility for benefits.

[45 C.F.R. §164.500(c), §164.512(k)(1), and §164.514(h)]

5. National security and intelligence activities. If the disclosure of health information is made to authorized federal officials conducting lawful intelligence, counter intelligence and other national security activities authorized by the National Security Act, *and* the disclosure is any of the following:

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- a. Required by law
- b. Compelled due to circumstances affecting the health or safety of an individual
- c. Compelled through subpoena or warrant

[45 C.F.R. §164.512(k)(2), and §164.514(h); 50 U.S.C. §401 (and implementing authority e.g., Executive Order 12333); CA Civil Code §1798.24(i)]

6. Protective services for the President and others. If the disclosure of health information is made to authorized federal officials to protect the President and other persons, including foreign heads of state, or to conduct investigations authorized by United States Code, *and* the disclosure is any of the following:

- a. Required by law
- b. Compelled due to circumstances affecting the health or safety of an individual
- c. Compelled through subpoena or warrant

[45 C.F.R. § 164.512(k)(3), and §164.514(h); 18 U.S.C. §871, §879, and §3056; 22 U.S.C. §2709(a)(3); CA Civil Code §1798.24(i)]

- B. State entities are responsible to verify the identity of federal officials or correctional and law enforcement representatives (*see SHIPM Chapter 3, Verification of Identity*).
- C. State entities are responsible for ensuring that only the minimum amount of health information necessary to achieve the purpose is disclosed (*see SHIPM Chapter 2, Minimum Necessary*).
- D. Accounting of disclosures. State entities are responsible to document, track and maintain information concerning disclosures of health information. This tracking must document what, when, why and to whom disclosures are made (*see SHIPM Chapter 5, Accounting of Disclosures*).

IV. References

45 C.F.R.

- §164.500(c)
- §164.501
- §164.512(j)
- §§164.512(k)(1) – (k)(6)
- §164.514(h)
- §164.524
- §164.528

18 U.S.C.

- §871
- §879
- §3056

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22 U.S.C. §2709(a)(3)

50 U.S.C. §401

CA Civil Code

- §56.10
- §56.10(c)(14)
- §1798.24
- §1798.24(j)

Executive Orders

- 10450
- 12968
- 12333

Foreign Services Act

- §101(a)(4)
- §101(b)(5)
- §504(t)
- §904

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Organ Procurement

SHIPM Chapter 2 – Required by Law and Required Disclosures

SHIPM Chapter 2 – Treatment, Payment and Health Care Operations (TPO)

SHIPM Chapter 3 – Verification of Identity

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.14 – Treatment, Payment and Health Care Operations (TPO)		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding uses or [disclosures](#) of [health information](#) for the purposes of [treatment](#), [payment](#), or [health care operations \(TPO\)](#).

II. Policy

Health information may be used or disclosed, without a [patient authorization](#), to facilitate TPO when it is collected for the purpose of providing [health care services](#).

Health information may NOT be used or disclosed, without a patient authorization, for TPO if it was collected for another purpose, not related to health care services.

[45 C.F.R §164.506; CA Civil Code §56.10, and §1798.24]

III. Implementation Specifics

Health information may be used or disclosed, without a patient authorization, to facilitate TPO when it is collected for the purpose of providing health care services, as detailed below:

A. [State entities](#) may use and disclose health information to a [covered entity](#), [business associate](#), [health care clearinghouse](#), [health care plan](#), [health care provider](#), or [hybrid entity](#), without a patient authorization for TPO activities as follows:

1. For treatment. State entities may disclose health information for either of the following:
 - a. The provision, coordination, or management of health care and related services among health care providers, consultation between providers regarding a patient, or patient referrals from one provider to another.
[45 C.F.R. §164.501; CA Civil Code §56.10(c)(1)]
 - b. Its own treatment activities *and* the treatment activities of another health care provider.
[45 C.F.R. §§164.506(c)(1) – (c)(2)]

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2. For payment. State entities may use health information for their own payment activities and may disclose health information for the payment activities of the entity (entities described in III.A. above) receiving the information, as follows:

[45 C.F.R. §§164.506(c)(1) – (c)(2)]

To an insurer, [employer](#), health care service plan, hospital service plan, employee benefit plan, governmental authority, business associate, or any other person or entity responsible for paying for health care services including a person or entity that provides billing, claims management health data processing, or other administrative services to health care providers, health care service plans, or any of the persons or entities specified above *to the extent necessary* to allow responsibility for payment to be determined and made.

[CA Civil Code §56.10(c)(2), and §56.10(c)(3)]

3. For health care operations. State entities may use health information for health care operations and may disclose health information to another entity (entities described in III.A. above) if both of the following are met:
- a. Each entity has or had a [treatment relationship](#) with the patient who is the subject of the requested health information
 - b. The health information pertains to that treatment relationship, and the disclosure is for one of the following purposes:
 - i. Conducting quality assessment and improvement activities
 - ii. Evaluating provider performance
 - iii. Health care fraud and abuse detection or compliance.

[45 C.F.R. §164.506(c)(1), and §164.506(c)(4); CA Civil Code §56.10(c)]

B. Additional restrictions exist when sharing health information between state entities.

State entities may use and disclose health information, without a patient authorization, for TPO to another state entity only if necessary for the other state entity to perform constitutional or statutory duties compatible with providing health care services.

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IV. References

45 C.F.R.

- §164.501
- §164.506
- §§164.506(c)(1) – (c)(2)
- §164.506(3)
- §164.506(4)

CA Civil Code

- §56.10(c)(1) - §56.10(c)(3)
- §1798.24

V. Related Policies

SHIPM Chapter 1 - CalOHII Authority

SHIPM Chapter 2 - Authorizations

SHIPM Chapter 2 - Law Enforcement

SHIPM Chapter 2 - Opportunity to Agree or Object

SHIPM Chapter 2 - Required by Law and Required Disclosures

SHIPM Chapter 2 - Victims of Abuse, Neglect or Domestic Violence

SHIPM Chapter 2 - Minimum Necessary

SHIPM Chapter 2 - Patient's (Personal) Representatives

SHIPM Chapter 5 - Notice of Privacy Practices

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.15 - Underwriting		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding when [health information](#) can be used or [disclosed](#) for [underwriting](#) purposes, without the [patient's](#) permission ([authorization](#) or consent).

II. Policy

Health information obtained for underwriting activities may only be used or disclosed for that purpose.

A [state entity](#) that is an enforcement or oversight agency must require [business associates](#), [health care plans](#), or [health care providers](#) to comply with this policy.

[45 C.F.R. §164.514(g)]

III. Implementation Specifics

At a minimum, state entities are responsible to do all of the following:

- A. Ensure that health information obtained during the underwriting process (including premium rating or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits) is not used for any other purpose if the patient's application for coverage is not approved.
- B. The health plan may only use or disclose the obtained health information for the intended underwriting purpose, or as may be required by law.
- C. Limit the use of health information, with respect to [genetic information](#) obtained for underwriting purposes, to determinations of health appropriateness or when a patient seeks a benefit.
- D. State entities are prohibited from disclosing the health, health, or genetic history of the patient to any financial or credit institution. *[CA Civil Code §56.265]*
- E. State entities that are business associates, [health care clearinghouses](#), health care plans, health care providers, or [hybrid entities](#) must implement policies and procedures to limit the health information disclosed to the amount reasonably necessary to achieve the purpose for the disclosure. *[45 C.F.R. §164.514(d)(3)(i)]*

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F. Any use or disclosure of information obtained during the underwriting process that is made on a routine and recurring basis, and which is allowed by state or federal law or regulations, must conform to the [minimum necessary](#) standards.

[45 C.F.R. §164.514(d)(3)(i)]

IV. References

45 C.F.R.

- §164.502
- §§164.502(a)(5)(i), and (a)(5)(i)(B)
- §164.502(b)
- §164.506(a), and (c)
- §164.514(g)

CA Civil Code §56.265

42 U.S.C. §2000ff-5

CA Civil Code §1798.24(d)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Genetic Information

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.2.0 – Uses and Disclosures		
2.2.16 – Victims of Abuse, Neglect, or Domestic Violence		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the permitted uses and [disclosures](#) of [health information](#) for victims of abuse, neglect, or domestic violence.

II. Policy

Health information may be disclosed, without the [patient's authorization](#), to a government authority authorized by law to receive reports when it's reasonably believed that the patient is the victim of abuse, neglect, or domestic violence.

[45 C.F.R. §164.512(c); CA Civil Code §56.10(c), §56.104(e)(3), and §1798.24; CA Health and Safety Code §124250(a)(1)]

III. Implementation Specifics

A. [State entities](#) may disclose health information, without a patient authorization, under any of the following circumstances:

1. To the extent the disclosure is required by law
2. If the victim agrees to the disclosure
3. To the extent the disclosure is expressly authorized by law, *and* either of the following:
 - a. When the state entity determines the disclosure is necessary to prevent serious harm to the patient or other potential victims
 - b. The patient is unable to agree due to incapacity; *and both of the following are met*:
 - i. A law enforcement or other public official, authorized to receive the report, represents that the health information is not intended to be used against the patient
 - ii. The law enforcement or other public official, authorized to receive the report, represents that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the patient is able to agree to the disclosure.

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4. To [Disability Rights California](#), if the disclosure is necessary for Disability Rights California to exercise its authority to investigate incidents of abuse of neglect of people with disabilities.

[CA Civil Code §1798.24(b)(4)(A)]

- B. State entities that make a disclosure permitted above must promptly inform the patient or the [patient's representative](#) that such a report has been or will be made, unless either of the following:
 - a. The state entity determines that informing the patient would place the patient at risk of serious harm
 - b. The report would be made to the patient's representative, and the state entity determines the patient's representative may be responsible for the abuse, neglect, or other injury, *and* that informing such person would not be in the best interests of the patient.

[45 C.F.R. §164.512(c); CA Civil Code §56.05(e), and §56.104(e)(3); CA Health and Safety Code §124250(a)(1); CA Welfare and Institutions Code §§5510(a)(1) – (a)(3)]

- C. State entities are responsible for documenting, tracking and accounting for all disclosures of health information involving victims of abuse, neglect or domestic violence. Documentation must be kept for a minimum of six (6) years (*see SHIPM Chapter 5, Accounting of Disclosures*).

IV. References

45 C.F.R. §164.512(c)

CA Civil Code

- §56.05(e)
- §56.10(c)
- §56.104(e)(3)
- §1798.24
- §1798.24(b)(4)(A)

CA Health and Safety Code §124250(a)(1)

CA Welfare and Institutions Code §§5510(a)(1) – (a)(3)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Law Enforcement

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2 – Uses and Disclosures		
2.2.17 – Health Information Exchange (HIE)		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To explain the permitted uses and [disclosures](#) of [health information](#) for [health information exchange](#) (HIE) purposes.

II. Policy

A valid written contract or other written agreement must be agreed to and implemented between organizations prior to using, disclosing, moving, or storing health information for health information exchange purposes.

[42 U.S.C. §17901, and §17938]

III. Implementation Specifics

Health information exchange is necessary and beneficial within a standardized framework that protects the [privacy](#) of health information and the [security](#) of data being exchanged.

[CA Civil Code §56.10(a), and §56.11]

A. A state entity that uses or discloses health information as part of a HIE, must comply with all SHIPM policies pertaining to specially protected health information, as well as its own policies and those of the CA Information Security Officer (CA ISO).

B. If the state entity is engaging in health information exchange with:

1. One other organization. A state entity must enter into a written contract or other written agreement with the organization with which it intends to exchange information. *At a minimum*, the agreement must address all of the following:
 - a. The minimum requirements of a valid [business associate agreement](#) to fulfill all of the requirements and obligations of a [business associate](#) in regards to the privacy, security, and administrative activities relating to health information (see *SHIPM Chapter 4, Business Associates*).
 - i. If the contracting entity and organization are *both* government entities, the entity can fulfill the agreement requirement with a memorandum of understanding that contains terms that accomplish the objectives of a business associate agreement.

[45 C.F.R. §164.504(e)(3)(i), and §164.314(a)(2)(ii)]

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- ii. If the contracting entity is a [group health plan](#) and the organization is a [plan sponsor](#), the written agreement must ensure the organization safeguards [electronic health information](#) created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan, and that the group health plan's plan documents address the same safeguards and protections for electronic health information as for any other health information shared with the sponsor.

[45 C.F.R. §164.314(b), and §164.504(f)]

- b. The scope of the organization's services and functions
- c. The uses, disclosures, and any further disclosures of health information the organization is permitted or required to make when it has received the information
- d. The safeguards the organization will implement to protect the privacy and security of health information
- e. If the organization is required by law to perform a function for or provide a service to the state entity, the entity may proceed to disclose electronic health information to the organization to the extent necessary to comply with the legal mandate without a written agreement, as long as the state entity attempts in good faith and documents its efforts to obtain assurances that the organization will protect and treat as confidential the information shared.

[42 U.S.C. §17938; 45 C.F.R. §164.308(b), and §164.314(a)]

2. [A health information organization \(HIO\)](#). The state entity must enter into a written contract or other written agreement with the HIO providing health information exchange oversight and services and the HIO's participating entities.

Examples of types of organizations that require such agreements include Regional Health Information Organizations, e-prescribing Gateways, and any vendor that contracts with a state entity to allow that state entity to offer personal health data to patients as part of its electronic health record.

[42 U.S.C. §17938]

At a minimum, the agreement must address all of the following:

- a. The minimum requirements of an adequate business associate agreement
- b. The scope of the HIO's governance, services and functions
- c. The use, disclosure, and any further disclosure of health information the HIO and its participating entities are permitted or required to make as they create, receive, move, transmit, store, or maintain electronic health information

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- d. The safeguards the HIO and its participating entities will implement to protect the privacy and security of the electronic health information.

[42 U.S.C. §17938; 45 C.F.R. §164.308(b), §164.314(a), §§164.502(e)(1-2), and §164.504(e)]

- e. In the context of a networked HIO environment, the entity may enter into a single, multi-party business associate agreement with multiple entities or organizations participating in the exchange of health information.

- 3. An organization consisting of multiple health information organizations (HIOs). The state entity must enter into a written agreement with any health information organization(s) (HIOs) providing health information exchange services along with their participating entities.

[42 U.S.C. §17938]

At minimum, the agreement must address all the following:

- a. The minimum requirements of an adequate business associate agreement
- b. The scope of the multi-HIO 's governance, services, and functions
- c. The use, disclosure, and further disclosures of health information the multi-HIO and its participating HIOs and entities are permitted or required to make as they create, receive, move, transmit, store, or maintain electronic health information
- d. The safeguards the multi-HIO and its participating HIOs and entities will implement to protect the privacy and security of the electronic health information.
[42 U.S.C. §17938; 45 C.F.R. §164.308(b), §164.314(a), §§164.502(e)(1) – (e)(2), and §164.504(e)]
- e. In the context of a networked multi-HIO environment, state entities are required to use the California Data Use and Reciprocal Support Agreement (CalDURSA) as its written agreement with the multi-HIO organization, or a written agreement with all the same elements as the CalDURSA.

State entities participating in health information exchange with a single HIO are encouraged, but not required, to use the CalDURSA as its written agreement where applicable.

[45 C.F.R. §164.308(b), and §§164.502(e)(1) – (e)(2); CA Civil Code §56.10(a), and §56.37(a)]

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IV. References

45 C.F.R.

- §160.103
- §164.308(b)
- §§164.314(a) – (b)
- §§164.502(e)(1) – (e)(2)
- §§164.504(e) – (f)

42 U.S.C. §17901 - §17953

CA Civil Code

- §56.10(a)
- §56.37(a)
- §1798

CA Health and Safety Code §130250 – §130282

CA Executive Orders S-12-06, and S-06-07

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Privacy

SHIPM Chapter 3 – Security

SHIPM Chapter 4 –Business Associates

SHIPM Chapter 4 – Health Information Organizations

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

Yes - California Data Use and Reciprocal Support Agreement (CalDURSA), dated July 24, 2014

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Chapter: 2 – Privacy		
Section: 2 – Uses and Disclosures		
2.2.18 – Hybrid Entities		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding requirements of [state entities](#) that self-designate as [Hybrid Entities](#).

II. Policy

Policies and procedures must be implemented and maintained which outline the requirement for Hybrid Entities to create and maintain adequate “firewalls” or separation between covered and non-covered healthcare components within their organization.

[45 C.F.R. §164.103, §164.105, §164.314, §164.316, §164.504, and §164.530]

III. Implementation Specifics

State entities that are Hybrid Entities have business activities that include HIPAA [covered functions](#) and non-covered functions. Any patient [health information](#) collected and used by the covered function portion of the organization cannot be used or shared with the non-covered portion of the organization, even if a single employee has duties in both areas.

A. Written Declaration of Hybrid Entity Status. State entities must declare in writing that they are a Hybrid Entity and must declare which components/portions of their organization are covered under HIPAA. The designations must be in writing as part of the state entity’s policies and procedures. It is recommended that the state entity also publish the designation on its website. The state entity must designate in writing all portions of the organization that meet the definition of covered entity and business associate.

[45 C.F.R 164.105(a)(2)(iii)(D)]

B. Inventory and Location/Movement of Health Information. To ensure separation between covered and non-covered components, Hybrid Entities must:

1. Determine what health information and document the location of health information as well as where it moves within the organization at least once per year.
2. Assess which workforce members have roles that require them to have access to health information. Ensure those [workforce members](#) do indeed work in areas the organization has designated as covered.

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3. Train all workforce members in the covered portions of the organization, to prevent access by staff of non-covered portions.
- C. Implement and Maintain Policies and Procedures. State entities that are Hybrid Entities must implement and maintain policies and procedures outlining the specific methods by which they will protect patient health information within their organizations, including methods to inventory the location and movement of protected health information and how they will separate covered and non-covered components.
- D. Separation between Covered and Non-Covered Components. State entities must create an adequate “firewall” and separation between covered and non-covered healthcare components within the organization in that patient health information that is collected and used by the covered component may not be disclosed to or used by the non-covered component. To satisfy this, the following are required:
1. Health information stored in the covered portion of an organization cannot be available or viewable by workforce members in the non-covered portion of the organization.
 2. If a single workforce member has duties in both covered and non-covered portions of the organization, they cannot use the health information they obtain during their duties in the covered portion of the organization for their duties in the non-covered portion.
 3. Documentation of who is designated to have access to what health information and for what purpose must be maintained for six years.
[45 C.F.R §164.105(c)]
- E. Any risks associated with the separation of covered and non-covered components of the organization and the movement of protected health information between these components must be considered and documented in the organization’s risk analysis.

IV. References

CA Health and Safety Code §§130300 – 130317

45 C.F.R.

- §164.103
- §164.105
- §164.314
- §164.316
- §164.504
- §164.530

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IV. Related Policies

- SHIPM Chapter 1 – CalOHII Authority
- SHIPM Chapter 4 – Business Associates

V. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.3.0 – Specially Protected Information		
2.3.1 – Genetic Information		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the use or [disclosure](#) of [genetic information](#) for [underwriting purposes](#).

II. Policy

Except for a [health care plan](#) that is an issuer of a long-term care policy where the policy is not a nursing home fixed indemnity policy, genetic information shall not be used by health care plans for underwriting purposes.

Underwriting does not include determination of medical appropriateness when a patient is seeking a benefit under a health care plan, coverage, or policy.

[45 C.F.R. §160.103, and §164.502(a)(5)(i); CA Health and Safety Code §124980(j); CA Civil Code §56.17]

III. Implementation Specifics

A. [State entities](#) that are health care plans, including [hybrid entities](#) that have a health care plan component, shall not collect or use genetic information to enroll individuals in a plan, or disclose genetic information to a third party administrator (TPA) or another state entity for underwriting purposes.

Exception to the prohibition: Issuers of long-term care policies in which an employee welfare benefit plan provides health benefits to employees of two or more [employers](#)

Note: This is a discrete exception which is unlikely to apply to many state entities.

B. State entities that are [group health care plans](#) and health insurance issuers may not adjust premiums or contribution amounts for a plan, or any group of similarly situated individuals under the plan, based on genetic information alone without manifestation of any disease or disorder of one or more individuals in the group.

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IV. References

45 C.F.R.

- §160.103
- §164.502(a)(5)(i)

CA Civil Code §56.17

CA Health and Safety Code §124980(j)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Research

SHIPM Chapter 2 – Underwriting

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.3.0 – Specially Protected Information		
2.3.2 – HIV/AIDS Information		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance on the uses and [disclosures](#) of human immunodeficiency virus ([HIV](#)) or acquired immunodeficiency syndrome ([AIDS](#)) information.

II. Policy

Information about HIV or AIDS is a type of [specially protected information](#) and must be protected, used, or disclosed *only* as allowed by law.

[CA Health and Safety Code §120980, and §121025(a)]

Due to the complexity and potential consequences related to HIV/AIDS information, [state entities](#) are encouraged to consult with their legal counsel prior to developing and applying operational policies and procedures governing the use and disclosure of HIV/AIDS information.

III. Implementation Specifics

A. State entities are responsible for doing all of the following:

1. Know and comply with any state or federal restrictions on disclosures of HIV/AIDS information.
2. State entities that are permitted by law to use and disclose HIV/AIDS information for public health or criminal investigative purposes are responsible to know and follow any specific departmental policies authorizing the use and disclosure.
3. Develop and implement policies and procedures regarding the collection, use and/or disclosure of public health records containing HIV/AIDS information.
4. Develop and implement policies and procedures regarding the disclosure of HIV/AIDS test results.

B. With a [patient authorization](#). State entities may use and disclose HIV/AIDS information as described in the written patient authorization.

Written authorization is required for each separate disclosure of HIV/AIDS test results, except for those disclosures that do not require an authorization, as described in *Section III.C - below*.

[CA Health and Safety Code §120980(g)]

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- C. Without a patient authorization. State entities are permitted to disclose HIV/AIDS test results to any of the following:
1. To the patient or the patient's representative.
 2. To the patient's health care provider who provides direct patient care and treatment.
 3. Health care plans and insurance entities are not included in the SHIPM health care provider definition. So, disclosures to health care plans and insurance entities for this purpose are not permitted without a patient authorization.
 4. To a health care provider who procures, processes, distributes, or uses a donated human body part.
 5. To a designated officer of an emergency response organization regarding possible exposure to HIV or AIDS.

However, the disclosure is only permitted to the extent necessary to comply with the provisions of the federal Ryan White Comprehensive AIDS Resources Emergency Act of 1990. *[Public Law 101-381; 42 U.S.C. §201]*

[45 C.F.R. §164.502(a)(1)(i); CA Health and Safety Code §120985, and §121010; CA Civil Code §56.05(m)]

- D. Minimum necessary. Disclosures must include only the information necessary for the purpose of that disclosure and the receiver must agree the information will be kept confidential and not further disclosed without a written authorization.
[45 C.F.R. §164.502(b), and §164.514(d); CA Health and Safety Code §121025(c)]
- E. Notice of Privacy Practices. State entities that disclose HIV/AIDS test results information must reference how this information will be used or disclosed, and provide an example in the Notice of Privacy Practices (see *SHIPM Chapter 5, Notice of Privacy Practices*).

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IV. References

Public Law 101-381

45 C.F.R.

- §§164.502(a)(1)(i) – (a)(1)(ii)
- §164.502(b)
- §164.512(b)(1)
- §164.514(d)

42 U.S.C. §201

CA Civil Code §56.05(m)

CA Health and Safety Code

- §120980
- §120985
- §121010
- §121025(a)
- §121025(c)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Treatment, Payment and Health Care Operations (TPO)

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.3.0 – Specially Protected Information		
2.3.3 – Mental Health Records		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance on the use and [disclosure](#) of [mental health records](#) to persons or entities other than the [patient](#) who is the subject of the record.

II. Policy

Mental health records are a type of [specially protected information](#) and may only be used or disclosed as provided by law.

[Psychotherapy Notes](#) and [Developmental Services Records](#) are addressed in other SHIPM policies (see SHIPM Chapter 2, *Psychotherapy Notes*; and *Developmental Services Records*).

Due to the complexity of state requirements related to mental health records, [state entities](#) are encouraged to consult with their legal counsel prior to developing and implementing operational policies and procedures governing the use and disclosure of mental health records.

III. Implementation Specifics

A. With an authorization. State entities may disclose mental health record information with either of the following:

1. An authorization from the patient or [patient's representative](#), or
2. The approval of the patient's medical professional or [mental health professional](#) and an authorization from the patient if there is no patient's representative.

[45 C.F.R. §164.524(c)(3)(ii); CA Civil Code §56.104; CA Welfare and Institutions Code §§5328(b), (d), and (j)]

If the information is provided to a county mental health patients' rights advocate providing services, the patient or patient's representative may revoke the authorization at any time, verbally or in writing.

[CA Welfare and Institutions Code §5328(m), §5541, and §5542]

B. Without an authorization. Without an authorization from the patient or patient's representative, a state entity may disclose information from mental health records, but only the [minimum necessary](#) information, under the following circumstances:

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1. To inform the patient's attorney upon verification. Mental health record information may be disclosed without a written release of information if, in the [professional judgment](#) of the mental health staff, the patient lacks capacity to sign the release.
[CA Civil Code §56.104; CA Welfare and Institutions Code §5328(j)]
2. For coordination of a minor's care and custody. Mental health record information may be disclosed to a county social worker, a probation officer, or any other person who is legally authorized to have custody or care of a minor patient who has been taken into temporary custody, or is a dependent child or ward of the court or juvenile court, for the sole purpose of coordinating [health care services](#) and medical [treatment](#), mental health services, or developmental services for the patient.
[CA Welfare and Institutions Code §5328.04]
3. To inform others of patient's admission to or presence in a treatment facility. If the patient is unable to authorize the release of information, only information confirming the patient's presence in a public or private treatment facility shall be provided upon request of a family member (spouse, parent, child, or sibling of a patient).
[CA Welfare and Institutions Code §5328.1(a)]
4. To inform others of patient activities in a 24-hour treatment facility. A 24-hour public or private health facility must make reasonable attempts to notify the patient's next of kin, or other person designated by the patient, of the patient's admission, unless the patient requests otherwise.
[CA Welfare and Institutions Code §5328.1]
5. In situations with risk of serious harm. A patient's psychotherapist who believes a patient presents a serious danger of violence may release mental health record information to potential victim(s), to [law enforcement officials](#) and county child welfare agencies if the psychotherapist determines the disclosure is needed to protect potential victims.
[45 C.F.R. §164.512(j); CA Welfare and Institutions Code §5328(r)]
6. To protect and advocate for disability rights. Mental health information and records must be disclosed to [Disability Rights California](#) under certain circumstances.
Due to the complexity of state requirements related to Disability Rights California, state entities are advised to consult with their legal counsel prior to developing and applying operational policies and procedures governing the use and disclosure of mental health records.
7. To determine or investigate conservatorships. Mental health information and records may be disclosed by treatment facilities to the courts conducting conservatorship procedures.
[CA Welfare and Institutions Code §5328(f), and §5354]

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8. When a committed patient escapes. The medical director of the treatment facility may disclose the least amount of information considered essential to identify an escapee (e.g., patient's name, reason for commitment, age, physical condition) for a patient who was committed to a state mental health facility, after being found not guilty by reason of insanity, unable to stand trial, or is a mentally disordered sex offender.
[45 C.F.R. §164.512(j); CA Welfare and Institutions Code §5328(o), §6250, §7325, and §7325.5; CA Penal Code §290.004, §1026, and §1368]
9. To provide services inside the facility. Mental health professionals working in the same facility or having responsibility for the patient's care may share the patient's mental health record information to provide services or referral for services.
[CA Welfare and Institutions Code §5328(a)]
10. In response to criminal activity while hospitalized. The director of the facility or designee may disclose mental health record information to law enforcement officials, when they believe a patient has committed, or has been the victim of, specified crimes (e.g., murder, manslaughter, mayhem, kidnapping, carjacking, robbery, arson, extortion, rape.).
The disclosure shall be limited to the minimum information necessary to investigate the crimes.
[45 C.F.R. §164.512(f); CA Welfare and Institutions Code §5328.4]
11. In support of a claim for [payment](#). Mental health record information necessary for the patient to make a claim for aid, insurance or medical assistance may be disclosed.
[CA Welfare and Institutions Code §5328(c)]
12. For the administration of justice. Mental health record information may be or is required to be shared with the courts, as indicated below:
 - a. When instructed through a court order – required.
 - b. When requested with a subpoena ordering delivery to the court - permitted as long as the patient has been given notice and an opportunity to object and other required conditions are met (*see SHIPM Chapter 2, Judicial and Administrative Proceedings*).
 - c. For all other law enforcement or justice related requests - *see SHIPM Chapter 2, Law Enforcement.**[45 C.F.R. §164.512(e), §164.512(f); CA Welfare and Institutions Code §5328(f), and §5328.02]*
13. To facilitate [research](#). Mental health record information may be disclosed, as provided for in regulations adopted by the California Departments of Health Care

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Services, State Hospitals, Social Services or Developmental Services, specifying rules and necessary approvals for the conduct of research, and specifying confidentiality requirements for researchers.

[CA Welfare and Institutions Code §5328(e), and §5329]

14. For purposes of licensing inspections. Mental health record information may be disclosed to licensing personnel, consistent with the minimum necessary standard, to enable the performance of their duties to inspect, license and investigate health facility and community care facilities, under certain conditions.

Due to the complexity of state requirements in this area, state entities are encouraged to consult with their legal counsel prior to developing and implementing operational policies and procedures governing the use and disclosure of mental health records for this purpose.

[45 C.F.R. §164.512(d); CA Welfare and Institutions Code §5328.15(a)]

15. For purposes of quality assurance. Mental health record information may be disclosed to the California Department of Health Care Services for mental health quality assurance purposes.

Due to the complexity of state requirements in this area, state entities are advised to consult with their legal counsel prior to developing and applying operational policies and procedures governing the use and disclosure of mental health records for this purpose.

[45 C.F.R. §164.512(d); CA Welfare and Institutions Code §5328(n) and §14725]

16. When a patient dies. If a patient dies, from any cause while hospitalized in a state mental hospital, information *must* be released to the coroner.

The information provided to the coroner shall remain confidential and not include any notes, summaries, transcripts, tapes or records of conversations between the patient and the mental health professionals of the hospital that is not related to the diagnosis, or treatment of the patient's physical condition.

[45 C.F.R. §164.512(g); CA Welfare and Institutions Code §5328.8]

IV. References

45 C.F.R.

- §§164.512(d) – (g)
- §164.512(j)
- §164.524(c)(3)(ii)

CA Civil Code §56.104

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CA Welfare and Institutions Code

- §5328
- §5329
- §5354
- §5541
- §5542
- §6250
- §6330
- §6332
- §7325
- §7325.5
- §14725

CA Penal Code

- §290.004
- §1026
- §1368
- §16590

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Developmental Services Records

SHIPM Chapter 2 – Judicial and Administrative Proceedings

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Research

SHIPM Chapter 2 – Specialized Government Functions

SHIPM Chapter 2 – Treatment, Payment, and Health Care Operations (TPO)

SHIPM Chapter 2 – Victims of Abuse, Neglect or Domestic Violence

SHIPM Chapter 2 – Genetic Information

SHIPM Chapter 2 – Psychotherapy Notes

SHIPM Chapter 2 – Substance Abuse Treatment Information

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Personal (Patient) Representative

SHIPM Chapter 5 – Patient Rights - Access

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.3.0 – Specially Protected Information		
2.3.4 – Substance Abuse Treatment		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance on the use and [disclosure](#) of a [patient's substance abuse treatment records](#), a subset of [specially protected information](#).

II. Policy

Substance abuse treatment records are a type of specially protected information and may only be used or disclosed as authorized by law or an [authorization](#).

[42 C.F.R. §2.12(a)(1); CA Health and Safety §11845.5]

Due to the complexity of federal and state laws related to substance abuse treatment records, [state entities](#) involved in the use or disclosure of this information are encouraged to consult with their legal counsel prior to developing and implementing operational policies and procedures governing the use and disclosure of these records.

III. Implementation Specifics

Note that special restrictions in this policy apply only to substance abuse treatment records.

A. Patient information that does not identify a patient as a substance abuser or relate to substance abuse [treatment](#) may be used or disclosed for treatment, [payment](#) and [health care operations](#) (TPO) purposes (see *SHIPM Chapter 2, Treatment, Payment and Health Care Operations*).

B. State entities may disclose substance abuse treatment records for specific purposes when the patient or [patient's representative](#) provides written authorization (see *SHIPM Chapter 2, Authorizations*).

There are additional requirements on authorizations for substance abuse treatment records:

1. The authorization can be revoked, in whole or part, verbally or in writing. A state entity may request but cannot require a revocation for substance abuse treatment records to be in writing.

[42 C.F.R. §2.1(b)(1), §2.2(b)(1), and §2.14; CA Health and Safety Code §11845.5(b) and §11845.5(c)(4)]

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2. The written authorization for a disclosure of substance abuse treatment records must also specifically include identification of the [program](#) or person permitted to make the disclosure, and identification of the program or person to whom the disclosure is to be made. [42 C.F.R. §2.31(a)]
 3. Each disclosure via an authorization must be accompanied by a notice prohibiting further disclosure. The following language must be used:

“This information has been disclosed to you from records protected by Federal confidentiality rules (42 C.F.R part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.” [42 C.F.R. §2.32]
 4. When needed for treatment, within a [treatment program](#) or between a treatment program and an entity. Communications by personnel within a program or between a program and an entity that has direct administrative control of the program having a need for information in connection with their duties that arise from provision of treatment or referrals may occur with an authorization. [42 C.F.R. §2.12(c)(3), and §2.12(d)(2), §2.34; CA Health and Safety Code §11845.5(c)(1)]
- C. State entities may disclose substance abuse treatment records - without an authorization in the following circumstances:
1. Child Abuse Reporting. State entities may disclose information that identifies a patient as a substance abuser to report suspected child abuse or neglect to appropriate state or local authorities. However, substance abuse treatment records may not be disclosed for any follow-up inquiries or requests for information without an authorization or court order (see *SHIPM Chapter 2, Victims of Abuse, Neglect, or Domestic Violence*).

Note: Consult your legal counsel for the sufficiency of any court order.
[42 C.F.R. §2.12(c)(6)]
 2. When needed for a qualified service organization to provide services to the program. A qualified service organization is one that has entered into a written agreement with the program that acknowledges being fully bound by these regulations and provides services to the program (e.g.; data processing; bill collecting; laboratory analyses; legal, medical, accounting, or other professional services; services to prevent or treat child abuse or neglect).

[42 C.F.R. §2.11, § 2.12(c)(4), and §2.12(d)(2); CA Health and Safety Code §11845.5(c)(1)]

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3. When needed to assist medical emergency personnel. Information may be disclosed about a patient for the purpose of treating a condition which poses an immediate threat to the health of *any* individual and which requires immediate medical intervention.

[42 C.F.R. §2.1(b)(2)(A), §2.2(b)(2)(A), and §2.51; CA Health and Safety Code §11845.5(c)(2)]

4. When needed to report a patient's crimes or threatened crimes on program premises or against program personnel. Disclosures between program personnel and [law enforcement officials](#) are limited to circumstances of the incident, including the patient's status, name, address, and last known whereabouts.

[42 C.F.R. §2.12(c)(5)]

5. When needed to conduct [research](#), management or financial audits, or program evaluation. The records can be disclosed to *qualified personnel*, as long as any report on such activities does not identify patients in any way.

Qualified personnel means persons whose training and experience are appropriate to the nature and level of work in which they are engaged, and who, when working as part of an organization, are performing that work with adequate [administrative safeguards](#) against unauthorized disclosures.

[42 C.F.R. §2.1(b)(2)(B), §2.2(b)(2)(B), §2.52, and §2.53; CA Health and Safety Code §11845.5(c)(3)]

6. When needed to comply with a sufficient court order. *State entities are encouraged to discuss court orders with their legal counsel.*

[42 C.F.R. §2.1(b)(2)(C), §2.2(b)(2)(C), §§2.61-2.67; CA Health and Safety Code §11845.5(c)(5)]

- D. Additional requirements. State entities are responsible to know and comply with the following additional requirements on substance abuse treatment records:

1. For deceased patients, disclosure of identifying information is permitted for the collection of death or other vital statistics, or to a coroner for resolving inquiries into the cause of death (*see SHIPM Chapter 2, Decedents*).

Any other disclosure of specially protected information identifying a deceased patient as an alcohol or drug abuser requires a patient's representative to provide authorization. [42 C.F.R. §2.15(b)]

2. State entities are responsible for protecting the [confidentiality](#) of substance abuse treatment records of an applicant to a program or any past or present patient.

[42 C.F.R. §2.1(a), §2.1(d), §2.2(a), §2.2(d); 42 U.S.C. §290dd-2; CA Civil Code §56.30(i); CA Health and Safety Code §11845.5(a), and §111845.5(e)]

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3. State entities may not acknowledge the presence of a patient presently in or having completed a program without an authorization or court order. A state entity may acknowledge the presence of a patient presently in a program without an authorization only when the facility is not a publically identified substance abuse treatment facility and the facility does not identify the patient as a substance abuser.

[42 C.F.R. §2.1(b)(1), §2.2(b)(1), §2.13(c) and §2.14; CA Health and Safety Code §11845.5(b) and §11845.5(c)(4)]

4. Disclosures for a patient referred by the criminal justice system. A program may disclose information about a patient to those persons within the criminal justice system who have made participation in the program a condition of the disposition of any criminal proceedings against the patient, or that patient's parole, or other release from custody, *if*:

- a. The disclosure of substance abuse treatment information is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or post-trial release, probation or parole officers responsible for supervision of the patient), *and*

[42 C.F.R. §2.35(a)]

- b. The written authorization includes a statement that automatically revokes it after a specific amount of time or the occurrence of a specific event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given, *and*

[42 C.F.R. §2.35(c)]

- c. The individual receiving the specially protected information uses or re-discloses it only to carry out official duties with regard to the patient's conditional release or other purposes for which the consent was given.

[42 C.F.R. §2.35]

- E. Substance abuse treatment records from a program that discontinues operations, or is acquired by or merged with other entities, must destroy its records or purge patient-identifying information from records, *unless*:
 1. The patient who is subject of the records gives written permission to the transfer of the record to the acquiring program, or to any other program designated in the permission, *or*

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2. There is a retention period specified by law, which does not expire until after the discontinuation or acquisition of the program. In which case the records must be sealed in an envelope or other container and labeled as follows:

“Records of [insert name of program] required to be maintained under [insert citation to statute, regulations, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]”

The envelope or container must be held by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

[42 C.F.R. §2.19]

- F. Notices to patients are required by federal law at the time of admission or as soon thereafter as the patient is capable of rational communication. Each program shall:
 1. Communicate to the patient that federal law and regulations protect the confidentiality of alcohol and drug abuse patient records, *and*
 2. Provide a written summary of the federal law and regulations, with the specific details defined in the law. Required elements of the notice:
 - a. A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser
 - b. A statement that violation of the federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with federal regulations
 - c. A statement that information related to a patient’s commission of a crime on the premises of the program or against personnel of the program is not protected
 - d. A statement that reports of suspected child abuse and neglect made under state law to appropriate state and local authorities are not protected
 - e. A citation to the federal law and regulations

[42 C.F.R. §2.22]

3. Provide the patient the program/organization’s Notice of Privacy Practices.

- G. Patients have the right to access their own substance abuse treatment records (see *SHIPM Chapter 5, Patient Rights – Access*).

[42 C.F.R. §2.23]

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IV. References

42 C.F.R. §§2.1 – 2.67
42 U.S.C. §§290dd–2
CA Civil Code §56.30(i)
CA Health and Safety Code §11845.5
CA Penal Code §1524(c)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority
SHIPM Chapter 2 – Privacy
SHIPM Chapter 3 – Security
SHIPM Chapter 4 – Administrative
SHIPM Chapter 5 – Patient Rights - Access

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.3.0 – Specially Protected Information		
2.3.5 – Developmental Services Records		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance on the use and [disclosure](#) of [developmental services records](#) to persons or entities other than the [patient](#) who is the subject of the record.

II. Policy

Developmental service records are a type of [specially protected information](#) and may only be used or disclosed as provided by law.

[Psychotherapy Notes](#) or [Mental Health Records](#) are addressed in other related SHIPM policies (see *SHIPM Chapter 2, Psychotherapy Notes; and Mental Health Records*).

Due to the complexity of state requirements related to developmental service records, [state entities](#) are encouraged to consult with their legal counsel prior to developing and applying operational policies and procedures governing the use and disclosure of developmental services records.

III. Implementation Specifics

- A. [Authorization special requirement](#). A new authorization for developmental service records related information must be obtained for each separate specific use.
- B. [With an authorization](#). State entities may disclose developmental service records and related information with an authorization from the [patient](#) if he or she has the capacity to give informed consent, or from the [patient's representative](#).
[CA Welfare and Institutions Code §4514(b), and §4514(d)]
- C. [Without an authorization](#). Without an authorization, a state entity may disclose information from developmental service records, but only the [minimum necessary](#) information, under the following circumstances:
 1. [For intake, assessment, services, referrals, and treatment](#). Developmental service records information may be disclosed without an authorization between professional persons within a regional center, state developmental center, or a [program](#) that is part of a regional center or state developmental center for these purposes.
[CA Welfare and Institutions Code §4514(a)]

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2. To inform the patient's attorney upon verification of representation. Developmental service records information may be disclosed without an authorization if the patient lacks capacity to sign an authorization.
[CA Welfare and Institutions Code §4514(j)]
3. In support of a claim or application for services. Developmental service records information necessary to make a claim or application for aid, insurance, government benefit or medical assistance on the patient's behalf may be disclosed.
[CA Welfare and Institutions Code §4514(c)]
4. To inform family members of patient status in a treatment facility. If the patient with developmental disabilities lacks the capacity to provide informed consent and the patient's representative is unable to authorize the release for any reason, upon request the patient's immediate family (spouse, parent, child, or sibling) may be notified of the patient's presence in, release from, or death while in a state hospital, community care or health facility.
[CA Welfare and Institutions Code §4514.5]
5. In situations of suspected abuse. In cases of suspected abuse, information and records shall be reported to an agency mandated to investigate abuse, and in response to a request from such an agency to investigate cases of suspected abuse.
[45 C.F.R. 164.512(b)(1)(ii), and §164.512(c); CA Welfare and Institutions Code §4514(r), §5328.5, and §15630; CA Penal Code §11164]
6. To protect and advocate for disability rights. Developmental service records information must be disclosed to [Disability Rights California](#) under certain circumstances.

Due to the complexity of state requirements related to Disability Rights California, state entities are encouraged to consult with their legal counsel prior to developing and applying internal policies and procedures governing the use and disclosure of DSRs to Disability Rights California.
[42 U.S.C. §10801, §10805(a)(4)(C), §15001 and §15043(a)(2)(I)(iii); CA Welfare and Institutions Code 4514(v), §§4900 - 4906, §4903(a)(4), and §5328.06]
7. For the administration of justice. Developmental service records information may, or is required to, be shared with the courts, as indicated below:
 - a. When instructed through a court order – *required*.
 - b. When requested with a subpoena ordering delivery to the court - *permitted* as long as the patient has been given notice and an opportunity to object, or other required conditions are met (see *SHIPM Chapter 2, Judicial and Administrative Proceedings*).

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c. For all other law enforcement or justice related requests (see *SHIPM Chapter 2, Law Enforcement*).

[45 C.F.R. §164.512(e), §164.512(f); CA Welfare and Institutions Code §4514(f), §5328(f), and §5328.02]

8. If reported missing or lost while hospitalized. The director of the facility or designee may disclose developmental service records information to [law enforcement officials](#), when they believe a patient is lost or missing.

The disclosure shall be limited to the minimum information necessary to investigate the disappearance.

[45 C.F.R. §164.512(f); CA Welfare and Institutions Code §4514(p)]

9. In response to criminal activity while hospitalized. The director of the facility or designee may disclose developmental service records information to law enforcement officials, when they believe a patient has committed, or has been the victim of, specified crimes (e.g., murder, manslaughter, mayhem, kidnapping, carjacking, robbery, arson, extortion, rape, etc.).

The disclosure shall be limited to the minimum information necessary to investigate the crimes.

[45 C.F.R. §164.512(f); CA Welfare and Institutions Code §4514(p)]

10. To facilitate research. Developmental service records information may be disclosed, as provided for in regulations adopted by the Director of Developmental Services, specifying rules and necessary approvals for the conduct of research, and specifying [confidentiality](#) requirements for researchers. These rules shall include that researchers sign and execute a Code of Confidentiality.

[45 C.F.R. §164.512(j); CA Welfare and Institutions Code §4515(e)]

11. For purposes of licensing inspections and investigations. Developmental service records information may be disclosed to authorized representatives of the California Department of Public Health or Department of Social Services, as necessary, to enable the performance of their duties to inspect, license and investigate health facilities or community care facilities, under certain conditions.

Due to the complexity of state requirements in this area, state entities are encouraged to consult with their legal counsel prior to developing and implementing operational policies and procedures governing the use and disclosure of developmental services records for this purpose.

[45 C.F.R. §164.512(d); CA Welfare and Institutions Code §§4514(n) – (o); CA Health and Safety Code §1278, §1293.2, §1421, and §1431]

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12. For purposes of quality assurance. Developmental service records information may be disclosed to the California Department of Developmental Services for developmental services quality assurance purposes.

Due to the complexity of state requirements in this area, state entities are encouraged to consult with their legal counsel prior to developing and implementing operational policies and procedures governing the use and disclosure of developmental services for this purpose.

[45 C.F.R. §164.512(d); CA Welfare and Institutions Code §4514(a),(o) and §14725]

13. When a patient dies. If a patient dies from any cause while hospitalized in a state developmental center, information shall be released to the coroner.

The information provided to the coroner shall remain confidential and not include any notes, summaries, transcripts, tapes or records of conversations between the patient and the health professionals of the facility unrelated to the diagnosis, or treatment of the patient's physical condition.

[45 C.F.R. §164.512(g); CA Welfare and Institutions Code §4514(m)]

IV. References

45 C.F.R.

- §§160.310(b) – (c)
- §164.512
- §164.524

42 U.S.C.

- §10801
- §§10805 (a)(4)(C)
- §15001
- §15043

CA Health and Safety Code

- §1278
- §1293.2
- §1421
- §1431

CA Welfare and Institutions Code

- §4514
- §4514.5
- §4900 – §4906
- §5328(f)
- §5328(n)

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- §5328.02
- §5328.06
- §5328.5
- §5329
- §14725
- §15630

CA Penal Code

- §11164
- §16590

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Judicial and Administrative Proceedings

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Research

SHIPM Chapter 2 – Specialized Government Functions

SHIPM Chapter 2 – Treatment, Payment and Health Care Operations (TPO)

SHIPM Chapter 2 – Victims of Abuse, Neglect or Domestic Violence

SHIPM Chapter 2 – Genetic Information

SHIPM Chapter 2 – Mental Health Records

SHIPM Chapter 2 – Psychotherapy Notes

SHIPM Chapter 2 – Substance Abuse Treatment

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Patient's (Personal) Representative

SHIPM Chapter 5 – Patient Rights - Access

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.3.0 – Specially Protected Information		
2.3.6 – Psychotherapy Notes		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance on the use and [disclosure](#) of [psychotherapy notes](#) to [patients](#) or others.

II. Policy

Psychotherapy notes are a type of [specially protected information](#) and may only be used or disclosed as specifically provided by law.

[45 C.F.R. §164.50,1 and §164.508 (a)(2)]

Due to the complexity of state requirements in this area, and the specific conditions and limitations that apply, [state entities](#) involved in the use or disclosure of psychotherapy notes and related records are encouraged to consult with legal counsel prior to developing and implementing operational policies and procedures governing use and disclosure of these records.

III. Implementation Specifics

A. Disclosure of psychotherapy notes to persons or entities other than the patient. State entities are responsible to obtain an [authorization](#) for any use or disclosure of psychotherapy notes to persons or entities other than the patient, *except when*:

1. Needed to carry out [treatment](#), [payment](#) or [health care operations](#) (TPO), only as described below (this use diverges from the [health information](#) TPO provisions):
 - a. Only when used for treatment by the originator of the psychotherapy notes.
 - b. Only when used or disclosed for an entity's own training programs in which mental health students, trainees, or practitioners under supervision practice or improve skills in group, joint, family, or individual counseling.
 - c. Only when used or disclosed by the entity to defend itself in a legal action or other proceeding brought by the patient who is the subject of the action.

Due to the complexity of laws and regulations regarding use or disclosure for legal action, state entities are encouraged to consult with their legal counsel prior to releasing information.

[45 C.F.R. §164.508 (a)(2)(i); CA Welfare and Institutions Code §5328.04(h)]

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2. The use or disclosure is:

- a. Required by the Secretary of Health and Human Services as necessary to investigate or determine HIPAA compliance.

[45 C.F.R. §164.502(a)(2)(ii)]

- b. Required by a health oversight agency providing oversight of the originator of the psychotherapy notes.

[45 C.F.R. §164.512(d)]

- c. To a coroner or medical examiner for the purpose of identifying a deceased patient, determining a cause of death, or other duties as authorized by law.

[45 C.F.R. §164.512(g)(1); CA Civil Code §56.10(c); CA Welfare and Institutions Code §4514(m)]

- d. Required by law. Provided that the use and disclosure is limited to the relevant requirements of such law for:

- i. Disclosures about victims of abuse, neglect, or domestic violence to appropriate government authorities (see *SHIPM Chapter 2, Victims of Abuse, Neglect or Domestic Violence*).

- ii. Disclosures for court orders.

[45 C.F.R. §164.512(a); CA Civil Code §56.10(b), and §56.10(c); CA Welfare and Institutions Code §4514, and §5328]

- iii. When necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and the disclosure is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat, and limited to a description of the perpetrator/escapee.

[45 C.F.R. §164.501, and §164.512(j)(1)(i); CA Welfare and Institutions Code §5328(r); CA Penal Code §1328; *Tarasoff v. Regents of the University of California – California Supreme Court decision*]

- B. Disclosure of psychotherapy notes to the patient. Regardless of a patient's (or patient representative's) authorization or request, a health care provider may decline to provide copies or permit inspection of the psychotherapy notes if the health care professional determines there is a substantial risk of significant adverse or detrimental consequences to a patient seeing or receiving copies the notes or records (see *SHIPM Chapter 5, Patient Rights - Access*).

[CA Health and Safety Code §123115(b)]

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IV. References

45 C.F.R.

- §164.501
- §164.502(a)(2)(ii)
- §164.508 (a)(2)
- §164.512(a)
- §164.512(d)
- §164.512(g)(1)
- §164.512(j)(1)(i)

CA Civil Code §§56.10(b) – (c)

CA Health and Safety Code §123115(b)

CA Welfare and Institutions Code

- §4514
- §5328
- §5328(r)

CA Penal Code §1328

Case Law - Tarasoff v. Regents of the University of California, 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Judicial and Administrative Proceedings

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Required by Law and Required Disclosures

SHIPM Chapter 2 – Treatment, Payment and Health Care Operations (TPO)

SHIPM Chapter 2 – Victims of Abuse, Neglect or Domestic Violence

SHIPM Chapter 2 – Mental Health Records

SHIPM Chapter 5 – Patient Rights – Access

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.4.0 – Breach and Breach Notification		
2.4.1 – Breach and Breach Notification		
Review Date: 09/01/2016	Revision Date: 09/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To provide guidance regarding what must be done if a [breach](#) (unlawful or unauthorized [access](#), acquisition, use or [disclosure](#)) of unencrypted/[unsecured health information](#) occurs or is thought to have occurred.

II. Policy

Breaches (and suspected breaches) of unencrypted or unsecured health information that compromise the [security](#) or [privacy](#) of [patients](#) must be investigated and mitigated, by:

- ❖ Notifying affected patients
- ❖ Documenting corrective actions
- ❖ Providing reports to appropriate oversight entities

[42 U.S.C. §17932; 45 C.F.R. §§164.400 – 164.414; CA Civil Code §1798.29, and §1798.82; CA Health and Safety Code §1280.15; CA SIMM §§5340A -5340C]

III. Implementation Specifics

- A. A breach is presumed to have occurred unless the [state entity](#) can demonstrate there is a low probability, based on a breach investigation and risk assessment, the health information has been compromised (*see section III.C – below*).
- B. Policies and procedures must be implemented and maintained to ensure compliance with legal requirements regarding investigating and reporting breaches or unauthorized disclosures of unencrypted or unsecured health information.
- C. Following the discovery of a breach (or suspected breach) of unencrypted or unsecured health information, state entities are responsible for conducting a breach investigation, including a risk assessment (a risk assessment is not required if the entity sends a privacy breach notification to patients who are impacted).

All the following factors should be included in the breach investigation and risk assessment:

1. The nature and extent of the health information involved, including the types of identifiers and the likelihood of re-identification.

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2. The unauthorized person or entity who used the health information or to whom the disclosure was made.
3. Whether the health information was actually acquired or viewed.
4. The extent to which the risk to patient(s) has been mitigated.

[45 C.F.R. §§164.402(2)(1)(i) – 164.402(2)(1)(iv), and §§164.400 – 164.414; CA Civil Code §§56.10 – 56.16, and §§1798.24 – 1798.24(b)]

D. Notification and reporting requirements. If it's determined that a breach of health information has/may have occurred, state entities and their [business associates](#) that own, license, or maintain state data (includes electronic, paper, or any other medium), must do all of the following that apply:

1. Notify the affected patients. Notifications must be sent to each patient who has had, or is reasonably believed to have had, unencrypted/unsecured health information accessed, acquired, used, or disclosed. See section III. G (below) regarding timing of notifications.
2. Report to the Secretary of Health and Human Services (HHS). In the event a breach of unencrypted/unsecured health information affects 500 or more patients, Health and Human Services shall be notified at the same time notice is made to the affected patients, in the manner specified on the HHS website.

If fewer than 500 of the state entity's patients are affected, the state entity will maintain a log of the breaches to be submitted annually to the Secretary of HHS no later than 60 days after the end of each calendar year, in the manner specified on the HHS website. The submission shall include all breaches discovered during the preceding calendar year.

[45 C.F.R. §164.402(2)(1)(i) – §164.402(2)(1)(iv), and §164.400 – §164.414]

3. Report to the California Department of Public Health (CDPH) Licensing and Certification Division. A state entity that is a clinic, health facility, home health agency, or hospice, licensed by CDPH must report a breach to CDPH no later than fifteen (15) business days after the breach has been detected.
4. Report to the California Compliance and Security Incident Reporting System (Cal-CSIRS). Cal-CSIRS will require specific information about the incident and will notify the California Information Security Officer (CISO) and the California Highway Patrol (CHP) Computer Crimes Investigation Unit (CCIU). Each state entity's Information Security Officer (ISO) is responsible for notifying the proper authorities.

[CA Civil Code 1798.29; CA SIMM 5340-A; CA Penal Code 502]

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5. Report to the California Attorney General's office. For any single breach that requires notification to more than 500 California residents, state entities shall submit a single sample copy of the notification, excluding personally identifiable information, to the Attorney General. *[CA Civil Code §1798.29]*
6. Provide the media with a press-release. In the event the breach affects more than 500 residents of a state, prominent media outlets serving the state and regional area shall be notified without unreasonable delay and in no case later than 60 calendar days after the discovery of the breach. The notice shall be provided in the form of a press release. *[45 C.F.R. §164.406]*
7. Notify other owners/licensees of the health information. State entity business associates, or other contracted entities, must immediately notify the state entity when there has been a suspected breach of health information.
8. Notify the California Office of Health Information Integrity (CalOHII). In the event of a breach affecting more than 500 individuals, notify CalOHII at OHIcomments@ohi.ca.gov.

In addition to notifying CalOHII in the event of a breach affecting more than 500 individuals, state entities must submit an annual accounting of any breaches and suspected breaches to CalOHII at the end of each calendar year (and when requested by CalOHII). Please use the attached Annual Breach Reporting Form to document any suspected or confirmed breaches with the steps taken to investigate and mitigate each event

- E. Methods of patient notifications. The notification must be written in plain language and sent by first-class mail to the patient, at his or her last known address.
1. If the patient agrees to an electronic notice, email notification is permitted.
 2. If the state entity believes there is possible imminent misuse of unencrypted/unsecured health information, notification may be provided by telephone or other means, as appropriate.
 3. Deceased patients. If the state entity knows the patient is deceased and has the address of the next of kin or [personal representative](#) of the patient, notification by first-class mail to the next of kin or personal representative shall be carried out.
 4. Substitute notification methods. If there is insufficient or out-of-date contact information that prevents written notification to the patient, a substitute form of notice shall be provided as follows:
 - a. To fewer than 10 patients, notice may be provided by an alternative form of written notice, by telephone, or by other means.

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- b. To 10 or more patients, notice may be provided by either a conspicuous posting for a period of 90 days on the home page of the entity's website, or a conspicuous notice in major print or broadcast media in the entity's geographic areas where the patients affected by the breach likely reside.

[45 C.F.R. §164.404(2)]

- F. Content of patient notifications. The notification shall be written in plain language and titled "Notice of Data Breach." The overall format of the notice shall call attention to the nature and significance of the information, titles and headings will be clear and conspicuously displayed as well the text of the notice will be no smaller than 10-point type. The notice shall include all of the following, to the extent possible, using the prescribed headings:
 1. Using the title "What Happened" provide a brief description of what happened, including the date of the breach and the date of the discovery of the breach. As well, include whether the notification was delayed as a result of a law enforcement investigation.
 2. Using the title "What Information Was Involved" provide a description of the types of unencrypted/unsecured health information involved in the breach (e.g., full name, SSN, date of birth, etc.).
 3. Using the title "What You Can Do" advice on any steps patients should take to protect themselves from potential harm resulting from the breach. Also, provide the toll-free telephone numbers and addresses of the major credit reporting agencies, if the breach exposed a social security number, driver's license, or California identification card number.
 4. Using the title "What We Are Doing" provide a brief description of what the state entity is doing to investigate the breach, to mitigate harm to the patients, and to protect against further breaches.
 5. Using the title "For More Information" provide the name and contact information of the reporting state entity.
 6. Additional information can be provided, such as the contact procedures for patients to ask questions, or learn additional information, which shall include a toll-free telephone number, an email address, web site, or postal address.

[45 C.F.R. §164.404(c)(1); CA Civil Code §1798.29; CA SIMM §5340A]

- G. Timing of notifications. Breach notifications shall be made in accordance with the following:
 1. A state entity that is a clinic, health facility, home health agency, or hospice, licensed by the California Department of Public Health (CDPH), must send a breach

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notification to the following no later than fifteen (15) days after the breach has been detected:

- a. CDPH
 - b. The affected patient or patient's representative
2. All other state entities must send a breach notification without unreasonable delay and, in no case, later than 60 calendar days after discovery of a breach.

Notification may be delayed if a law enforcement agency determines the notification will impede a criminal investigation. A law enforcement agency may delay notification by a state entity that is a clinic, health facility, home health agency, or hospice no more than 60 days after a written request or 30 days after an oral request is made by the law enforcement agency.

[45 C.F.R. §164.412; CA Civil Code §1798.29, and §1798.82; CA Health and Safety Code §1280.15]

- H. Documentation retention. All documentation related to the breach investigation, including the risk assessment and results, notifications, and reports made, must be retained for a minimum of six (6) years from the date the document was created.

[45 C.F.R. §164.414(b) and §164.530(j)]

IV. References

42 U.S.C. §17932

45 C.F.R.

- §§164.400 – 164.414
- §164.530(j)

CA Civil Code

- §§56.10 – 56.16
- §§1798.24 – 1798.29
- §1798.82

CA Health and Safety Code §1280.15

CA SAM §§5300 – 5365.3

CA SIMM §§5340A – 5340C

CA Penal Code §502

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V. Related Policies

- SHIPM Chapter 1 – CalOHII Authority
- SHIPM Chapter 2 – Law Enforcement
- SHIPM Chapter 3 – Incident Procedures
- SHIPM Chapter 3 – Security Management Process
- SHIPM Chapter 3 – Security Awareness and Training
- SHIPM Chapter 4 – Trading Partner Agreements
- SHIPM Chapter 4 – Sanctions of Violation
- SHIPM Chapter 4 – Business Associates
- SHIPM Chapter 5 – Accounting of Disclosures

VI. Attachments

- Yes – CalOHII Annual Breach Reporting Form

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Chapter: 2 – Privacy		
Section: 2.5.0 – De-identification		
2.5.1 – De-identification		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the two methods that can be used to satisfy the HIPAA [Privacy](#) Rule’s de-identification standard: Expert Determination and Safe Harbor.

II. Policy

[Health information](#) that identifies, or can reasonably be used to identify a [patient](#), shall not be [disclosed](#) unless the disclosure is in compliance with federal and state laws, or the health information has been appropriately [de-identified](#).

[State entities](#) are responsible for understanding requirements for de-identifying health information so it is no longer [individually identifiable health information](#).

III. Implementation Specifics

A. Through “Expert Determination”. State entities may determine that health information is no longer individually identifiable when a person with appropriate knowledge of, and experience with, generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

1. Determines after applying principles and methods, that there is minimal risk the information could be used, alone or in combination with other reasonably available information, by a recipient to identify a patient
2. Documents the methods and results of the analysis that justifies (or supports) the determination.

Experts may be found in the statistical, mathematical, or other scientific domains. From an enforcement perspective, the relevant professional experience and academic or other training of the expert used by the [covered entity](#), as well as actual experience of the expert using health information de-identification methodologies would be reviewed.

3. Guidance of generally accepted statistical and scientific principles and methods may be found in:
 - a. The Statistical Policy Working Paper 22 – [Report on Statistical Disclosure Limitation Methodology \(https://fcs.m.sites.usa.gov/files/2014/04/spwp22.pdf\)](#)

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prepared by the Subcommittee on Disclosure Limitation Methodology, Federal Committee on Statistical Methodology, Office of Management and Budget.

- b. [The Checklist on Disclosure Potential of Proposed Data Releases \(http://fcsmlsites.usa.gov/files/2014/04/checklist_799.doc\)](http://fcsmlsites.usa.gov/files/2014/04/checklist_799.doc) prepared by the Confidentiality and Data Access Committee, Federal Committee on Statistical Methodology, Office of Management and Budget.
- B. “Safe Harbor” approach to de-identification. In order to de-identify health information, state entities must remove all the following identifiers of the patient or their relatives, [employers](#), or household members:
1. Names, including initials of the patients associated with the corresponding health information (i.e., the subjects of the records) and of their relatives, employers, and household members must be suppressed. There is no explicit requirement to remove the names of providers or [workforce](#) members of the covered entity or [business associate](#).
 2. All geographic subdivisions smaller than a state, including:
 - a. Street address
 - b. City
 - c. County
 - d. Precinct
 - e. Zip codes, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people
 - ii. The initial three digits of a restricted zip code for all such geographic units containing 20,000 or fewer people are changed to 000. State entities are expected to rely on the most current publicly available Bureau of Census data regarding ZIP codes. This information can be downloaded from, or queried at, the [American Fact Finder website \(http://factfinder.census.gov\)](http://factfinder.census.gov).
 3. All elements of dates (except year) directly related to a patient, including:
 - a. Birth date
 - b. Admission date
 - c. Discharge date
 - d. Date of death

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- e. All ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone and Fax numbers
5. Electronic mail addresses
6. Social Security Numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate or license numbers
11. Vehicle identifiers and serial numbers, including license plate numbers
12. Device identifiers and serial numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images
17. Any other unique identifying number, characteristic, or code, except as permitted by HIPAA

State entities may not release information if they know that the information can be used alone, or in combination with other information available to the intended recipient of the information, to identify a patient. [Office for Civil Right's de-identification paper is available at \(http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html\)](http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html)

- C. Re-identification of information. State entities may assign a code or other means of record identification to allow information to be re-identified, if:
 1. The code or other means of record identification is not derived from or related to information about the patient and is not otherwise capable of being translated so as to identify the patient (such as when a derivative of the patient's name is used as the unique record identifier)
 2. The state entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.
 3. Generally, a code or other means of record identification that is derived from health information would have to be removed from data de-identified following the "safe harbor" method.

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The implementation specifications provide an exception with respect to re-identification by the state entity.

45 C.F.R. §164.514(c) permits covered entities to assign certain types of codes or other record identification to the de-identified information so that it may be re-identified by the covered entity at some later date. Such codes or other means of record identification assigned by the covered entity are not considered direct identifiers that must be removed.

IV. References

45 C.F.R. §§164.514(a) – (c)

CA Civil Code

- §56.05
- §1798

CA State Administrative Manual 5300

NIST SP800-53

V. Related Policies

Chapter 1 – CalOHII Authority

Chapter 2 – Research

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.6.0 – Incidental Disclosures		
2.6.1 – Incidental Disclosures		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding incidental uses and [disclosures](#) of [health information](#) and required policies and procedures.

II. Policy

[State entities](#) must exercise due diligence to limit and prevent [incidental disclosures](#).

III. Implementation Specifics

A. Policies and Procedures. State entities are responsible to develop and implement policies and procedures that require their [workforce](#) to limit and prevent disclosures of health information. When those disclosures are incidental to a permitted or required use or disclosure, it does not apply to *impermissible* uses or disclosures.

Policies and procedures must address all of the following:

1. The [minimum necessary](#) requirement. Health information should not be used or disclosed when it is not necessary to satisfy a particular purpose or carry out a function. *[45 C.F.R. §164.502(b)]*
2. The [implementation](#) specifications for the minimum necessary requirement. Policies and procedures must identify the persons or classes of persons within the state entity who need access to the information to carry out their job duties, the categories or types of health information needed, and conditions appropriate to such access. *[45 C.F.R. §164.514(d)]*
3. The requirement that a state entity has appropriate safeguards in place to protect the [privacy](#) of health information. *[45 C.F.R. §164.530(c)]*

B. Safeguards. State entities must limit and prevent, to the extent possible, incidental uses or disclosures made to an otherwise permitted or required use or disclosure.

Reasonable safeguards include all of the following:

1. Speaking quietly when discussing a patient's condition with family members in a waiting room or other public area

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2. Avoiding using patient names in public hallways and elevators, and posting signs to remind employees to protect patient [confidentiality](#)
 3. Isolating or locking file cabinets or records rooms
 4. Using secure [treatment](#) screens in joint treatment areas
- C. Accounting of disclosures. A state entity is not required to include incidental disclosures in an accounting of disclosures.
- D. Notice of Privacy Practices. State entities must include language to address incidental disclosures in their Notice of Privacy Practices (*see SHIPM Chapter 5, Notice of Privacy Practices*).

IV. References

45 C.F.R.

- §164.502(b)
- §164.514(d)
- §164.520
- §164.528(a)(1)(iii)
- §164.530(c)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Breach and Breach Notification

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 3 – Physical Safeguards

SHIPM Chapter 4 – Policy and Procedures

SHIPM Chapter 5 – Accounting of Disclosures

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.7.0 – Minimum Necessary		
2.7.1 – Minimum Necessary		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance that [health information](#) requested, used, or [disclosed](#), must be limited to only the [minimum necessary](#) required for the specific use, disclosure, or request.

II. Policy

When health information is requested, used, or disclosed, steps must be taken to limit the amount of health information only to that which is relevant and necessary to accomplish the intended purpose.

[45 C.F.R. §164.502(b); CA Constitution, Article 1, §1; CA Civil Code §56.10, and §1798]

III. Implementation Specifics

A. [State entities](#) are responsible to:

1. Limit the use and disclosure of health information to the minimum amount of information necessary to accomplish the intended purpose.
[45 C.F.R. §164.502(b)(1); CA Civil Code §56.10, §56.11, and §1798.24]
2. When requesting health information from another entity, ask for only the information needed to accomplish the purpose.
[CA Civil Code §1798.14]
3. Exempt from the minimum necessary requirement. The minimum necessary requirement does not apply to the following:
 - a. To providers for [treatment](#) purposes.
 - b. Disclosures made to the patient who is the subject of the record, when requested or required.
 - c. Uses or disclosures made pursuant to a valid [authorization](#).
 - d. Disclosures to the Secretary of the U.S. Department of Health and Human Services.
 - e. Uses or disclosures required by state or federal law.

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IV. References

45 C.F.R. §§164.502(b) – (b)(1)

CA Civil Code

- §56.10
- §56.11
- §1798
- §1798.14
- §1798.24

CA Constitution, Article 1, §1

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Uses and Disclosures

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.8.0 – Patient’s (Personal) Representative		
2.8.1 – Patient’s (Personal) Representative		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the requirements to treat a [patient’s representative](#) as the [patient](#), with respect to the uses and [disclosures](#) of the patient’s [health information](#), as well as the patient’s rights under the law.

II. Policy

Patient representatives are to be treated the same as the patient for purposes of authorizing the uses and disclosures, as well as [access](#) of health information, and for an accounting of disclosures of health information.

[45 C.F.R. §164.502(g)(1) – (g)(3)(i); CA Civil Code §56.10, and §1798.24(c); CA Health and Safety Code §123100]

III. Implementation Specifics

A. A patient’s representative, except in the situations described under section *III.C Access to records - exceptions*, below, has all of the rights of the patient for the purposes of authorizing uses and disclosures, accessing health information and receiving an accounting for disclosures.

B. A patient representative is someone who:

1. Is the parent, legal guardian, or someone who has the legal right to make healthcare decisions for the patient.

The legal right to act on behalf of the patient must be supported by documentation which includes a description of the representative’s authority to act for the patient (*See SHIPM Chapter 2, Uses and Disclosures and Authorizations*).

[45 C.F.R. §164.502(g)(3)(i), and §164.508(b)(6)(vi); CA Welfare and Institutions Code §5350, and §5541; CA Health and Safety Code §§123105(e)(1) – (e)(4) and §123110]

2. Is the executor, administrator, or other person with the authority to act on behalf of a deceased patient or the deceased patient’s estate.

[45 C.F.R. §§164.404(d)(1)(ii) – (d)(2), §164.502(g), and §164.502(g)(4)]

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- C. Access to records - exceptions. An individual meeting the conditions of being a patient's representative for a living patient does NOT have to be treated as a patient by state entities under certain conditions.

It is state policy that a health care provider considering the facts and their patients' best interest, can decide to deny access to a patient's representative in the following scenarios:

1. The state entity has information and a reasonable belief that the patient has been or may be a victim of abuse, neglect, or domestic violence through the actions or inactions of the patient's representative (*See SHIPM Chapter 2, Victims of Abuse, Neglect or Domestic Violence*).
[45 C.F.R. §164.502(g)(5)(i)(A), and §164.512(c)(2)(ii)]
2. The state entity has information the patient may be endangered by extending patient's rights to the patient's representative
[45 C.F.R. §164.502(g)(5)(i)(B), and §164.512(c)(2)(i)]
3. The state entity, in exercise of professional judgment, decides it is not in the patient's best interest to extend patient's rights to the patient's representative
[45 C.F.R. §164.502(g)(5)(ii), and §164.512(c)(2)(ii)]
4. The patient is an unemancipated minor, and either of the following:
 - a. The minor patient has the right to consent to a health care service and he or she has not requested another person be treated as the patient's representative.
[45 C.F.R. §164.502(g)(3)(i)(A)]
 - b. The minor patient may lawfully obtain a health care service without the consent of the parent or guardian.
[45 C.F.R. §164.502(g)(3)(i)(B)]

Note: Failing to provide records to a patient's representative may result in a determination of unprofessional conduct under California law. Consult your organization's legal office before providing records.

- D. State entities must verify the authority and identity of the person acting as the patient representative (*See SHIPM Chapter 3, Verification of Identity*).
- E. Documentation. A state entity must retain any documentation, modifications or revocations related to a patient's representative for a minimum of six (6) years.
[45 C.F.R. §164.508)(b)(6)]

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IV. References

45 C.F.R.

- §§164.404(d)(1) – (d)(2)
- §§164.502(g)(1) – (g)(5)(ii)
- §164.508(b)(6)(vi)
- §164.512(c)(2)

CA Civil Code

- §56.10
- §1798.24(c)

CA Health and Safety Code

- §§123105(e)(1) – (e)(4)
- §123100
- §123110

CA Welfare and Institutions Code

- §5326
- §5350
- §5526.1
- §55.41

Genetic Information Nondiscrimination Act of 2008 §26

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 3 – Verification of Identity

SHIPM Chapter 4 – Administrative Requirements

SHIPM Chapter 5 – Accounting of Disclosures

SHIPM Chapter 5 – Patient Rights – Access

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 2 – Privacy		
Section: 2.9.0 – Requirements for Telehealth		
2.9.1 – Requirements for Telehealth		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To explain the [privacy](#) requirements related to [telehealth](#) activities.

II. Policy

[Health care providers](#) using telehealth to deliver [health care services](#) are responsible for implementing and maintaining [security](#) and [privacy](#) policies and procedures that address the unique circumstances involved in providing telehealth services.

III. Implementation Specifics

- A. Health care providers initiating the use of telehealth shall follow all requirements regarding the [confidentiality](#) and security of health information.
[45 C.F.R. §160.103, and §164.530; CA Business and Professions Code §2290.5(b), §2290.5(f), and §2290.5(g); CA Health and Safety Code §1348.8]
- B. Policy and Procedures. While not specifically required by law, because of the unique environment of providing telehealth services, policies and procedures are required by CalOHII for special adaptations including, but are not limited to:
1. Methods for verifying the identities of the patient, their [personal representatives](#), if applicable, and health care providers at the beginning of each telehealth encounter
 2. Updating risk analyses to include telehealth
 3. Taking a more active compliance role in the coordination of telehealth services with outside organizations
- C. Documentation requirements. The following types of records related to telehealth services shall be kept for a minimum of six (6) years from the later of the creation of the document or the date the document was last in effect:
1. Policies and Procedures, and changes to Policies and Procedures
 2. Training offered, provided, and taken by workforce members
 3. Risk Analyses conducted and the results and corrective actions to mitigate the risks
[45 C.F.R §164.530; CA Health and Safety Code §1348.8, and §1348.8(a)(7); CA Business and Professions Code §2290.5]

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IV. References

45 C.F.R.

- §160.103
- §164.530

CA Business and Professions Code

- §2290.5
- §2290.5(b)
- §2290.5(f)
- §2290.5(g)

CA Health and Safety Code

- §1348.8
- §1348.8(a)(7)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 1 – Authorizations

SHIPM Chapter 3 – Security Management Process

SHIPM Chapter 3 – Security Awareness and Training

VI. Attachments

None

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Chapter: 2 – Privacy		
Section: 2.10.0 – Multiple Covered Functions		
2.10.1 – Multiple Covered Functions		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the permitted uses and [disclosures](#) of [health information](#) for organizations which perform [multiple covered functions](#), such as those of a [health care plan](#), [health care provider](#), and/or [health care clearinghouse](#).

II. Policy

Organizations which serve multiple functions may use or disclose [health information](#) only for the purpose related to the function being performed, and must segregate the information from any joint information systems.

[45 C.F.R. §164.504(g)]

III. Implementation Specifics

- A. [State entities](#) which perform multiple functions must comply with all requirements of the types of functions performed within their organization. For example, if a state entity, within its organization, performs the functions of a health care plan and a health care provider, the entity would have to comply with the rules for both functions.
- B. With the exception of the permitted sharing of health information for [treatment](#), [payment](#), or [health care operation](#) purposes, state entities that perform multiple functions may disclose health information internally, without patient [authorization](#), only for the purpose of the permitted function being performed.
- C. [State entities](#) that serve multiple functions must segregate any patient information into separate systems, so that health information is not used or disclosed for a different purpose than that for which it was collected.
- D. Some functions are common to multiple covered functions, such as treatment, payment, or health care operations (TPO), and can be shared between functions.

However, health information that is not common to the purposes for which information was collected must be kept separate and not shared. For example, if a patient is only engaged with the organization's health care provider function, his or her health information cannot be shared internally to market the organization's health care plan function.

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IV. References

45 C.F.R. §164.504(g)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Treatment, Payment, and Health Care Operations (TPO)

VI. Attachments

None

Chapter 3 – Security

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Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.1 – Contingency Plans		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance for contingency planning in the event an emergency or other occurrence damages systems containing [health information](#).

II. Policy

Policies and procedures must be implemented specifying how to respond to an emergency, or other unexpected occurrences (e.g., fires, natural disasters, system failures), that may damage systems containing health information.

[45 C.F.R. §164.308(a)(7); CA Health and Safety Code §§123149 – 123149.5]

III. Implementation Specifics

A. At a minimum, policies and procedures must contain the following with regard to health information:

1. Procedures to create and maintain retrievable exact copies of [electronic health information](#) (data backup plan) *[45 C.F.R. §164.308(a)(7)(ii)(A)]*
2. Procedures to restore any loss of this information (disaster recovery plan) *[45 C.F.R. §164.308(a)(7)(ii)(B)]*
3. Procedures to continue critical business practices for protection of this information while operating in an emergency mode (emergency mode operation plan) *[45 C.F.R. §164.308(a)(7)(ii)(C)]*
4. Procedures for periodic testing and revision of contingency plans (testing and revision procedures) *[45 C.F.R. §164.308(a)(7)(ii)(D)]*
5. Assessment of the importance of specific applications and data, in support of the various contingency plan components (applications and data criticality analysis), including all of the following:
 - a. Identifying the steps to safeguarding the [state entity's](#) electronic systems and electronic health information.
 - b. Identifying the state entity's most vulnerable points with regard to electronic systems and electronic health information.

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- c. Identifying the state entity's biggest threats to electronic systems and electronic health information.
- d. Identifying the steps, in priority order, for the state entity to achieve recovery of electronic systems, electronic health information, and business operations in the event of an emergency.

[45 C.F.R. §164.308(a)(7)(ii)(E)]

B. ADDITIONAL REQUIREMENTS APPLICABLE TO STATE ENTITIES

State entities are responsible for complying with the information [security](#) and [privacy](#) policies, standards, and procedures issued by the California Information Security Office (CISO). *[CA SAM §5300; CA SIMM §5325; CA Government Code §11549.3]*

IV. References

45 C.F.R. §164.308(a)(7)
CA Government Code §11549.3
CA Health and Safety Code §§123149 – 123149.5
CA SAM Chapter §5300
CA SIMM §5325

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority
SHIPM Chapter 3 - Incident Procedures
SHIPM Chapter 3 – Security Management Process

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.2 – Incident Procedures		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To explain the requirements related to the development and [implementation](#) of policies and procedures to identify and respond to [security incidents](#).

II. Policy

As part of an overall [security](#) program, policies and procedures must be implemented that describe how [workforce](#) members are to identify, report, respond, and mitigate security incidents affecting [health information](#).

III. Implementation Specifics

- A. At a minimum, [state entities](#) are responsible for implementing policies and procedures for all workforce members that:
1. Define what a security incident is for the state entity's business functions
 2. List the possible types of security incidents and the required response for each type
 3. Identify who the security incident must be reported to within the state entity
- B. Additional policies and procedures are required to assist those workforce members responsible for the state entity's security incident response efforts, including how to do all of the following:
1. Identify and respond to a suspected or known security incident.
 2. Mitigate, to the extent reasonable, the situation that caused the harmful effects.
 3. Document the security incident, how the state entity responds, and the results (outcomes).
 4. Evaluate security incidents as part of the state entity's ongoing risk management activities.

[45 C.F.R. §164.308(a)(6)]

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C. ADDITIONAL STATE ENTITY REQUIREMENTS

State entities are also responsible for complying with their own policies and procedures, and the information security and privacy policies, standards and procedures issued by the California Information Security Office (CISO), per California State Administrative Manual (SAM). [CA SAM §5300.2; CA Government Code §11549.3]

If the incident proves to be a [breach](#) of health information, affecting 500 or more individuals, notify the California Office of Health Information Integrity (CalOHII) at ohicomments@ohi.ca.gov concurrently with other required breach reporting (see SHIPM Chapter 2, *Breach and Breach Notification*.)

IV. References

45 C.F.R.

- §164.304
- §164.308(a)(6)
- §164.314(a)(2) - §164.314(b)(2)

CA Government Code §11549.3

CA SAM §5300.2

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Breach and Breach Notification

SHIPM Chapter 3 – Contingency Plans

SHIPM Chapter 3 – Security Management Process

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.3 – Information Access Management		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance on authority to [access](#) and restriction of access to [health information](#), and explain the limits and conditions on [workforce](#) access.

II. Policy

Information access management policies and procedures must be developed, implemented and maintained that specify *who* has access to *what* specific health information and under what conditions.

Following an organization's risk analysis, authority to access health information must be all of the following:

- ❖ Limited to instances where access is specifically permitted or required by law
- ❖ Limited to the [minimum necessary](#) information required to accomplish the intended purpose, as defined in the [state entity's](#) policies and procedures (including definition of what information can be accessed by classes of workforce or specific programs)
- ❖ Consistent with legal requirements on use and disclosure

[45 C.F.R. §164.308(a)(4); CA Health & Safety Code §1280.18, and §123149(g); CA Civil Code §56.10, §1798.24, §1798.24(a), and §1798.24(b)]

III. Implementation Specifics

A. A state entity's information access management policy and procedures must:

1. Include periodic review of whether access or the extent of access is necessary (role-based access)
2. Include procedures for gaining access when it is appropriate but the workforce is not usually granted access, but it is appropriate (e.g., when an attorney has access to an electronic medical record)
3. Include triggers for review of whether and what type of access is necessary (e.g., workforce transfers or a project ends)
4. Include naming someone or a program that has responsibility for reviewing and authorizing access

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5. Document:
 - a. Which workforce members can have access
 - b. A list of who has access
 - c. Levels of access
 - d. Triggering events for termination, beginning or change of access
6. Identify the types of access (e.g., such as to facilities and/or systems)
7. Isolate functions under specific conditions to protect health information from unauthorized access. If a state entity is a [health care clearinghouse](#) or a [hybrid entity](#) that is part of a larger organization, the health care clearinghouse or [health care component](#) of its organization must implement policies and procedures that protect the health information from unauthorized access by the larger organization.
8. For medical records kept electronically, address how:
 - a. Electronic health information is protected from unauthorized access, such as access to a workstation, transaction, program or process. (e.g., the right to use specified applications, access specific data, facilities, and equipment, and functions particular staff are allowed to perform).
 - b. Access to electronically stored [patient](#) records relating to licensed health care professionals shall be made available to the California Department of Public Health (CDPH) Licensing and Certification promptly upon request when needed to fulfill the organization's statutory responsibilities.
 - c. A [health care provider](#) utilizing an electronic recordkeeping system shall be required to develop and implement policies and procedures to safeguard confidentiality and unauthorized access to electronically stored patient medical records, authenticate by electronic signature keys, and maintain systems.
[CA Health and Safety Code §123149]
9. Address how a user's access to health information is established, documented, reviewed, and modified by [workstations](#), transactions, programs or processes.

B. ADDITIONAL REQUIREMENTS APPLICABLE TO STATE ENTITIES

All state entities must comply with the information [security](#) and [privacy](#) policies, standards, and procedures issued by the California Information Security Office (CISO), contained in the California SAM. *[CA Government Code §11549.3, and CA SAM §5300 – §5365.3]*

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IV. References

45 C.F.R. §164.308(a)(4)

CA Civil Code

- §56.10
- §§1798.24 –1798.24b

CA SAM §§5300 – 5365.3

CA Government Code §11549.3

CA Health and Safety Code

- §1280.18
- §123149
- §123149(g)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Uses and Disclosures

SHIPM Chapter 3 – Workforce Security

SHIPM Chapter 3 – Access Control

SHIPM Chapter 3 - Access Administration

SHIPM Chapter 4 – Policies and Procedures

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.4 – Security Management Process		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To provide guidance regarding requirements to conduct risk analysis and other risk management activities to prevent, detect, contain, and correct [security](#) violations related to the protection of [health information](#).

II. Policy

Health information must be protected through [implementation](#) of security policies and procedures that require all the following:

- ❖ Periodic risk analyses
- ❖ Implementation of risk management activities
- ❖ A [workforce](#) member sanction policy
- ❖ Regular review of information system activity (such as review of audit logs and incident tracking reports)
- ❖ Documentation of measures

[45 C.F.R. §164.306(e), §§164.308(a)(1)(i) – (a)(1)(ii), and §164.316(b)(2)(iii); CA Government Code §11549.3; NIST SP 800-30, SP 800-39, and SP 800-53]

III. Implementation Specifics

A. For all information systems that contain health information, [state entities](#) are responsible to have policies and procedures for risk management that include all of the following:

1. Define processes to conduct an accurate and thorough assessment of the potential risk and vulnerabilities to the [confidentiality](#), integrity, and the [availability](#) of health information, which should include identifying where all health information is located, and who has a need to [access](#) it (as well as who currently has access to it).
2. Update appropriate documentation (including training) as policies and procedures change, or are retired. *[45 C.F.R. §164.316(b)]*
3. Implement security measures to reduce risks and vulnerabilities to health information and ensure the confidentiality, integrity, and availability of the information.

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4. Protect against reasonably anticipated threats or hazards.
5. Protect against any reasonably anticipated unlawful uses or disclosures
6. Ensure that the state entities' workforce complies with policies and procedures (see *SHIPM Chapter 4, Sanctions of Violation*).
7. Regularly review information system activity, through review of audit logs, access reports, incident tracking reports, and similar documents.

[45 C.F.R. §164.306(a), §164.308(a)(1), §164.316, and §164.316(b)]

B. Recommended best practice risk management steps include (at a minimum) the following:

1. Develop and implement a risk management plan.
2. Implement security measures.
3. Evaluate and maintain security measures

C. Recommended best practice risk analysis/assessment steps include (at a minimum) the following:

1. Identify the scope of the analysis.
2. Gather data.
3. Identify and document potential threats and vulnerabilities.
4. Assess current security measures.
5. Determine the likelihood of threat occurrence.
6. Determine the potential impact of threat occurrence.
7. Determine the level of risk.
8. Identify security measures and finalize documentation.

D. **ADDITIONAL REQUIREMENTS APPLICABLE TO STATE ENTITIES**

State entities are also responsible for complying with the information security and [privacy](#) policies, standards and procedures issued by the California Information Security Office (CISO).

[CA Government Code §11549.3; CA SAM §5300 – §5365.3]

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IV. References

45 C.F.R.

- §164.306(a)
- §164.306(e)
- §§164.308(a)(1)(i) – (a)(1)(ii)
- §164.316
- §§164.316(b)(2) – (b)(2)(iii)

CA Government Code §11549.3

CA SAM §§5300 – 5365.3

NIST SP

- 800-30
- 800-39
- 800-53

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 3 - Workforce Security

SHIPM Chapter 4 – Sanctions for Violation

SHIPM Chapter 4 – Consequences of Non-Compliance

VI. Attachments

Yes - Risk Analysis/Assessment Checklist

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Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.5 – Security Awareness and Training		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding requirements to promote [security](#) awareness by providing mandatory training on how to protect [health information](#) to all [workforce](#) members, including management.

II. Policy

Reasonable and appropriate [administrative safeguards](#) must be implemented to protect health information, including promoting security awareness, providing mandatory training to all workforce members regarding the organization's security policies and procedures, so they know how to protect health information.

[45 C.F.R. §164.306(d)(3), §164.308(a)(5), §§164.530(j)(1) – (j)(2); CA SAM §5300]

III. Implementation Specifics

- A. [State entities](#) are responsible to ensure all workforce members, before accessing health information, are given security training regarding the organization's security policies and procedures.

At a minimum, this security awareness and training should reflect the organization's security policies and procedures about all the following topics:

1. [Security reminders](#). Periodic security updates to remind workforce members of their role in protecting health information (e.g., discussion topics at monthly meetings, focused reminders posted in affected areas).

[45 C.F.R. §164.308(a)(5)(ii)(A)]

2. [Protection from malicious software](#). How to guard against, detect, and report malicious software (e.g., unauthorized downloads from the Internet, opening email attachments from unknown senders, etc.).

[45 C.F.R. §164.308(a)(5)(ii)(B)]

3. [Log-in monitoring](#). The procedures for monitoring log-in attempts and reporting discrepancies. The purpose is to make workforce members aware of log-in attempts that are not appropriate.

[45 C.F.R. §164.308(a)(5)(ii)(C)]

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4. Password management. The procedures for creating, changing, and safeguarding passwords (e.g., prevent the sharing of passwords, not leaving written passwords in areas that are visible or accessible to others, etc.).

[45 C.F.R. §164.308(a)(5)(ii)(D)]

- B. Periodic security retraining for ongoing awareness, based on operational changes, technology updates, and security risks should be conducted as needed and at least annually. *[CA SAM §5320.1]*

- C. Documentation requirements. State entities are required to document all of the following:

1. Security awareness and training. Workforce member names and dates of training.
2. Security reminders. State entities are responsible to document the security reminders they implement. Documentation should include the type of reminder, its message and the date it was implemented.
3. Retention. A state entity must retain the security awareness and documentation for six years from the date of its creation, or the date when it last was in effect, whichever is later.

[45 C.F.R. §§164.530(j)(1) – (j)(2)]

D. ADDITIONAL REQUIREMENTS FOR STATE ENTITIES

All state entities must also comply with the information security and [privacy](#) policies, standards, and procedures issued by the California Information Security Office (CISO), contained in the California SAM, Chapter 5300, which include training and awareness requirements for information security and privacy.

[CA Government Code §11549.3; CA SAM §5300]

IV. References

45 C.F.R.

- §160.103
- §164.306(d)(3)
- §164.308(a)(5)
- §§164.530(j)(1) – (j)(2)

CA Government Code §11549.3

CA SAM §§5300 –5365.3

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V. Related Policies

- SHIPM Chapter 1 – CalOHII Authority
- SHIPM Chapter 3 – Security Management Process
- SHIPM Chapter 3 – Security Awareness and Training
- SHIPM Chapter 3 – Workforce Security

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.6 – Security Evaluations		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the legal requirements for conducting and documenting technical and non-technical evaluations/assessments of [security](#) measures implemented to protect [health information](#).

II. Policy

Security measures to protect health information (paper and electronic) must be reviewed periodically, and policies and procedures updated when either of the following occurs:

- ❖ Weaknesses are identified
- ❖ There are environmental or operational changes which may affect the security of health information.

[45 C.F.R. §164.306(e), §164.308(a)(8) and §164.316(b)(2)(iii); CA Health and Safety Code §1280.18

III. Implementation Specifics

- A. [State entities](#) are responsible to perform periodic (no less frequently than every two years, per the CA SAM) security evaluations/assessments of implemented security measures, to ensure the [confidentiality](#), integrity, and [availability](#) of health information.
1. The frequency of these security evaluations/assessments should be addressed in the state entities security policies and procedures.
 2. Security evaluations/assessments must do all of the following:
 - a. Cover both technical (e.g., systems, hardware, workstations, mobile devices) and non-technical (e.g., physical and administrative) areas
 - b. Establish a baseline using the initial security requirements implemented to comply with state and federal laws
 - c. At a minimum, once an initial (baseline) security assessment is completed, be conducted in response to environmental or operational changes affecting the security of health information.
 - d. Must establish the extent of compliance with applicable state and federal security standards for the protection of health information

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- e. Must be retained in writing for a minimum of six (6) years from the date of its creation, or the date it was last in effect, whichever is later.
- B. State entities must update required security policies and procedures whenever either of the following occurs:
1. Security weaknesses are identified through required security evaluations/assessments.
 2. In response to environmental or operational changes
- C. All state entities are also responsible to comply with the information security and [privacy](#) policies, standards and procedures issued by the California Information Security Office (CISO). *[CA SAM §5300; CA Government Code §11549.3]*

IV. References

45 C.F.R.

- §164.306(e)
- §164.308(a)(8)
- §164.316(b)(2)(iii)

CA Health and Safety Code §1280.18

CA Government Code §11549.3

CA SAM §§5300 –5365.3

NIST

- SP 800-30
- SP 800-39
- SP 800-53

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 3 – Security

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.7 – Verification of Identity		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To explain the process and documentation required to verify a requestor's identity and authority prior to the disclosure of [health information](#).

II. Policy

Policies and procedures must be implemented and maintained (i.e., periodically updated, on file, and used regularly) which specify that prior to disclosing health information, the identity of the requestor must be verified, and the authority that entitles the requestor to [access](#) health information must be established.

[45 C.F.R. §164.514(h)]

III. Implementation Specifics

A. Prior to disclosing health information to someone other than or claiming to be the [patient](#), [state entities](#) are responsible to obtain documentation to verify the *identity* and the *authority* of the requesting party. This includes, but is not limited to, requests:

1. Made in person (non-public official, or non-law enforcement)
2. By mail
3. From third-party(s) (e.g., attorney, family member, friend of the patient)
4. From law enforcement
5. On behalf of a minor or dependent adult
6. By a healthcare provider or health plan

[45 C.F.R. §§164.514(h)(1)(i) – (ii); CA Civil Code §1798.34; CA Health and Safety Code §123110]

B. Verify the identity and authority of the person requesting the health information based on the purpose of the request, if the identity and authority isn't already known.

1. Verification of *identity* for public officials. The following may be relied on to verify the *identity* of public officials:
 - a. For in-person requests, presentation of an agency identification badge, other official credentials, or proof of government status

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- b. Requests made on official public letterhead, when the requests are made in writing

Consult with your entity's legal counsel if a request is received from persons acting on behalf of the public official, a written statement on appropriate government letterhead that the person is acting under the government's authority, or other evidence or documentation that establishes that the person is acting on behalf of the public official, such as a contract for services, memorandum of understanding, or purchase order.

2. Verification of authority for public officials. A written statement of the legal authority under which the information is being requested may be relied on to determine the *authority* of public officials to access health information.

Consult with your entity's legal counsel if the request is made as a result of a legal process, a warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal.

[45 C.F.R. §164.514(h)]

IV. References

45 C.F.R. §164.514(h)

CA Civil Code §1798.34

CA Health and Safety Code §123110

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Opportunity to Agree or Object

SHIPM Chapter 2 – Required by Law and Required Disclosures

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Research

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.1.0 – Administrative Safeguards		
3.1.8 – Workforce Security		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To ensure only authorized [workforce](#) members have [access](#) to [health information](#).

II. Policy

Policies and procedures must be developed and implemented to do both of the following:

- ❖ Ensure all members of an organization's workforce have appropriate (authorized) access to health information
- ❖ Prevent those workforce members who do not have [authorization](#) (unauthorized) from obtaining access to health information.

[45 C.F.R §§164.308(a)(3) and (4)]

III. Implementation Specifics

A. [State entities](#) are responsible to implement policies and procedures that limit or restrict access of health information to only those workforce members whose work requires access. The policies and procedures should address all of the following:

1. [Authorization and supervision](#). Workforce members who access health information must be authorized and supervised. The policy should outline:
 - a. Authorization levels
 - b. The supervision requirements for access to health information.
2. [Workforce clearance](#). Workforce members accessing health information must have a business need to do so. The policy should outline all of the following:
 - a. Access levels, established based on employee roles
 - b. Procedures for granting access rights
 - c. How workforce members are evaluated for the appropriate qualifications for access
3. [Access Revision and Termination](#). Authorization to access health information must be reviewed periodically, and revised or revoked when the access needs change or should be terminated (e.g., revoking passwords or retrieving card keys when

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termination occurs). The policy should address a workforce member who is any of the following:

- a. Leaving the organization
 - b. Promoted
 - c. Reassigned (including leaving a project)
4. Authentication. Authentication is utilized to establish the identity, and the related access rights of the workforce member. Typically authentication (*verification of identity*) is accomplished through the use of electronic credentials, such as passwords and electronic tokens.
 5. Systems Maintenance. Conduct repairs and modifications to the facility and electronic systems which are related to security protecting health information (e.g., hardware, door locks, and changes to password configurations).

[45 C.F.R. §164.308(a)(3)(i); CA Civil Code §56.101, and §1798.21; CA Health and Safety Code §1280.18, and §123149]

B. ADDITIONAL REQUIREMENTS APPLICABLE TO STATE ENTITIES.

State entities must also comply with the information security and privacy policies, standards, and procedures issued by the California Information Security Office (CISO), contained in the California SAM.

[CA SAM §5300]

IV. References

45 C.F.R.

- §164.308(a)(3)
- §164.308(a)(4)

CA Civil Code

- §56.101
- §1798.21

CA Government Code §11549.3

CA Health and Safety Code

- §1280.18
- §123149

CA SAM §§5300 –5365.3

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V. Related Policies

- SHIPM Chapter 1 – CalOHII Authority
- SHIPM Chapter 3 – Security Awareness and Training
- SHIPM Chapter 3 – Information Access Management
- SHIPM Chapter 3 – Security Management Process
- SHIPM Chapter 4 – Privacy Training

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.2.0 – Physical Safeguards		
3.2.1 – Access Control		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance on authority to [access](#) and restriction of access to [health information](#), and explain the limits and conditions on [workforce](#) access.

II. Policy

Information access management policies and procedures must be developed, implemented and maintained that specify *who* has access to *what* specific health information *and* under what conditions.

Following an organization's risk analysis, authority to access [health information](#) must be:

- ❖ Limited to instances where access is specifically permitted or required by law
- ❖ Limited to the [minimum necessary](#) information required to accomplish the intended purpose, as defined in the [state entity's](#) policies and procedures (*including definition of what can be accessed by workforce members or different classes of workforce or specific programs*)
- ❖ Consistent with legal requirements on use and disclosure

III. Implementation Specifics

A. A state entity's information access management policy and procedures must include all of the following:

1. Periodic review of whether access or the extent of access is necessary (role-based access)
2. Procedures for gaining access when the workforce is not usually granted access, but it is appropriate (e.g., when an attorney has access to an electronic medical record)
3. Triggers for review of whether and what type of access is necessary (e.g., workforce transfers or a project ends)
4. Naming someone or a program that has responsibility for reviewing and authorizing access

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5. Document all of the following:
 - a. which workforce members can have access
 - b. a list of who has access
 - c. levels of access
 - d. triggering events for termination, beginning or change of access
6. Include the types of access (e.g., to facilities and/or systems)
7. Isolate functions under specific conditions to protect health information from unauthorized access. If a state entity is a [health care clearinghouse](#) or a [hybrid entity](#) that is part of a larger organization, the health care clearinghouse or [health care component](#) of its organization must implement policies and procedures that protect the health information from unauthorized access by the larger organization.
8. Medical records kept electronically. State entities are responsible to address all of the following:
 - a. How electronic health information is protected from unauthorized access, such as access to a [workstation](#), transactions, programs or processes (e.g., the right to use specified applications, access specific data, facilities, and equipment, and functions particular staff are allowed to perform).
 - b. Access to electronically stored [patient](#) records relating to licensed health care professionals shall be made available to the California Department of Public Health (CDPH) Licensing and Certification promptly upon request when needed to fulfill the organization's statutory responsibilities.
 - c. Any [health care provider](#) choosing to utilize an electronic recordkeeping system shall develop and implement policies and procedures to include safeguards for [confidentiality](#) and unauthorized access to electronically stored patient health information records, authentication by electronic signature keys, and systems maintenance.
9. Based on the state entity's access authorization policies, address how a user's access to health information is established, documented, reviewed, and modified by workstations, transactions, programs or processes.

[45 C.F.R. §164.306(d)(3), §164.308, and §§164.312(a) – (e)]

B. ADDITIONAL REQUIREMENTS APPLICABLE TO STATE ENTITIES

All state entities must comply with the information [security](#) and [privacy](#) policies, standards, and procedures issued by the California Information Security Office (CISO), contained in the California SAM.

[CA SAM §§5300 – 5365.3; and CA Government Code §11549.3]

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IV. References

45 C.F.R.

- §164.306(d)(3)
- §164.308
- §§164.312(a) – (e)

CA SAM §§5300 – 5365.3

CA Government Code §11549.3

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Uses and Disclosures

SHIPM Chapter 3 – Workforce Security

SHIPM Chapter 3 – Access Control

SHIPM Chapter 3 - Access Administration

SHIPM Chapter 4 – Policies and Procedures

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.2.0 – Physical Safeguards		
3.2.2 – Device and Media Controls		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide information regarding the [security](#) device and media controls to safeguard and protect [health information](#) against unauthorized [access](#), use, [disclosure](#), alteration or modification.

II. Policy

Policies and procedures must be implemented to govern the receipt and removal of hardware and electronic media that contain health information, into and out of an entity/organization, and the movement of these items within the entity/organization.

[45 C.F.R. §164.310(d)(1); CA SAM §§5300 – 5365.3]

III. Implementation Specifics

[State entities](#) must comply with the information security and [privacy](#) policies, standards and procedures regarding physical security issued by the California Information Security Office (CISO).

[CA SAM §§5300 – 5365.3; CA Government Code §11549.3]

IV. References

45 C.F.R. §164.310(d)(1)

CA Government Code §11549.3

CA SAM §§5300 –5365.3

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Privacy

SHIPM Chapter 4 – Administration

SHIPM Chapter 5 – Patient Rights

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.2.0 – Physical Safeguards		
3.2.3 – Facility Access Controls		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide information regarding the facility [access](#) controls to safeguard and protect [health information](#) against unauthorized access, use, [disclosure](#), alteration or modification.

II. Policy

Procedures must be implemented to control and validate a person’s access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

[45 C.F.R. §164.310(a)(2)(iii); CA SAM §§5300-5365.3]

III. Implementation Specifics

[State entities](#) must comply with the information [security](#) and [privacy](#) policies, standards and procedures regarding Facility Access Controls issued by the California Information Security Office (CISO).

[CA SAM §§5300 – 5365.3; CA Government Code §11549.3]

IV. References

45 C.F.R. §164.310(a)(2)(iii)

CA Government Code §11549.3

CA SAM §§5300 –5365.3

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Privacy

SHIPM Chapter 4 – Administration

SHIPM Chapter 5 – Patient Rights

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 3 – Security		
Section: 3.2.0 – Physical Safeguards		
3.2.4 – Workstation Use and Security		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To outline the [security](#) requirements for all [workstations](#), including [mobile devices](#), that process, store, and transport/transmit [health information](#).

II. Policy

[Administrative](#), [physical](#) and [technical safeguards](#) must be implemented for all workstations, including mobile devices, that [access health information](#) in order to restrict access to individuals with [authorization](#).

[45 C.F.R. §164.310, and §164.310(b); CA Health and Safety Code §1280.18]

III. Implementation Specifics

[State entities](#) are responsible for implementing workstation and mobile device security policies and procedures to ensure health information is protected from unauthorized access. In addition, the policies and procedures should specify the proper functions to be performed, the manner in which they are performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access health information.

This policy outlines administrative, physical, and technical safeguard requirements separately.

A. Administrative safeguards include all of the following:

1. Procedures for the authorization and supervision of workforce members who work with health information.
[45 C.F.R. §164.308(a)(3)(ii)(A); CA Health & Safety §1280.18; CA SAM §5305.4]
2. Procedures to determine appropriate access levels to health information for its workforce members.
[45 C.F.R. §164.308(a)(3)(ii)(B); CA Health & Safety §1280.18; CA SAM §5305.4]
3. Procedures for terminating access to health information when employment of a workforce member ends or as workforce members change assignments.
[45 C.F.R. §164.308(a)(3); CA Health & Safety §1280.18; CA SAM §5305.4]

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B. Physical safeguards include all of the following:

1. Restricting physical access of workstations to only workforce members with authorization (e.g., ensuring monitors are positioned away from public view or installing privacy screen filters or other physical barriers to prevent public viewing). *[45 C.F.R. §164.310(c); CA Health and Safety §1280.18; CA Civil Code §56.11]*
2. Implementing physical security and environmental protection controls, to guard against unauthorized access, use, disclosure, disruption, modification, or destruction of health information. *[45 C.F.R. §164.306(a); CA Health and Safety Code §1280.18; CA SAM §5365, and §5315; and NIST SP 800-53]*
3. Implementing policies and procedures for workstation, mobile device and media controls to prevent inadvertent loss or disclosure of health information when disposing of, or reusing workstations or mobile devices containing health information. *[45 C.F.R. §164.310(d)(2); CA SAM §5365.3; and NIST SP 800-53]*

C. Technical safeguards include all of the following:

1. Enabling a password-protected screen saver or application which locks the screens of workstations, after a specific period of inactivity, so the workstation will be protected against unauthorized access. *[45 C.F.R. §164.312(a)(2)(iii)]*
2. Complying with all applicable password procedures. Best practices include passwords created with letters, numbers, and symbols. *[45 C.F.R. §164.308(a)(5)(ii)(D)]*
3. The [implementation](#) of [encryption](#) policies and the use of approved encryption standards for health information. *[45 C.F.R. §164.312(a)(2)(iv); CA SAM §5350.1, and §5355; and FIPS 140-2]*
4. Compensating control(s) or alternatives to encryption must be in place in the rare instances where encryption cannot be implemented. *[45 C.F.R. §164.312(a)(2)(iv); CA SAM §5350.1; and NIST SP 800-53]*
5. Implementing secure configuration standards for hardware, software, and network devices to protect against reasonably anticipated threats or hazards to the security or integrity of health information. *[45 C.F.R. §164.306(a)(2); CA SAM §5315]*
6. Implementing procedures to authorize, and provide emergency access to health information. *[45 C.F.R. §164.312(a)(1)]*

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D. ADDITIONAL STATE REQUIREMENTS

All [state entities](#) are responsible for implementing information security control requirements mandated by the California SAM. *[CA SAM §5300]*

IV. References

45 C.F.R.

- §164.306(a)
- §164.308(a)
- §164.310
- §164.312(a)

CA Civil Code §56.11

CA Health and Safety Code §1280.18

CA SAM §§5300 –5365.3

FIPS 140-2

NIST

- SP 800-53 and SP 800-53a
- SP 800-12
- SP 800-14
- SP 800-66

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 3 – Access Control

SHIPM Chapter 3 - Access Administration

SHIPM Chapter 3 – Device and Media Controls

SHIPM Chapter 3 – Encryption

SHIPM Chapter 3 – Facility Access Controls

SHIPM Chapter 3 – Information Access Management

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.3.0 – Technical Safeguards		
3.3.1 – Audit Controls		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide information regarding the [security](#) audit control measures to safeguard and protect [health information](#) against unauthorized [access](#), use, [disclosure](#) or modification.

II. Policy

Implement hardware, software, and policies and procedures to record and examine activity accessing health information in electronic information systems.

[45 C.F.R. §164.312(b); CA SAM §§5300-5365.3]

III. Implementation Specifics

[State entities](#) must comply with the information security and [privacy](#) policies, standards and procedures regarding Audit Controls issued by the California Information Security Office (CISO).

[CA SAM §§5300-5365.3; CA Government Code §11549.3]

IV. References

45 C.F.R. §164.312(b)

CA Government Code §11549.3

CA SAM §§5300-5365.3

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Privacy

SHIPM Chapter 4 – Administration

SHIPM Chapter 5 – Patient Rights

VI. Attachments

None

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Chapter: 3 - Security		
Section: 3.3.0 – Technical Safeguards		
3.3.2 – Encryption		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the requirements for [encryption](#) of computer systems and the protection against unauthorized [access](#).

II. Policy

When [health information](#) is maintained electronically, policies and procedures must be implemented and complied with to ensure all of the following:

- ❖ Electronic information systems permit access only to persons or software programs that have been granted access rights
- ❖ Protection against unauthorized access of health information when transmitted over an electronic communications network.

[45 C.F.R. §164.312(a)(1), and §164.312(e)(1)]

III. Implementation Specifics

- A. [State entities](#) are responsible for implementing policies and procedures regarding the encryption methods their organization utilizes to prevent unauthorized access to health information.
- B. Requirements also include implementing mechanisms to encrypt health information, consistent with federal minimum encryption standards guidance.
- C. State entities are also responsible for implementing compensating control(s) or alternatives to encryption, in the rare instances where encryption cannot be implemented, consistent with CA SAM and the alternative to encryption approval process.
[45 C.F.R. §164.312(e)(2)(ii); and NIST SP 800-53]
- D. **ADDITIONAL STATE REQUIREMENTS** - State entities are also responsible for complying with their own security and privacy policies, standards, and procedures which must be consistent with those issued by the California Information Security Office, SAM.
[CA SAM §5300.2, and §5350.1; and CA Government Code §11549.3]

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IV. References

45 C.F.R.

- §164.312(a)(1)
- §164.312(a)(2)(iv)
- §164.312(e)(1)
- §164.312(e)(2)(ii)

CA SAM §§5300-5365.3

CA Government Code §11549.3

FIPS PUBs 140-2, and 197

NIST SP 800-53

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Breach and Breach Notification

SHIPM Chapter 3 – Technical Safeguards

VI. Attachments

None

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Chapter: 3 – Security		
Section: 3.3.0 – Technical Safeguards		
3.3.3 – Access Administration		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the [access](#) control and access administration measures that must be implemented to safeguard and protect [health information](#) against unauthorized access.

II. Policy

Technical policies and procedures must be developed, implemented, and maintained for electronic information systems that utilize [electronic health information](#), to allow access only to those persons or software programs that have been granted access rights.

[45 C.F.R. §164.308(a)(4); CA SAM §§5300 – 5365.3]

III. Implementation Specifics

[State entities](#) are responsible for establishing an information [security](#) program. The program shall include planning, oversight, and coordination of its information security program activities to effectively manage risk, provide for the protection of information assets, and prevent illegal activity, fraud, waste, and abuse in the use of information assets.

- A. For all information systems that contain health information, policies and procedures must be implemented that limit access only to those persons or software programs that have been granted access rights according to applicable state and federal requirements.

Policies and procedures must address all of the following:

1. Access rights, which at a minimum must be limited through use of the following:
 - a. A unique name and/or number for identifying and tracking user identity and access. Assign a unique name and/or number for identifying and tracking user identity, based on the user identification and the [authorization](#) role (role-based access).
[45 C.F.R. §164.312(a)(2)(i)]
 - b. Mechanisms to obtain necessary health information during an emergency.
Procedures must be established to instruct [workforce](#) members on possible ways

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to gain access to needed health information to allow continuation of critical business processes and for the protection/security of health information while operating in emergency mode.

[45 C.F.R. §164.312(a)(2)(ii)]

- c. Termination of a session after a specified time of inactivity (automatic logoff). As a normal practice, workforce members and other users, should logoff the system they are working on, when their workstation is unattended. To prevent unauthorized access of health information state entities are responsible to implement automatic logoff procedures to terminate an electronic session, after a predetermined time of user inactivity.

[45 C.F.R. §164.312(a)(2)(iii)]

- d. Encryption and decryption. State entities are responsible for implementing policies and procedures regarding the encryption methods their organization utilizes to prevent unauthorized access to health information (see *SHIPM Chapter 3, Encryption*).
2. Implementation of policies and procedures to verify that a person or entity seeking access to health information is the one claimed.
 3. Implementation of technical security measures to guard against unauthorized access to health information that is being transmitted over an electronic communications network.

[45 C.F.R. §164.306(d)(3), §164.308, and §§164.312(a)-(e)]

B. ADDITIONAL STATE ENTITY REQUIREMENTS

State entities must also comply with the information security and privacy policies, standards and procedures issued by the California Information Security Office (CISO), SAM, including the policies for the following:

1. All categories of automated and paper information, including but not limited to, records, files, and databases.
2. Information technology facilities, software, and equipment, including mobile devices and personal computer systems owned or leased by state entities.

[CA SAM §§5300 – 5365.3; CA Government Code §11549.3]

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IV. References

45 C.F.R.

- §164.306
- §164.308
- §164.312

CA Government Code §11549.3

CA SAM §§5300-5365.3

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Privacy

SHIPM Chapter 4 – Administration

SHIPM Chapter 5 – Patient Rights

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 3 – Security		
Section: 3.4.0 – Policy and Procedures		
3.4.1 - Documentation		
Review Date: 09/01/2016	Revision Date: 09/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the requirements for the development and [implementation](#) of [security](#) policies and procedures, to safeguard and protect [health information](#), regardless of its form (electronic, optical, oral, print or other media).

II. Policy

Security policies and procedures must be developed, implemented, utilized and maintained to ensure the [confidentiality](#), integrity, and [availability](#) of health information that is created, received, maintained, or transmitted.

[45 C.F.R. §§164.316(a) – (a)(iii); CA Civil Code §56.101, and §1798.21; CA Government Code §§14740 – 14770; CA Health and Safety Code §1280.15, and §123149; CA SAM §5305]

III. Implementation Specifics

A. Consider all of the following when developing and implementing information security policies and procedures:

1. The size, complexity, and capabilities of the organization
2. The technical infrastructure, hardware, and software security capabilities of the organization
3. The costs of implementing security measures
4. The probability and criticality of potential risks to health information that the organization creates, receives, maintains or transmits electronically

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B. Security policies and procedures shall address the following standards:

Administrative Safeguards	Specifics	45 C.F.R. §164.308	CA State SAM Chapter 5300
Security Management Process	Risk Analysis	R	R
	Risk Management	R	R
	Sanction Policy	R	R
	Information System Activity Review	R	R
Assigned Security Responsibility	Assigned Security Responsibility	R	R
Workforce Security	Authorization and/or Supervision	A	R
	Workforce Clearance Procedure	A	R
	Termination Procedures	A	R
Information Access Management	Isolating Healthcare Clearinghouse Function	R	R
	Access Authorization	A	R
	Access Establishment and Modification	A	R
Security Awareness Training	Security Reminders	A	R
	Protection from Malicious Software	A	R
	Log-in Monitoring	A	R
	Password Management	A	R
Security Incident Procedures	Response and Reporting	R	R
Contingency Plan	Data Backup Plan	R	R
	Disaster Recovery Plan	R	R
	Emergency Mode Operation Plan	R	R
	Testing and Revisions Procedures	A	R
	Applications and Data Criticality Analysis	A	R
Evaluation	Evaluation	R	R
Business Associate Contracts	Written contract or other arrangement	R	R

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Physical Safeguards	Specifics	45 C.F.R. §164.310	CA State SAM Chapter 5300
Facility Access Controls	Contingency Operations	A	R
	Facility Security Plan	A	R
	Access Control and Validation Procedures	A	R
	Maintenance Records	A	R
Workstation Use	Workstation Use	R	R
Workstation Security	Workstation Security	R	R
Device and Media Controls	Media Disposal	R	R
	Media Re-use	R	R
	Media Accountability	A	R
	Data Backup and Storage (during transfer)	A	R
Technical Safeguards	Specifics	45 C.F.R. §164.312	CA State SAM Chapter 5300
Access Control	Unique User Identification	R	R
	Emergency Access Procedure	R	R
	Automatic Logoff	A	R
	Encryption and Decryption (including data at rest)	A	R
Audit Controls	Audit Controls	R	R
Integrity and Implementation Process	Mechanism to authenticate ePHI	A	R
Person or Entity Authentication	Person or Entity Authentication	R	R
Transmission Security	Integrity Controls	A	R
	Encryption (FTP and email over internet)	A	R

R = required - the specification must be implemented

A = **addressable** - one of the following must be done for each addressable specification (*and the choice must be documented*):

1. Implement the addressable implementation specifications

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2. Implement one or more alternative security measures to accomplish the same purpose
 3. Not implement either an addressable implementation specification or an alternative, but justify and document why/how that specification is not met
- C. [State entities](#) must make the necessary documentation available to those [workforce](#) members responsible for implementing the entity's security policies and procedures.
[45 C.F.R. §164.316(b)(2)(ii)]
- D. State entities must do the following regarding security policies and procedures:
1. Periodically review and update as needed in response to environmental or operational changes affecting the security of health information.
 2. Document (security policies and procedures) in written form, which may be electronic, and keep or maintain a minimum of six (6) years.
Outdated policies and procedures must be kept as documentation of compliance for at least six (6) years from the date of creation, or the date when the policy and procedure was last in effect, whichever is later.
[45 C.F.R. §164.316]
- E. State entities that have electronic health record systems (EHRs) or electronic medical record systems (EMRs) shall do both of the following:
1. Protect and preserve the integrity of [electronic health information](#).
 2. Automatically record and preserve any change or deletion of any electronically stored health information.
[CA Civil Code §56.101]
- F. ADDITIONAL STATE ENTITY REQUIREMENTS - State entities are also responsible for complying with their own policies and procedures, and the information security and privacy policies, standards, and procedures issued by the California Information Security Office (CISO), per California SAM.
[CA SAM §5300.2, and §5305; CA Government Code §11549.3]

IV. References

45 C.F.R.

- §164.308 – §164.312
- §164.316

CA Civil Code

- §56.101
- §1798.21

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CA Health and Safety Code

- §1280.15
- §123149

CA Government Code

- §11549.3
- §§14740 - 14770

CA SAM §§5300-5365.3

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 3 – Security

SHIPM Chapter 4 – Business Associates

VI. Attachments

None

Chapter 4 – Administrative

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Chapter: 4 – Administrative		
Section: 4.1.0 – Administrative Requirements		
4.1.1 – Policies and Procedures		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To ensure compliance with state and federal requirements to maintain current, written policies and procedures regarding [privacy](#) and [confidentiality](#) of [health information](#).

II. Policy

Health information must be safeguarded from inappropriate [access](#), use, or [disclosure](#) by maintaining current privacy policies and procedures, and ensuring [workforce](#) members comply with them. These privacy policies and procedures must:

- ❖ Demonstrate compliance with California’s SHIPM
- ❖ Be consistent with the entity’s Notice of Privacy Practices
- ❖ Be compliant with state and federal requirements for use and disclosure of health information, including laws and regulations specific to individual departments
- ❖ Address any applicable reporting requirements, such as those for abuse, neglect, or communicable disease reporting

[45 C.F.R. §164.306, §164.316, and §164.530; CA Civil Code §§1798–1798.99; CA Health and Safety Code §1280.18; CA SAM §§5300 – 5365.3]

III. Implementation Specifics

- A. [State entities](#) are responsible to develop and maintain operational privacy policies and procedures that are compliant with California’s SHIPM.
1. Required scope of privacy policies and procedures. Current privacy policies and procedures (which may be in electronic form or in hard paper copy) must be maintained and designed to comply with federal and applicable state privacy requirements. The privacy policies and procedures must cover and specify all of the following:
 - a. All persons in the state entity who are involved in the design, development, operation, disclosure, or maintenance of records containing health information;
 - b. All legally permissible and prohibited uses and disclosures of, and requests for health information the state entity is likely to make and how the state entity handles each.

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2. Operational privacy policies and procedures must clearly address all of the following:
 - a. The person or persons in the organization responsible for development and [implementation](#) of the privacy policies and procedures
 - b. When health information would, or would not, be disclosed to entities external to the organization
 - c. Who is responsible for carrying out each specific activity and where in the organization the activity is to be performed
 - d. How the documentation requirements are met (see #7 below)
 - e. The timeframes for performing each activity
 - f. How compliance with the Notice of Privacy Practices is achieved
 - g. How any [business associates](#) or contractors are informed of the required privacy policies and procedures
 - h. [Breach](#) policy and procedures
 - i. Rules of conduct for persons involved in the design, development, operation, disclosure or maintenance of records containing health information
3. Training. All workforce members must be trained on the privacy policies and procedures annually. New workforce members must be trained within a reasonable period of time. Workforce members must also receive training within a reasonable period of time after any material change to the privacy policies and procedures becomes effective.
4. Changes. Changes must be made promptly to the privacy policies and procedures if necessary to comply with changes in law.

While not required, it is recommended and a best practice to expressly state in the Notice of Privacy Practices (NPP) that the state entity reserves the right to make changes in actual practice in advance of updating the NPP.

Unless this right is stated in the NPP, the state entity must update the NPP prior to making the actual procedural change. Other changes that are not material may be made at any time if applicable documentation requirements are met, including changes to the privacy policies and procedures.
5. Complaints. State entities are responsible to provide a process for a [patient](#) to make complaints concerning the privacy policies and procedures, the state entity's compliance with its own policies, and/or any privacy provisions the state entity has or has not implemented.
6. Sanctions. Workforce members who fail to comply with the privacy policy and procedures of the state entity, shall be subject to disciplinary action(s), as appropriate.

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7. Documentation and maintenance. Privacy policies and procedures must be maintained in writing, which includes electronic storage. Paper records are not required.

State entities are responsible to do all of the following:

- a. Document training provided
- b. Document any sanctions or discipline due to non-compliance with privacy policies and procedures
- c. Retain documentation of privacy policies and procedures for at least six (6) years from the date of their creation or the date when it was last in effect, whichever is later
- d. Make privacy policies and procedures available to staff responsible for implementing them
- e. Review privacy policies and procedures periodically and update them as needed

IV. References

45 C.F.R.

- §164.306
- §164.316
- §164.530

CA Civil Code §§1798–1798.99

CA Health and Safety Code §1280.18

CA SAM §§5300-5365.3

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Breach and Breach Notification

SHIPM Chapter 4 – Policies and Procedures

SHIPM Chapter 4 – Staffing: Privacy Official, Security Official

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

Yes - HIPAA Required Policies and Procedures Checklist

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Chapter: 4 – Administrative		
Section: 4.1.0 – Administrative Requirements		
4.1.2 – Privacy Training		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance for all [workforce](#) members regarding the required [privacy](#) training, about the organizations policies and procedures that protect [health information](#), consistent with each workforce member’s job responsibilities and functions.

II. Policy

Formal education and training on privacy policies and procedures must be provided to all workforce members to prepare them to understand and carry out their job functions.

[45 C.F.R. §160, §162 and §§164.530(b)(1) – (2)]

III. Implementation Specifics

A. [State entities](#) are responsible to provide training to all workforce members regarding Privacy Policies and Procedures.

The scope and content of the training, or periodic (and at least annual) refresher training, should target the workforce member’s specific job functions. The privacy training must:

1. Be provided to each new workforce member within a reasonable period of time after the person joins the workforce and prior to accessing health information.

[45 C.F.R. §164.530(b)(2)(i)(B); CA SAM §5320.1]

2. Be provided within a reasonable period of time after a material change in the policies and procedures becomes effective.

[45 C.F.R. §164.530(b)(2)(i)(C)]

3. Be documented in writing, which may be an electronic training record, and include which workforce members were trained, topics covered, and training dates.

[45 C.F.R. §164.530(b)(2)(ii); §§164.530(j)(1) - (2)]

4. Establish rules of conduct and instruct each workforce member about the rules and procedures concerning the privacy of individuals’ information.

[CA Civil Code §1798.20]

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B. State entities that are [hybrid entities](#) need to provide training to workforce members in those portions of the organization designated as covered components.

C. ADDITIONAL STATE ENTITY REQUIREMENTS

State entities are also responsible for complying with their own policies and procedures as well as the information security and privacy policies, standards, and procedures issued by the California Information Security Office (CISO).

[CA SAM 5300.2; CA Government Code §11549.3]

IV. References

45 C.F.R.

- §160
- §162
- §§164.530(b)(1) – (2)

CA Civil Code §1798.20

CA Government Code §11549.3

CA SAM

- §5300.2
- §5320.1

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 3 – Security Awareness and Training

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 4 – Administrative		
Section: 4.1.0 – Administrative Requirements		
4.1.3 – Sanctions for Violation		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding required sanctions which must be included in policy, and applied against any [workforce](#) member who views, uses, or [discloses health information](#) outside of the constraints of their position or does not follow policy.

II. Policy

Policies and procedures must specify appropriate sanctions outlining what the consequences will be against any workforce member who improperly views, uses, or discloses health information.

[State entities](#) are encouraged to consult with their labor relations or Human Resources departments prior to developing and applying operational policies and procedures governing workforce sanctions for violating privacy and security policies.

[45 C.F.R. §164.308; CA Health and Safety Code §1280.18; CA Civil Code §1798.21]

III. Implementation Specifics

A. [State entities](#) are responsible to implement, maintain, and apply written policies which contain all the following required elements:

1. Language that outlines specific sanctions against and consequence to, any workforce member who fails to comply with [security](#) and [privacy](#) policies by improperly viewing, using, disclosing, or allowing [access](#) to health information.
2. The sanction language should be included in any training materials provided to workforce members.
3. Language that specifically states the sanctions must be appropriate to the severity of the violation, up to and including termination.
4. Language that, depending on the severity of the violation, law enforcement notification may be required.
5. Language about civil sanctions and penalties. The policy must state that workforce members can be charged with a misdemeanor, or suffer fines and civil penalties, depending on the economic loss to the [patient](#) and the degree of malice.

[45 C.F.R. §164.308(a)(1)(ii)(C), and §164.530(e)(1); CA Civil Code §56.36, and §§1798.55 – 1798.57]

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- B. [Whistleblower](#) and victims of crime exemptions. Federal law allows a workforce member to disclose health information without an [authorization](#) in certain situations (e.g., state entity or [business associate](#) is engaging in illegal conduct, etc.). See *SHIPM Chapter 2, Victims of Abuse, Neglect, or Domestic Violence*.

Please refer to your organization's legal counsel for guidance on Victims of Crime exception matters.

[45 C.F.R. §164.502(j); CA Civil Code §56.10(c)(14), §1798.24(e), §1798.24(j), and §1798.24(o)]

- C. [Documentation](#). State entities are responsible to document any sanctions that were applied, and maintain the documentation for a minimum of six (6) years. *[45 C.F.R. §164.530(e)(2)]*

IV. [References](#)

45 C.F.R.

- §164.308
- §164.502(j)
- §164.512(f)(2)(i)
- §164.530(e)(i)
- §§164.530(e)(1) – (2)

CA Civil Code

- §56.10(c)(14)
- §56.36
- §1798

CA Health and Safety Code §1280.18

V. [Related Policies](#)

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Required by Law and Required Disclosures

SHIPM Chapter 2 – Breach and Breach Notification

SHIPM Chapter 2 – Minimum Necessary

SHIPM Chapter 2 – Victims of Abuse, Neglect, or Domestic Violence

SHIPM Chapter 3 – Incident Procedures

SHIPM Chapter 3 – Security Awareness and Training

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SHIPM Chapter 3 – Access Control

SHIPM Chapter 3 - Access Administration

SHIPM Chapter 3 - Workstation Use and Security

SHIPM Chapter 3 – Encryption

VI. Attachments

None

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Chapter: 4 – Administrative		
Section: 4.1.0 – Administrative Requirements		
4.1.4 – Staffing: Privacy Official, Security Official		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe certain [workforce](#) staffing roles required within an organization to support [health information privacy](#) and [security](#) compliance.

II. Policy

Specific workforce roles related to privacy and security must be designated to ensure privacy and security policies and procedures are developed, implemented, followed, and maintained.

III. Implementation Specifics

A. [State entities](#) are responsible to designate all the following workforce staffing roles:

1. Privacy Official. A privacy official must be designated to be responsible for the development, [implementation](#), and compliance with the state entity's policies and procedures relating to privacy. In part, privacy leadership and or the Privacy Official responsibilities include, but are not limited to: ¹
 - a. Assist in the development and implementation of privacy policies and procedures
 - b. Perform ongoing compliance monitoring activities
 - c. Work with legal counsel and management to ensure forms, authorizations, and notices are current
 - d. Ensure adequate privacy training
 - e. Assist with, coordinate, or track staff member access to medical information
 - f. Ensure patients right to access their PHI
 - g. Ensure a process for addressing complaints on privacy policies and procedures, including complaints on denial of access to PHI
 - h. Ensure compliance with privacy policies and procedures and legal requirements

¹ Responsibilities paraphrased and quoted from information found on the American Health Information Management Association (AHIMA) website <http://www.ahima.org/>

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- i. Coordinate with the Security Official
- j. Maintain current knowledge of applicable federal and state privacy laws and standards
- k. Answer and address privacy questions and issues
- l. Coordinate and cooperate with any compliance reviews or investigations
- m. Cooperates with the U.S. Department of Health and Human Service's Office for Civil Rights, CalOHII, State regulators and/or other legal entities, and organization or officers in any compliance reviews or investigations.

[45 C.F.R. §164.530(a)(1)(i)]

2. Privacy Notice Contact Person or Office.

- a. A contact person or office must be identified with their name (or title) and telephone number in any notice describing how a [patient's](#) health information may be used and [disclosed](#), and how the patient can get [access](#) to their information (see *SHIPM Chapter 5 , Notice of Privacy Practices*).
- b. The designated contact person or office is responsible for receiving privacy-related complaints and providing additional information about the content of the privacy notice.

[45 C.F.R. §164.520(b)(1)(vii), and §164.530(a)(1)(ii)]

3. Security Official. A security official must be identified who is responsible for development and [implementation](#) of an entity's policies and procedures relating to security. Responsibilities include, but are not limited to:²

- a. Builds a strategic and comprehensive information security program that defines, develops, maintains and implements policies and processes that enable consistent, effective information security practices which minimize risk and ensure the integrity, confidentiality and availability of information that is owned, controlled and processed within the organization. Ensures information security policies, standards, and procedures are up-to-date.
- b. Initiates, facilitates, and promotes activities to foster information security awareness within the organization.
- c. Creates a culture of cyber security both with the IT organization and driving behavioral changes for the business.

² Responsibilities paraphrased and quoted from information found on the American Health Information Management Association (AHIMA) website <http://www.ahima.org/>

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- d. Evaluates security trends, evolving threats, risks and vulnerabilities and applies tools to mitigate risk as necessary.
- e. Manages security incidents and events involving electronic protected health information (ePHI)
- f. Ensure that the disaster recovery, business continuity, risk management and access controls needs of the facility are addressed.
- g. Ensures the institution/organization complies with the administrative, technical and physical safeguards.
- h. Works closely with the Privacy Official to ensure alignment between security and privacy compliance programs including policies, practices and investigations, and acts as a liaison to the information systems and compliance departments.
- i. Is responsible for initial and periodic information security risk assessment/analysis, mitigation and remediation. Responsible for development and implementation of security risk management plan.
- j. Ensure organization has audit controls to monitor activity on electronic systems that contain or use electronic protected health information.
- k. Oversee periodic monitoring and reviewing of audit records to ensure that system activity is appropriate. Such activity would include, but is not limited to, logons and logoffs, file accesses, updates, edits and printing.
- l. Ensure the organization has and maintains appropriate system use and disclosure / confidentiality statement.
- m. Oversees, develops and/or delivers initial and ongoing security training to the workforce. Initiates, facilitates and promotes activities to foster information security awareness within the organization and related entities
- n. Participates in the development, implementation, and ongoing compliance monitoring of all Business Associates and business associate agreements, to ensure security concerns, requirements, and responsibilities are addressed.
- o. Assists Privacy Official as needed with breach determination and notification processes under HIPAA and applicable State breach rules and requirements.
- p. Establishes and administers a process for investigating and acting on security incidents which may result in a privacy breach.
- q. Partners with Privacy Official to ensure consistent sanctions for security violations
- r. Maintains current knowledge of applicable federal and state security laws, licensing and certification requirements and accreditation standards.

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- s. Cooperates with the U.S. Department of Health and Human Service's Office for Civil Rights, CalOHII, State regulators and/or other legal entities, and organization or officers in any compliance reviews or investigations.

[45 C.F.R. §164.308(a)(2)]

B. Each state entity has different business needs depending on size and workload. Although there are no statutory restrictions against the same person filling more than one of the above roles, CalOHII recommends the above roles are filled by separate people. Ultimately, state entities are responsible to assess what allocation of time and resources will adequately support the workload commensurate with each role.

C. ADDITIONAL STATE ENTITY REQUIREMENTS

State entities are also responsible for complying with the information security and privacy policies, standards, and procedures issued by the California Information Security Office (CISO). *[CA SIMM 5305-A]*

IV. References

45 C.F.R.

- §164.308(a)(2)
- §164.520(b)(1)(vii)
- §164.530(a)(1)(i) – (ii)

CA Civil Code §56

CA Health and Safety Code

- §130200
- §§130300 –130317

CA SAM §§5300 – 5365.3

CA SIMM §5305-A

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 4 – Privacy Training

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 4 – Administrative		
Section: 4.1.0 – Administrative Requirements		
4.1.5 – Trading Partner Agreements		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the responsibilities for the use of trading partner agreements (TPAs), related to the [electronic data interchange](#) of [health information](#).

II. Policy

Trading partner agreements are used to specify technical requirements not included in a [business associate agreement \(BAA\)](#). These technical details must be followed during the electronic exchange of health information between entities (e.g., ANSI x12 electronic health transactions standards).

[45 C.F.R §160.103, §162.103, and §162.915]

III. Implementation Specifics

A. [State entities](#) that are [business associates](#), [health care clearinghouses](#), [health care plans](#), [health care providers](#), or [hybrid entities](#) that use trading partner agreements are responsible to ensure that such agreements do not do any of the following:

1. Change the definition, data condition, or use of a data element or segment in a standard, except where necessary to implement state or federal law, or to protect against fraud and abuse.
2. Add any data elements or segments to the maximum defined data set.
3. Use any code or data elements that are either marked "not used" in the HIPAA standard's [implementation](#) specification or are not in the HIPAA standard's implementation specification(s).
4. Change the meaning or intent of the standard's implementation specification(s).

B. It is recommended that the trading partner agreement include or reference a Companion Guide to define specific details, requirements, processes and implementation steps in accordance with the HIPAA Implementation Guides for the applicable electronic transactions. In addition, the Companion Guide also includes general information and instructions on electronic data interchange, including, but not limited to, communications protocols, testing, requirements, and acknowledgments.

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IV. References

45 C.F.R.

- §160.103
- §162.103
- §162.915

[HIPAA Implementation Guides \(American National Standards Institute \(ANSI\) Standards\)](#)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 4 – Transactions and Code Sets (TCS)

SHIPM Chapter 4 – Business Associates

SHIPM Chapter 4 – Providers, Health Plans, Employers

VI. Attachments

None

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Chapter: 4 – Administrative		
Section: 4.1.0 – Administrative Requirements		
4.1.6 – Waiver of Rights Related to HIPAA Complaints		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To explain that a [patient](#) cannot waive his or her right to file complaints for non-compliance with [privacy](#), [security](#), or patients' rights requirements.

II. Policy

A patient always has the right to file a complaint with the federal Secretary of Health and Human Services (HHS) if she or he believes there has been noncompliance with requirements. It is prohibited to request that a patient waive this right for any reason; this right *cannot be waived*.

III. Implementation Specifics

- A. [State entities](#) that are [business associates](#), [health care clearinghouses](#), [health care plans](#), [healthcare providers](#), or [hybrid entities](#) shall not require any patient to waive his or her right to file a complaint with the federal Secretary of HHS, as a condition of the provision of [treatment](#), [payment](#), enrollment in a [health care plan](#), or eligibility for benefits.

[45 C.F.R. §164.306, §164.530(d), §164.530(g), and §164.530(h)]

IV. References

45 C.F.R.

- §164.306
- §164.530(d)
- §164.530(g)
- §164.530(h)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Treatment, Payment and Health Care Operations (TPO)

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 4 – Administrative		
Section: 4.2.0 – Compliance		
4.2.1 – Consequences of Non-Compliance		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To describe the responsibilities related to compliance activities, and the possibility of consequences (e.g., criminal convictions, administrative fines and civil monetary penalties) which may be applied, should a court or a federal or state oversight agency determine the use or [disclosure](#) of [health information](#) is not compliant with laws and regulations.

II. Policy

[State entities](#), as well as their [business associates](#), [workforce](#) members and [agents](#), are required to cooperate with federal and state agencies responsible for determining compliance with HIPAA and other laws relating to the [privacy](#), [security](#), and administration of health information.

[45 C.F.R. §160.402, §160.404, and §160.410]

III. Implementation Specifics

The U.S. Department of Health and Human Services (HHS) is authorized by law to determine compliance with HIPAA, and other federal laws relating to privacy, security, transactions and code sets, and the administration of health information.

[45 C.F.R. §160.300, and §§164.302 – 164.308]

- A. State entities are responsible to support and cooperate with HHS compliance activities. Specifically, state entities are responsible to do all of the following:
1. Provide records and compliance reports. A state entity must keep records and submit compliance reports in a time and manner requested by HHS, to ascertain whether the entity complies with federal regulations regarding health information,
 2. Cooperate with complaint investigations and compliance reviews. A state entity must cooperate with an HHS investigation or compliance review of the entities policies, procedures, or practices, to determine whether it is complying with federal regulations regarding health information,
 3. Permit [access to information](#). A state entity must permit access by HHS during normal business hours to its facilities, books, records, accounts, and other sources

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of data that are pertinent to ascertaining compliance with regulations regarding health information.

Health information obtained by HHS or its agents in connection with this type of investigation or compliance review, shall not be subsequently disclosed, unless necessary for ascertaining or enforcing compliance, or if otherwise required by law.

[45 C.F.R §160.310]

- B. Non-compliance due to acts by business associates (or agents). State entities are responsible for all violations by their business associates. Business associates are also responsible for the acts of their agents.

[45 C.F.R. §160.402(c)]

State entities may be held responsible for their business associates' actions. As a result, state entities must be reasonably diligent to ensure that business associates are compliant (e.g., use of appropriate business associate agreements), and business associates are responsible to do the same for their subcontractors (see *SHIPM Chapter 4, Business Associates*).

- C. The State of California Office of Health Information Integrity (CalOHII) is authorized by law to coordinate [implementation](#) and compliance activities within state government for HIPAA and other laws relating to privacy, security, and administration of health information.

[CA Health and Safety Code §130310]

State entities are also responsible to support and cooperate with CalOHII's coordination and compliance activities. Specifically, state entities, business associates, their [workforce](#) members, and agents are required to comply with all of the following:

1. Respond in a timely and complete manner to all activities undertaken to assess and ensure HIPAA implementation, progress and compliance with HIPAA, and other laws and policies relating to health information.

Required responses from state entities include, but are not limited to:

- a. Assisting in periodic statewide assessments,
- b. Providing documentation or information upon request in the format requested.

[CA Health and Safety Code §130310, and §130311]

2. Comply with the decisions of the CalOHII director in achieving compliance with HIPAA. *[CA Health and Safety Code §130311]*

- D. HHS violation penalty considerations. An HHS finding that an individual or organization failed to comply with HIPAA and/or other regulations regarding health information may result in criminal convictions, administrative fines and civil penalties.

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In determining the type and size of the penalty, HHS may consider any of the following as aggravating or mitigating factors, as appropriate:

1. The nature and extent of the violation, including the number of [patients](#) affected and the time period during which the violation occurred
2. The nature and extent of the harm resulting from the violation (such as financial impact or damage to patient's reputation)
3. The history of prior compliance, including previous violations
4. The financial condition of the entity or business associate, including whether financial difficulties affected the ability to comply, and whether the imposition of the penalties would risk ability to continue to provide or pay for healthcare.

[45 C.F.R. §160.408]

The following table reflects some of the possible consequences of non-compliance described in federal law. In addition to financial penalties, a sentence of up to 10 years of prison time is possible for individuals who are non-compliant with intent to sell, transfer, or use health information for commercial advantage, personal gain, or malicious harm.

Violation Category	Each Violation	Total for Violations of an Identical Provision in a Calendar Year
<i>Did Not Know</i>	\$100 – \$50,000	\$1,500,000
<i>Reasonable Cause</i>	\$1,000 – \$50,000	\$1,500,000
<i>Willful Neglect – Corrected</i>	\$10,000 – \$50,000	\$1,500,000
<i>Willful Neglect – Not Corrected</i>	<u>At least</u> \$50,000	\$1,500,000

[42 U.S.C. §1320d-5; 45 C.F.R §160.404, and §160.406]

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E. Additional State of California penalties. In addition to federal law, California law identifies possible penalties for non-compliance, including criminal convictions and administrative fines (or civil monetary penalties) to individuals and organizations ranging from \$1,000 up to \$250,000 for illegally disclosing health information.

[CA Civil Code §§56.10(a), §§56.35–56.36, §1798.24, and §§1798.55 - 1798.57]

F. Documentation and retention. State entities are responsible to document any official findings of non-compliance by a state or federal compliance oversight entity, and any penalties that are imposed by for non-compliance.

[45 C.F.R. §164.530(e)]

Documentation must be maintained for six (6) years.

[45 C.F.R. §164.530(j)]

IV. References

42 U.S.C. §1320d–5

45 C.F.R.

- §160.402
- §160.404
- §160.406
- §160.408
- §160.410
- §164.300
- §§164.302 - 164.308
- §164.310
- §§164.530(e), and (j)

CA Civil Code

- §56.10(a)
- §§56.35 - 56.36
- §1798.24
- §§1798.55 –1798.57

CA Health and Safety Code

- §130310
- §130311
- §130311.5

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V. Related Policies

- SHIPM Chapter 1 – CalOHII Authority
- SHIPM Chapter 1 – State Agency Responsibilities
- SHIPM Chapter 2 – Breach and Breach Notification
- SHIPM Chapter 2 – Minimum Necessary
- SHIPM Chapter 3 – Incident Procedures
- SHIPM Chapter 3 – Security
- SHIPM Chapter 4 – Business Associates

VI. Attachments

None

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Chapter: 4 – Administrative		
Section: 4.3.0 – Transactions and Code Sets		
4.3.1 – Transactions and Code Sets (TCS)		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the use of HIPAA's standardized [transactions and code sets](#) (TCS) in the [electronic data interchange](#) of [health information](#).

II. Policy

When health information is moved electronically for certain administrative and financial reasons, TCS standards must be used.

[45 C.F.R. §162.923, §162.925, and §162.930]

III. Implementation Specifics

A. [State entities](#) are responsible to use current standard electronic transactions, identifiers, and code sets to exchange health information electronically including, but not limited to:

1. Standard electronic transactions:

- a. Health care claims or equivalent encounter information
- b. Eligibility for a [health care plan](#)
- c. Health care claim status
- d. Enrolling and dis-enrolling in a health plan
- e. Health care electronic funds transfers (EFT) and remittance advice
- f. Health plan premium payments
- g. Coordination of benefits
- h. Medicaid pharmacy subrogation
- i. Claims attachments

[45 C.F.R. §§162.900 - 162.1902]

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2. Unique Identifiers. There are national identification number requirements for use with the standard electronic transactions, listed above:

- a. Providers
- b. Health Plans
- c. Employers

(See SHIPM Chapter 4, Providers, Health Care Plans and Employers)

3. Medical code sets. The following medical code sets must be used with the standard electronic transactions, listed above:

- a. International Classification of Diseases (ICD-10-CM) is used for reporting diagnosis and inpatient hospital procedures. The ICD is the international standard for defining and reporting diseases and health conditions.
- b. Health Care Financing Administration Common Procedure Coding System (HCPCS) and the Current Procedure Terminology (CPT-IV), are used by [health care providers](#) and [health care plans](#) in conjunction with medical billing processes to identify procedures and services.
- c. National Drug Codes (NDC) for drugs and biologics is used to identify each medication listed in the U.S. Federal Food, Drug and Cosmetic Act.
- d. The American Dental Association's Codes on Dental Procedures and Nomenclature for dental services.

[45 C.F.R. §§162.1000 - 162.1011]

- B. Security and privacy. State entities are responsible to comply with all of the other SHIPM policies pertaining to Privacy, Security, Administrative Requirements and Patient Rights (see SHIPM Chapters 2, 3, 4, and 5).
- C. Electronic Signature. State entities are responsible to comply with the information security and privacy policies, standards and procedures issued by the California Information Security Office (CISO), per SAM section 5300.2.
- D. Electronic transfer of information between multiple health care plans. State entities are responsible to adopt standards for transferring appropriate standard data elements needed for the coordination of benefits, sequential processing of claims and other data elements between health care plans for those [patients](#) who have more than one health care plan.
- E. It is recommended that TCS standards and processes are documented in a Companion Guide.

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IV. References

45 C.F.R.

- §§162.900 - 162.902
- §162.923
- §162.925
- §162.930
- §§162.1000 -162.1011

CA SAM §5300.2

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – De-identification

SHIPM Chapter 3 – Security

SHIPM Chapter 4 – Administrative Requirements

VI. Attachments

None

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Chapter: 4 – Administrative		
Section: 4.4.0 – Business Associates		
4.4.1 – Business Associates		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To provide guidance regarding the contractual requirements that allow for the sharing or disclosure of [health information](#) with [business associates](#).

II. Policy

Business associates need [access](#) to health information to carry out, assist with the performance of, or perform a function or activity on behalf of a [state entity](#). A state entity is responsible to have a contract or other written agreement with its business associate. When a [business associate agreement \(BAA\)](#) is executed, a state entity may permit business associates to use or [disclose](#) health information (e.g., create, receive, access, maintain, and transmit) on the state entity's behalf.

A state entity that is a [covered entity](#) can also be the business associate of another covered entity, if they perform duties on behalf of that covered entity.

State entities that share health information with other government entities, may utilize a Memorandum of Understanding (MOU) as the legal instrument that specifies the contractual requirements with regard to handling and safeguarding health information. These MOUs must contain certain minimum provisions required in a BAA between covered entities and their business associates.

[45 C.F.R. §164.308(b), §§164.314(a)(1)-(2), §164.502, §164.504, §164.504(e)(2), and §164.504(e)(3)(i); CA SAM §5305.8, and §5310.3; NIST SP 800-53]

III. Implementation Specifics

- A. A business associate is permitted to use or disclose health information only in the manner specified in an executed legal agreement between their organization and the state entity. This includes information about any restrictions for the use or disclosure of information as requested by the patient as well as any requests by the patient regarding Confidential Communications.
- B. Each state entity may have specific program requirements that may need to be incorporated into the BAA or MOU.

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C. The BAA must provide that the business associate will comply with all applicable requirements.

[45 C.F.R. §164.314]

D. BAAs must contain language that requires the business associate to do all of the following:

1. Maintain the [confidentiality](#), integrity, and [availability](#) of all health information that the business associate uses or discloses.
2. Follow the permitted and required uses and disclosures of health information as specified in the BAA. The agreement:
 - a. Must state the purpose for which use or disclosure is:
 - i. permitted
 - ii. the rationale for these permissions
 - iii. to whom the business associate may make further disclosures.
 - b. Is *not* required to list each specific item for which use or disclosure is permitted.
 - c. Cannot authorize the business associate to use or further disclose health information in a manner that violates state or federal law.
 - d. May permit the business associate to use or disclose the health information for either of the following:
 - i. To carry out the legal responsibilities of the business associate
 - ii. For the proper management and administration of the business associate, consistent with federal and state laws.
 - e. May permit the business associate to provide data aggregation services related to the health care operations of the state entity only.
3. Ensure a business associate's use of software to identify patterns in large batches of data (also known as "data mining"), for any purpose not specified in the BAA or MOU, is documented as a violation of the agreement and grounds for termination of the agreement by the state entity.
4. Protect against any reasonably anticipated threats or hazards to the [security](#) or integrity of health information by using physical, technical, and [administrative safeguards](#).
5. Protect against any reasonably anticipated uses or disclosures of health information that are either of the following:
 - a. Not permitted or required by state or federal requirements, or
 - b. Not provided for by the BAA or MOU (contract).

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6. Ensure ongoing communications between the Covered Entity and Business Associate regarding any updates or changes by the patient regarding the use and disclosure of their information or confidential communication requests.
7. Ensure that its [workforce](#) complies with all applicable state and federal requirements and the BAA or MOU.
8. Ensure that any of the business associate subcontractors that create, receive, maintain, or transmit health information on behalf of the business associate, agree to the same restrictions and conditions that apply to the business associate, including an executed BAA or MOU.
9. Report to the state entity any [breaches](#) or security incidents of [unsecured health information](#).
10. Make available health information for amendments requested by the [patient](#) and incorporate any allowable amendments or addenda.
11. Make available the information required to provide an accounting of disclosures.
12. Comply with the requirements in the same manner as the state entity in carrying out the obligations related to the assigned responsibilities.
13. Make its internal practices, books, and records relating to the use and disclosure of health information received from, received by or created by the business associate on behalf of the state entity available to state and federal representatives for purposes of determining the state entity's and/or the business associate's compliance with state and federal requirements.
14. Describe the conditions for termination of the BAA by the covered entity, specifically situations involving material breach by the Business Associate including conditions for allowing the Business Associate to cure the breach or end the violation.
15. At termination or expiration of the BAA or MOU (contract), do either of the following:
 - a. Return or destroy all health information received from, or created or received by the business associate on behalf of the state entity that the business associate still maintains in any form and retain no copies of such information
 - b. If such return or destruction is not feasible, extend the protections of the BAA or MOU (contract) to the health information and limit further uses and disclosures to those purposes that make the return or destruction of the health information not feasible

Consultation with your organization's legal counsel is recommended if this termination or expiration provision is inconsistent with the statutory obligations of the state entity or its business associate as this may support omitting this provision.

[45 C.F.R. §164.504(e)(1), and §164.504(e)(2); CA Civil Code §56.10, §1798.19, and §1798.24]

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IV. References

45 C.F.R.

- §164.308
- §164.314
- §164.410
- §164.502
- §164.504
- §164.524
- §164.526
- §164.528

CA Civil Code

- §§56.01 - 56.99
- §§1798 - 1798.77

CA Health and Safety Code §§123111-123149.5

CA SAM

- §5305.8
- §5310.3

NIST SP 800-53

V. Related Policies

SHIPM Chapter 1 - CalOHII Authority

SHIPM Chapter 2 - Breach and Breach Notification

SHIPM Chapter 2 - Minimum Necessary

SHIPM Chapter 2 - De-identification

SHIPM Chapter 2 - Public Health Activities

SHIPM Chapter 2 - Required by Law and Required Disclosures

SHIPM Chapter 3 – Security

SHIPM Chapter 5 – Restrictions for Self-Pay and Confidential Communications

VI. Attachments

Yes – HIPAA Business Associate Agreement (template)

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Chapter: 4 – Administrative		
Section: 4.4.0 – Business Associates		
4.4.2 – Oversight of Business Associates		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the requirement that covered [state entities](#) provide oversight to their [business associates](#).

II. Policy

State entities are responsible to provide oversight of all business associates to verify that they comply with all requirements outlined in their [business associate agreements](#). For governmental entities: This includes memoranda of understanding (MOU) that act as business associate agreements (BAA).

[45 C.F.R. §164.504(e)(1)(ii); CA Health and Safety Code §§130300-130315]

III. Implementation Specifics

State entities are responsible to conduct oversight of their business associates to verify compliance with the patient privacy and security requirements in their business associate agreements - see SHIPM Chapter 4, Business Associates.

- A. Oversight by State Entities. State entities are responsible to develop a program of periodic verification that their business associates are complying with all state and federal requirements in business associate agreements.
- B. Demonstration of Compliance with Business Associate Agreements. State entities must demonstrate through documentation (such as: protocols, procedures, communication logs, policies, emails, etc.) that they have implemented the following internal control requirements:
 1. Whenever there is a change in the law affecting what is required in a business associate agreement, business associate agreements or MOUs must be updated.
 2. Business associate agreement templates must be reviewed and updated often enough to ensure they are accurate and consistent with the law, and distributed to all units within your organization that use the templates to ensure updated templates are being used.
 3. All patient requests regarding confidential communications and patient restrictions on use and disclosure must be communicated to the business associate within 2 business days.

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4. Any risks from business associate relationships must be evaluated and included in the state entity's risk analysis.
5. Business associate adherence with privacy and security protocols required by law, SHIPM, and the business associate agreement must be verified and documented periodically. The frequency of this verification should be based on the results of the state entity's own risk analysis. Suggested factors to consider in the risk analysis might be the number and size of business associates, whether businesses associates access health information, length of the relationships, etc.
6. Method of verifying that the business associate has a process to notify the state covered entity if and when there are any violations of law, policy, or contract occurs, including any breaches or security incidents.

Although the business associate agreement requires the state entity be notified without unreasonable delay, best practices suggest notification occur no later than 24-48 hours after detection.

[45 C.F.R. §164.410, §164.524, §164.526, and §164.528]

7. Procedure to take to ensure that if the state entity becomes aware of any pattern or practice that constitutes a violation of law and/or the business associate's obligations under contract, the state entity takes reasonable steps to mitigate the defect or to end the business relationship. Reasonable steps will vary with the circumstances and nature of the business associate relationship.

[45 C.F.R. §164.308, §164.314, §164.410, §164.524, §164.526, and §164.528; CA Civil Code §§56.01-56.99, and §§1798-1798.77, CA Health and Safety Code §§123111-123149.5]

IV. References

CA Health and Safety Code

- §§123111 - 123149.5
- §§130303 – 130315

CA Civil Code

- §§56.01 - 56.99
- §§1798 - 1798.77

45 C.F.R.

- §164.308
- §164.314
- §164.410
- §164.504
- §164.522
- §164.524

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- §164.526
- §164.528

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Marketing

SHIPM Chapter 3 – Security Management Process

SHIPM Chapter 4 – Business Associates

SHIPM Chapter 5 – Restrictions for Self-Pay and Confidential Communications

VI. Attachments

None

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Chapter: 4 – Administrative		
Section: 4.5.0 – Identifiers		
4.5.1 – Provider, Health Care Plan, Employers		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the use of established/adopted national identification (identifier) numbers for [health care providers](#), [health care plans](#), and [employers](#).

II. Policy

Health care providers, health care plans, and employers who file electronic claims and conduct related electronic transactions ([electronic data interchange](#)) of [health information](#) *must* use national identification numbers (identifiers).

[45 C.F.R. §162.404, §162.406(a), §162.408, §162.410, §162.412(a), §162.412(b), §162.414, §162.504, §162.506, §162.508, §162.510, §162.512, §162.514, §162.600, §162.605, and §162.610]

III. Implementation Specifics

B. [State entities](#) are responsible to know when they are required to use one of the national identification standards. HIPAA has established national identification numbers (identifiers) for different entities, for the following reasons:

1. [National health plan identifier \(HPID\)](#). A unique identifier for health care plans makes it easier for health care providers to conduct standard electronic transactions with different health care plans. Health care plans obtain a HPID by requesting a number through CMS' Health Plan and Other Entity Enumeration System (HPOES), once the plans register their organizations on the CMS Enterprise Portal.
[45 C.F.R. §162.504, §162.506, §162.508, §162.510, §162.512, and §162.514]
2. [National health care provider identifier \(NPI\)](#). A standard identifier for hospitals, doctors, nursing homes, and other health care providers. It facilitates the filing of electronic claims, as well as other standard electronic transactions with public and private insurance programs. Providers obtain an NPI by requesting a number through CMS' [National Plan and Provider Enumeration System \(NPPES\)](#) (<https://nppes.cms.hhs.gov/NPPES/Welcome.do>).

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- a. A health care plan or [health care clearinghouse](#) must use the NPI of any health care provider (or subpart(s), if applicable), on all standard electronic transactions where that health care provider's identifier is required

[45 C.F.R. §162.412(a), and §162.414]

- b. A health care plan may not require a health care provider that has been assigned an NPI to obtain an additional NPI

[45 C.F.R §162.412(b)]

3. Employer identifier number. Adopts the existing employer identification number (EIN) assigned by the Internal Revenue Service for [employers](#) in the health care industry, as a unique employer identifier when conducting standard electronic transactions for health care plan enrollments/premium payments.

[45 C.F.R. §162.600, §162.605, §162.610, and §162.610(b)]

IV. References

45 C.F.R.

- §162.404
- §162.406(a)
- §162.408
- §162.410
- §§162.412(a) - (b)
- §162.414
- §162.504
- §162.506
- §162.508
- §162.510
- §162.512
- §162.514
- §162.600
- §162.605
- §162.610

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – De-identification

SHIPM Chapter 3 –Security

SHIPM Chapter 4 – Administrative

VI. Attachments

None

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Chapter: 4 – Administrative		
Section: 4.6.0 – Requirements for Specific Organizations		
4.6.1 – Contractors		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide information regarding contractors' responsibilities to maintain the [privacy](#) and [security](#) of [health information](#).

II. Policy

Contractors who perform work for a [covered entity](#) that involves the use or [disclosure](#) of health information, must comply with the same privacy and security requirements as the organization with which they contract.

III. Implementation Specifics

A. [State entities](#) that are [business associates](#), [health care clearinghouses](#), [health care plans](#), [health care providers](#) or [hybrid entities](#) are responsible to do all of the following:

1. Ensure contractors comply with the same requirements and restrictions for health information that apply to the state entity
2. Account for [breaches](#) by its contractor(s)
3. Treat breaches by a contractor as if they were breaches by the state entity

[45 C.F.R. §160.402(c), §162.923(c)(2), §164.314(b)(2)(iii), §164.404(a)(2), §164.501, and §164.514(h)(2)(ii)(C)]

IV. References

45 C.F.R.

- §160.402(c)
- §162.923(c)(2)
- §164.314(b)(2)(iii)
- §164.404(a)(2)
- §164.501
- §164.514(h)(2)(ii)(C)

CA Civil Code §§56.10 - 56.16

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V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 4 – Administrative Requirements

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

None

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Chapter: 4 – Administrative		
Section: 4.6.0 – Requirements for Specific Organizations		
4.6.2 – Health Care Clearinghouses		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the [privacy](#) and [security](#) requirements for [health care clearinghouses](#).

II. Policy

Health care clearinghouses are defined as [covered entities](#) under HIPAA, and must comply with the privacy, security, and transactions and code sets obligations. Health care clearinghouses may have either of the following with a [patient](#):

- ❖ A [direct treatment relationship](#)
- ❖ An indirect treatment relationship

[45 C.F.R. §162.930, §164.500(b), §164.502(e), §§164.504(d) - (e), §164.524, and §164.526]

III. Implementation Specifics

- A. Health care clearinghouses, that have a direct treatment relationship, must comply with all privacy and security requirements.
- B. Health care clearinghouses, that have an indirect patient relationship, do not need to do any of the following:
 1. Provide a Notice of Privacy Practices (NPP)
 2. Provide patients [access](#) to their medical records
 3. Provide an accounting of [health information](#) disclosures

When no direct patient relationship exists, a health care clearinghouse must only use or disclose health information as expressly stated in their [business associate agreement \(BAA\)](#).

[45 C.F.R. §164.500(b), §164.502(e), and §164.504(e)]

- C. Business associate agreements. BAAs must clearly state that the health care clearinghouse will comply with the privacy and security regulations of the covered entity (see *SHIPM Chapter 4, Business Associates*).

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IV. References

45 C.F.R.

- §162.930
- §164.500(b)
- §164.502(e)
- §164.504(d) – (e)
- §164.524
- §164.526

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Breach and Breach Notification (and all other Privacy topics)

SHIPM Chapter 3 – Incident Procedures

SHIPM Chapter 4 – Administrative Requirements

SHIPM Chapter 4 – Business Associates

SHIPM Chapter 5 – Notice of Privacy Practices

SHIPM Chapter 5 – Accounting of Disclosures

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 4 – Administrative		
Section: 4.6.0 – Requirements for Specific Organizations		
4.6.3 – Health Information Organizations		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To explain how [privacy](#), [security](#) and administrative requirements apply to [health information organizations \(HIOs\)](#).

II. Policy

HIOs must comply with all of the privacy, security and administrative requirements applicable to [business associates](#) or a [state entity](#) when providing services involving [health information](#).

In addition, a HIO must enter into a valid written contract or other written agreement with all of the entities, business associates and other organizations which will be participating with the HIO to use, disclose, move, or store health information for [health information exchange](#) purposes.

[42 U.S.C. §17901, and §17938; 45 C.F.R. §160.103; CA Civil Code §1798.19]

III. Implementation Specifics

[Health information exchange](#) is necessary and beneficial within a standardized framework that protects the privacy of health information and the security of data being exchanged.

- A. A state entity that is a HIO, or conducts business with a HIO, must comply with all of the SHIPM policies pertaining to the privacy, security, and administrative requirements involving health information, as well as its own policies and those of the CA Information Security Officer (CA ISO).
- B. A HIO (including Regional Health Information Organizations, E-Prescribing Gateways, Health Information Organizations, and any vendor that contracts with an entity to allow that entity to offer health information to patients as part of its electronic health record), regardless of whether the HIO is considered a [covered entity](#) or business associate, must enter into a written contract or other written agreement with the entities, for which it provides health information exchange services. *At a minimum*, the agreement must address:
 1. The responsibility of participating organizations to obtain appropriate [authorization](#) from the patient to allow health information exchange.

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2. The minimum requirements of a valid [business associate agreement](#).
 3. The scope of the health information organization's (HIO's) governance, services, and functions.
 4. The uses and disclosures of health information the HIO and all participating entities are permitted or required to make as they create, receive, move, transmit, store, or maintain electronic health information.
 5. The safeguards the HIO and all participating entities will implement to protect the privacy and security of the electronic health information.
[42 U.S.C. §17938; 45 C.F.R. §164.308(b), §164.314(a), §§164.502(e)(1) – (e)(2), and §164.504(e)]
 6. In the context of its networked environment, the HIO may enter into a single, multi-party business associate agreement with multiple entities or organizations participating in health information exchange with the HIO.
- C. A HIO may participate in an organization made up of other HIOs and other participating organizations. Such participation requires the HIO to enter into a written contract or other written agreement with the multiple HIOs in the organization providing health information exchange services and their participating entities, business associates and other participating organizations. *At minimum*, the agreement must address the following:
1. The responsibility of participating organizations to ensure appropriate authorization is obtained from the [patient](#) to allow health information exchange.
 2. The minimum requirements of an adequate business associate agreement.
 3. The scope of the multi-HIO organization's governance, services and functions.
 4. The uses and disclosures of health information the multi-HIO organization and its participating HIOs and entities are permitted or required to make as they create receive, move, transmit, store, or maintain electronic health information.
 5. The safeguards the multi-HIO and its participating HIOs and other participating organizations will implement to protect the privacy and security of the electronic health information.
[42 U.S.C. §17938; 45 C.F.R. §164.308(b), §164.314(a), §§164.502(e)(1) – (e)(2), and §164.504(e)]
 6. In the context of a networked multi-HIO environment, the HIO is permitted to enter into a single, multi-party data use (and reciprocal support) agreement with the multiple HIOs, entities, business associates and other organizations participating in the exchange of health information through the multi-HIO. *See attached example of the California Data Use and Reciprocal Support Agreement (CalDURSA).*

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D. To help meet the goals set for health information exchange by the State of California and the federal Office of the National Coordinator for Health Information Technology, state entities that provide services as a health information organization or a multi-HIO organization are required to use the CalDURSA as its written agreement with participating organizations, or a written agreement with all the same elements as the CalDURSA.

[45 C.F.R. §164.308(b), and §§164.502(e)(1) - 164.502(e)(2); CA Civil Code §56.10(a), and §56.37(a)]

IV. References

45 C.F.R.

- §160.103
- §164.308(b)
- §164.314(a)
- §§164.502(e)(1) – (e)(2)
- §164.504(e)

42 U.S.C.

- §17901
- §17938

CA Civil Code

- §56.10(a)
- §56.37(a)
- §1798.19

CA Health and Safety Code §130250 – §130282

CA Executive Orders

- S-12-06
- S-06-07

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V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Health Information Exchange (HIE)

SHIPM Chapter 3 – Security

SHIPM Chapter 4 – Administrative Requirements

SHIPM Chapter 4 – Business Associates

SHIPM Chapter 5 – Notice of Privacy Practices

VI. Attachments

Yes - California Data Use and Reciprocal Support Agreement (CalDURSA), dated July 24, 2014.

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Chapter: 4 – Administrative		
Section: 4.6.0 – Requirements for Specific Organizations		
4.6.4 – Pharmaceutical Companies		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To explain that [privacy](#), [security](#), and administrative requirements apply to permitted communications from [pharmaceutical companies](#) to a [patient](#).

II. Policy

Pharmaceutical companies that communicate with patients are required to protect the privacy and security of the patient's [health information](#).

III. Implementation Specifics

State entities contracting with pharmaceutical companies are responsible to ensure refill reminders or communications about a drug or biologic currently prescribed for a patient, comply with both of the following:

1. The pharmaceutical company has a *current* [direct treatment relationship](#), *and*
2. A current valid prescription

This type of communication is exempt from regulations regarding use of health information for [marketing](#) purposes. [45 C.F.R §164.501]

IV. References

45 C.F.R. §164.501

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority
SHIPM Chapter 2 – Privacy
SHIPM Chapter 3 – Security
SHIPM Chapter 4 – Administrative
SHIPM Chapter 5 – Patient Rights

VI. Attachments

None

Chapter 5 – Patient Rights

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Chapter: 5 – Patient Rights		
Section: 5.1.0 – Accounting of Disclosures		
5.1.1 – Accounting of Disclosures		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the requirements for tracking [disclosures](#) of [health information](#) and the [patient's](#) right to request and receive an accounting of those disclosures.

II. Policy

Disclosures of health information must be documented and tracked in order to provide an accounting of such disclosures to the patient upon the patient's request.

[45 C.F.R. §164.528; CA Civil Code §1798.25; Eisenhower Medical Center v. Superior Court, 226 Cal.App.4th 430 (2014)]

III. Implementation Specifics

- A. [State entities](#) are responsible to document, track and maintain information concerning disclosures of health information. This tracking must document what, when, why and to whom disclosures are made.
- B. State entities that are [health care plans](#), [health care providers](#) or [hybrid entities](#) are responsible to provide the patient with an accounting of the disclosures of their health information.

The accounting must include disclosures made by the state entity as well as any disclosures made to or by any [business associates](#) of the state entity.

[45 C.F.R. §164.528(b)(1)]

1. Timing of response to an accounting of disclosure request. State entities are responsible to respond to a request for an accounting of disclosures no later than 60 days after receipt of such a request.

If unable to respond within this period of time, the state entity may extend the time by no more than 30 days provided that, within the initial 60 day period, the state entity provides the patient with a written statement of the reasons for the delay and the date by which the accounting will be provided. Only one 30-day extension is permitted. *[45 C.F.R. §164.528(c)(1)]*

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2. Content of disclosures accounting. The accounting for each disclosure of health information must include all of the following:
 - a. The date(s) of the disclosure(s).
 - b. The name and title of the entity or person to whom the information was provided, and their recorded address.
 - c. A brief description of the health information disclosed.
 - d. A brief statement describing the reason for the required or permitted disclosure (e.g., pursuant to a subpoena), or a copy of the written request if applicable.

[45 C.F.R. §164.528(b)(2); CA Civil Code §1798.25]

Special Note: Subsequent patient requests for Accounting of Disclosures, within 12 months of the first Accounting of Disclosure, need only include any incremental disclosures made since the original accounting).

3. Charge for the accounting.
 - a. The first accounting of disclosures made to a patient during any 12-month period of time must be provided free of charge.
 - b. For any subsequent request for an accounting of disclosures made by the same patient made within this 12-month period, the state entity may impose a reasonable, cost-based fee for the accounting, provided that the patient is informed in advance of the fees that will be charged and provides the patient with an opportunity to withdraw or modify the request for a subsequent accounting to avoid or reduce the fee.

[45 C.F.R. §164.528(c)(2)]

- C. Exceptions to required disclosure accounting. The following types of disclosures are excluded from the accounting of disclosures requirement (please see section V. *Related Policies* – below):

1. Disclosures made for [treatment](#), [payment](#), and [health care operations](#)
2. Disclosures made to the patient about themselves
3. Disclosures resulting from or incident to otherwise permitted disclosure
4. Disclosures made pursuant to an [authorization](#)
5. Disclosures made for a facility's directory, or to persons involved in the patient's care or for related purposes
6. Disclosures that are part of a [limited data set](#)

[45 C.F.R. §164.528(a)(1)]

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- D. Disclosure accounting for research purposes. If during the period of time covered by the requested accounting, the state entity makes disclosures for specific [research](#) purposes regarding 50 or more individuals' records, the state entity may account for the disclosures by providing all of the following:
1. The name of the protocol or other research activity
 2. A plain language description of the research protocol or activity, including the purpose of the research and the criteria for selecting certain records
 3. A brief description of the type of health information that was disclosed
 4. The dates or periods of time during which the disclosures occurred, or may have occurred, including the date of the last disclosure during the accounting period.
 5. The name, address, and telephone number of the entity that sponsored the research and the researcher to whom the information was disclosed
 6. A statement that the health information may or may not have been disclosed for a particular protocol or particular research activity

If it is reasonably likely that the health information was disclosed for a research protocol or activity, the state entity shall, if requested by the patient, assist the patient in contacting the entity that sponsored the research and the researcher.

[45 C.F.R. §164.528(b)(4)]

- E. Documentation. The state entity shall maintain a written, including electronic, record of each accounting of disclosures sufficient to demonstrate compliance with requirements. At a minimum, this must include documentation of the information required to be included in each accounting, and the titles of persons or offices responsible for receiving and processing requests for accounting of disclosures.

[45 C.F.R. §164.528(d)]

The state entity [Business Associate Agreement \(BAA\)](#) needs to include a requirement that all business associates document, track and account for all disclosures required to comply with an Accounting of Disclosures. In addition, the BAA should address how and when (timeframe) the business associate is to provide the state entity with the information necessary to comply with an accounting when requested by the patient.

IV. References

45 C.F.R.

- §164.528

CA Civil Code §1798.25

Case Law - Eisenhower Medical Center v. Superior Court, 226 Cal.App.4th 430 (2014)

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V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Health Oversight

SHIPM Chapter 2 – Law Enforcement

SHIPM Chapter 2 – Opportunity to Agree or Object

SHIPM Chapter 2 – Research

SHIPM Chapter 2 – Victims of Abuse, Neglect or Domestic Violence

SHIPM Chapter 2 – De-identification

VI. Attachments

None

Statewide Health Information Policy Manual

Chapter: 5 – Patient Rights		
Section: 5.2.0 – Amendments		
5.2.1 – Amendments		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding [patient](#) requests for changes or corrections (amendments) to their medical records.

II. Policy

Patients or [patient representatives](#) may request any portion of the patient’s medical record be changed, corrected, or amended by submitting a 250 word maximum addendum of additions or corrections to the medical record. The addendum must be kept and distributed with the record for as long as the covered entity, [health care provider](#), [health care plan](#), or [health care clearinghouse](#) maintains the records.

A [state entity](#) must either make the requested amendment or notify the requestor that the request has been denied within 30 days of the request.

[45 C.F.R §164.501, and §164.526; CA Civil Code §1798.35; CA Health and Safety Code §123111(a)]

III. Implementation Specifics

A. State entities are responsible to create and maintain policies and procedures stating how to process and document patient requests for amendment to their medical records.

1. Patient amendment requests must be in writing.
2. State entities are responsible to advise their patients in advance of this requirement by including a statement in the Notice of Privacy Practices (*see SHIPM Chapter 5, Notice of Privacy Practices*).
3. Correspondence regarding patient requests for amendment, and relating to denial or acceptance of requests to amend, should be filed in the patient’s medical record and appended to the information in question; as well as be accessible and available to staff in designated areas.
4. Initial patient amendment requests. State entities have 30 days to do either of the following:
 - a. Amend the patient’s medical records
 - b. Deny the patient’s request in whole or part

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5. Response to appeal of denial. State entities must respond to the patient within either of the following:

- a. Within 30 days of receipt of the denial appeal
- b. Notify the patient that the appeal may take another 30 days (for a total of no more than 60 days) from receipt of the denial appeal

[45 C.F.R. §164.526(b)(1); CA Civil Code §1798.36]

B. Acceptance of request for amendment. When a correction is made, state entities are responsible to make reasonable efforts to provide the corrected information to its business associates and others who are known to have the health information that was amended.

[CA Civil Code §1798.35]

While not required by law, if the state entity accepts the requested amendment, in whole or in part, at a minimum the policies and procedures must address all the following:

1. The state entity should place a copy of the amendment in the patient's medical record appended to the original documentation, with a clear indication that the original has been amended and the date of the amendment.
2. The state entity should also ensure that the amended documents are placed appropriately in the patient's electronic medical record when one exists.
3. The state entity should notify the relevant persons with whom the amendment needs to be shared, as identified by the patient on the original amendment request. If the patient is unsure as to who should receive the amended information, the state entity should work with the patient to ensure that all parties are appropriately identified.
4. The entity must identify other persons, including business associates, that are known to have the patient's health information and that may have or may rely on it.
5. State entities are responsible to inform the patient in writing that the amendment has been accepted.

If only a portion of the amendment has been accepted, the entity must also notify the patient that a portion has been accepted and a portion denied. The portion denied must follow the same procedures as in *Section D below*.

[45 C.F.R. §164.526; CA Civil Code 1798.35(a)]

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C. Denial of request for amendment. A state entity may deny a patient's request for amendment, for any of the following reasons, if it determines that the health information or record that is the subject of the request:

1. Was not created by the state entity, unless the patient explains that the originator of health information is no longer available
2. Would not be available for inspection
3. Is accurate and complete

[45 C.F.R §164.524, and §164.526(a)(2); CA Civil Code §1798.35(b), and §§1798.36 - 1798.37]

D. Content of the denial. The denial, in whole or in part, should be written in plain language and at a minimum must address all of the following:

1. The reason for the refusal.
2. A description of how the patient can request a review by the head of the state entity, or an official specifically designated by the head of the state entity.

The reviewer cannot be the same person who denied the patient's request initially

3. The name, title, and business address of the reviewing official.
4. A notice that the patient has a right to submit a written statement disagreeing with the denial with an explanation of how the patient may file such a statement.
5. A notice that, if the patient does not submit a statement of disagreement, the patient may request that any future disclosures of the disputed health information include the request for amendment and the denial.
6. A description of how the patient may file a complaint with the state entity or to the Secretary of the U.S. Department of Health and Human Services. The description must include the name or title and telephone number of the contact person for the complaint.
7. If the patient submits a written statement of disagreement:
 - a. The state entity may prepare a written rebuttal and is responsible to provide a copy of the written rebuttal to the patient.
 - b. The statement of disagreement must be included in any future disclosure of the health information with a clear indication of which portion of the medical record is disputed.

[45 C.F.R. §§164.526(d)(1) – (d)(3); CA Civil Code §§1798.35 - 1798.37]

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E. Documentation. All the following documentation must be appended (or otherwise linked) to the health information that is the subject of the disputed amendment and must be kept for six (6) years:

1. The patient's request for amendment
2. The organization's amendment denial letter
3. The patient's statement of disagreement, if any
4. The organization's written rebuttal, if any

[45 C.F.R §164.526(d)(4), and §164.530]

IV. References

45 C.F.R.

- §164.501
- §164.524
- §164.526
- §164.530

CA Civil Code

- §§1798.35 – 1789.37

CA Health and Safety Code §123111(a)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 –Patient's (Personal) Representatives

SHIPM Chapter 2 –Opportunity to Agree or Object

SHIPM Chapter 5 – Patient Rights - Access

VI. Attachments

None

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Chapter: 5 – Patient Rights		
Section: 5.3.0 – Notice of Privacy Practices		
5.3.1 – Notice of Privacy Practices		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

I. Purpose

To ensure that all [patients](#) are informed about state and federal requirements regarding their right to know how their [health information](#) will be used and [disclosed](#), and the actual [privacy](#) practices of the entities.

II. Policy

A Notice of Privacy Practices (NPP), which reflects the actual privacy practices of the entity, must be given to patients and must include all the following:

- ❖ The uses and disclosures of health information that may be made
- ❖ The patient's rights and how to exercise them
- ❖ The entities' legal duties to maintain privacy of health information.

All [state entities](#) that provide health care must comply with this policy.

[45 C.F.R. §164.520]

III. Implementation Specifics

A. Contents of the Notice of Privacy Practices. A complete list of the required components can be found in *Attachment A - Model Notice of Privacy Practices (see attached)*.

To validate that a Notice has the required components, please refer to *Attachment B - Notice of Privacy Practices Checklist (see attached)*.

B. Distribution of Notice to patients by [health care providers](#).

1. Health care providers with a [direct treatment relationship](#) (e.g., face-to-face treatment, telemedicine or [telehealth](#) interactions and phone consults) must:
 - a. Ensure the NPP is provided to the patient no later than the date of the first service delivery. If the first service is delivered electronically, the provider must send the NPP electronically, close to the time of service.
 - b. In an emergency situation, the NPP may be provided as soon as possible.
 - c. Post the NPP in a clear and visible location, like waiting rooms and registration areas, where patients can read the notice.

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- d. Prominently post the NPP, so that it stands out, on any website that the provider maintains containing information about the provider's services. Also make the NPP available electronically through the website.
 - e. Whenever updated, make the revised NPP available upon request and post the revised version in the facility and on the facility's website.
2. Health care providers with an indirect [treatment relationship](#) (e.g., laboratories, pharmacies) are only required to produce the NPP upon request.
- C. Distribution of NPP to patients by [health care plans](#). Health care plans must provide an NPP:
1. No later than the 2003 compliance date, to patients then covered by the plan; if you have not previously provided the NPP, you must provide it immediately.
 2. To patients who are new enrollees, at the time of enrollment, *and*
 3. To patients covered by the plan within 60 days of a material revision to the NPP (e.g., change in practices, law or uses and disclosures) or prominently post on its web site the change or providing a revised NPP by the effective date of the material change. In its next annual mailing to patients covered by the plan, the health plan must also provide the revised NPP, or information about the material change and how to obtain the revised NPP.
 4. To the named insured of the policy at least once every three years and notify the patients covered by the plan of the ongoing availability of the NPP and how to obtain a copy.
- D. Patient acknowledgement. Health care providers must make a good faith effort to obtain a written acknowledgement that the patient received the provider's NPP. Except in emergency [treatment](#) situations, providers are also required to document good faith efforts to obtain the acknowledgement, including addressing situations where a patient refuses to sign an acknowledgement. A model acknowledgement form is attached as *Attachment C, Notice of Privacy Practices - Acknowledgement of Receipt*.
- E. Health information must not be used or disclosed in any manner inconsistent with the Notice of Privacy Practices.
- F. Incidental uses and disclosures. There are certain incidental uses or disclosures of health information that may occur while providing services or conducting business. Reasonable efforts to limit these incidental uses and disclosures must be referenced in the NPP.
- G. Exceptions. Health care providers are not required to distribute the Notice to inmates. See *Attachment D: Notice of Privacy Practices FAQ* section on inmates.

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- H. Translation in other languages. The NPP must be translated and made available in all languages, other than English, frequently spoken by the health care provider's patient population, to ensure effective communication.
- I. Documentation requirements. NPPs shall be kept for a minimum of six (6) years from the later of the creation of the notice or the date the notice was last in effect:

IV. References

45 C.F.R.

- §164.502(i)
- §164.520(a)(1)
- §164.520(c)

CA Health and Safety Code

- §1259(c)(4)
- §12314

65 Federal Register 82, 462-01 (2000)

78 Federal Register 5, 566-01 (2013)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Incidental Disclosure

VI. Attachments

Yes:

A – Model Template Notice of Privacy Practices

B – Notice of Privacy Practices – Checklist

C – Notice of Privacy Practices – Acknowledgement of Receipt

D – Notice of Privacy Practices FAQ

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Chapter: 5 – Patient Rights		
Section: 5.4.0 – Patient Rights - Access		
5.4.1 – Patient Rights – Access		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding [patients](#)' rights, and limitations, to [access](#) their [health information](#).

II. Policy

[Patients](#) have the right to inspect, review, and obtain a copy of their [health information](#) held by [covered entities](#), [business associates](#), [health care plans](#), [health care providers](#), and [hybrid entities](#), with a few exceptions listed below.

[45 C.F.R. §164.504(e)(2)(ii)(E), §164.504(f)(2)(ii)(E), and §164.524]

III. Implementation Specifics

With a few exceptions, [state entities](#) that are covered entities, business associates, health care plans, health care providers, or hybrid entities have the responsibility to provide access to the health information they maintain in the [designated record set](#), upon patient request.

- ❖ For organizations with a designated record set, patient access is limited to the health information defined in the designated record set for as long as the health information is maintained in the designated record set.
- ❖ For organizations without a designated record set, patient access is allowed for all health information in the possession of the organization, with the exception of health information covered by policies found in SHIPM Chapter 2 - Specially Protected Information (for example, Psychotherapy Notes).

[45 C.F.R. §164.524; CA Health and Safety Code §123110; CA Civil Code §1798.34]

A. Patients have the following rights to access their health information:

1. Inspect or receive a copy of health information within prescribed timeframes. Upon receiving a request to [access](#), inspect, or receive a copy of the designated record set, the state entity is responsible to do all the following:

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- a. To grant access to inspect health information or billing records within five (5) business days. *[CA Health and Safety Code §123110, and §123115]*
- b. To receive copies of health information, related to health history, diagnosis, condition of the patient, or to [treatment](#) provided, or to billing records and other elements of the designated record set within 15 days.
[CA Health and Safety Code §123110]
- c. To provide a copy of the patient's health information within 15 days of the receipt of [payment](#) for copies and an [authorization](#)
- d. To advise the patient in writing within 60 days where to direct their request for access, if the state entity does not maintain the designated record set (*if the state entity knows where the requested health information is maintained by the business associate or third party*)
- e. Within 30 days of receipt of a written request, provide a copy at no charge of the portion of the patient's medical records necessary to support an appeal regarding eligibility for the following public benefits: Medi-Cal, Social Security disability insurance benefits, Supplemental Security Income, State Supplementary Program for the Aged, Blind, and Disabled.

[CA Health and Safety Code §123110(d)]

[45 C.F.R. §§164.524(a) – (d); CA Health and Safety Code §123110, and §123110(c)]

2. Obtain medical records in the format they choose. If it is reasonable to do so, the state entity must provide the health information in the format requested by the patient such as a readable hard copy or in some other form that can be agreed upon by the state entity and the patient. *[45 C.F.R. §164.524(c)(4)(ii)]*
 - a. The state entity may not deny access or refuse to provide copies of the health information based on a disagreement as to format.
 - b. If the state entity maintains the health information in an electronic medical record, the state entity must provide the patient with an electronic copy of that health information, if the patient chooses, and any fees are limited to the labor and supply costs for putting the electronic copy on the portable media.
 - c. A state entity may provide a summary or explanation of the health information requested if the patient agrees in advance, both to receive records as a summary and to the proposed fees. If a summary is to be provided to the patient, it must be done within 10 working days from the date of the patient's request.

[CA Health and Safety Code §123130]

If more time is needed to prepare the summary, the patient must be notified as such, along with the date the summary will be completed, but not more than 30 days after the patient's request.

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[45 C.F.R. §164.524(c)(2); CA Health and Safety Code §123130]

The summary shall contain for each injury, illness, or episode any information included in the record relative to the following:

- i. Chief complaint or complaints including pertinent history
 - ii. Findings from consultations and referrals to other health care providers
 - iii. Diagnoses, where determined
 - iv. Treatment plan and regimen including medications prescribed
 - v. Progress of the treatment
 - vi. Prognoses including significant continuing problems or conditions
 - vii. Pertinent reports of diagnostic procedures and tests and all discharge summaries.
 - viii. Objective findings from the most recent physical examination, such as blood pressure, weight, and actual values from routine laboratory tests.
 - ix. The summary shall contain a list of all current medications prescribed, including dosage, and any sensitivities or allergies to medications recorded by the provider.
3. To know why access was denied. If access is denied, the state entity must provide a written denial in plain language to the patient that includes all of the following:
- a. The basis for the denial
 - b. An explanation of the patient's review rights
 - c. A description of how the patient may request a review of the denial, including the name or title, and telephone number of the state entity's Privacy Official designated to receive complaints or requests for review.
4. When a health care provider determines there is a substantial risk of significant adverse or detrimental consequences to a patient in seeing or receiving a copy of [mental health records](#) (MHRs) requested, the provider may decline to permit inspection or provide copies of the records to the patient, subject to all the following conditions:
- a. The health care provider shall make a written record, to be included with the mental health records requested, noting the date of the request and explaining the health care provider's reason for refusing to permit inspection or provide copies of the records, including a description of the specific adverse or detrimental consequences to the patient that the provider anticipates would occur if inspection or copying were permitted.
 - b. The health care provider shall permit inspection by, or provide copies of the mental health records to, a licensed physician and surgeon, licensed

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- psychologist, licensed marriage and family therapist, licensed clinical social worker, or licensed professional clinical counselor, designated by request of the patient.
- c. The health care provider shall inform the patient of the provider's refusal to permit inspection or receipt of copies of the requested records, and inform the patient of the right to require the provider to permit inspection by, or provide copies to, a licensed physician and surgeon, licensed psychologist, licensed marriage and family therapist, licensed clinical social worker, or licensed professional clinical counselor designated by written authorization of the patient.
 - d. The health care provider shall indicate in the MHRs of the patient whether the request was made.
[45 C.F.R. §160.306, §164.524(d)(2), §164.530(a)(1)(ii), and §164.530(d); CA Health and Safety Code §123115(b)]
5. Have any denial reviewed by reviewing official. State entities are responsible to designate a licensed health care professional to act as the reviewing official. The reviewing official may not have participated in the denial of access decision and must provide a written decision to the patient within a reasonable time period.
[45 C.F.R. §164.524(a)(4), and §164.524(d)(4)]
 6. Not to have access to health information denied due to unpaid bills. State entities shall not deny access, or refuse to provide copies, because of an unpaid bill for [health care services](#). *[CA Health and Safety Code §123110(j)]*
 7. Access by minors. State entities shall allow a patient, who is a minor, to inspect or obtain copies of health information pertaining only to health care of a type for which the minor is lawfully authorized to consent.
[45 C.F.R. §164.502(g)(3); CA Health and Safety Code §123110]
 8. Be charged only reasonable fees. State entities may charge reasonable fees for copying (including supplies and labor), postage, and the cost of creating a summary, if requested.
 - a. Fees may not exceed 25 cents (\$.25) per page, or 50 cents (\$.50) per page for records that are copied from microfilm, and any additional reasonable clerical costs in making the records available. *[CA Health and Safety Code §123110(b)]*
 - b. If the records are provided in electronic form, fees are limited to the labor costs and supplies for putting the electronic copy on the portable media.
 - c. For requests for health information to support an appeal regarding eligibility for a public benefit program (e.g., Medi-Cal, Social Security disability insurance, or Supplemental Security Income or State Supplementary Program for the Aged, Blind and Disabled), patients are entitled to receive one copy free of charge

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provided that the patient makes the request in writing and provides proof that health information is needed. [45 C.F.R. §164.524(c)(4)]

9. Release of information. Patients may designate another person (including a [patient representative](#)) to whom the state entity must provide access to the patient's health information. [45 C.F.R. §164.524(c)(3)(ii); CA Civil Code §56.10(b)(9)]
10. Patient representatives. For access purposes, patient representatives are treated in the same manner as the patient who is the subject of the health information. [45 C.F.R. §164.502(g)(1); CA Health and Safety Code §123110]
 - a. Minor patients. The patient representative of a minor shall not be entitled to inspect or obtain copies of the minor health information in the following scenarios:
 - i. When the minor patient has a right to inspect or obtain copies [CA Health and Safety Code §123110]
 - ii. If the health care provider determines that access to the health information, requested by the patient's representative, would have a detrimental effect on the provider's professional relationship with the minor patient, or the minor's physical safety or psychological well-being [45 C.F.R. §164.502(g)(3)(ii)(B); CA Health and Safety Code §123115]
 - iii. If a psychotherapist knows that the minor patient has been removed from the physical custody of his or her parent or guardian.

This restriction shall not apply, if the juvenile court has issued an order authorizing the parent or guardian to inspect or obtain copies of the mental health information of the minor patient, after finding that such an order would not be detrimental to the minor patient.

[45 C.F.R. §164.502(g)(3)(ii)(B); CA Health and Safety Code §123116]
 - iv. State entities may elect not to treat an individual as the patient's representative if there is a reasonable belief that:
 - a) The patient has been, or may be subject to domestic violence, abuse, or neglect by the individual
 - b) Treating such individual as the patient's representative could endanger the patient
 - c) The state entity, in the exercise of their expert knowledge and opinion, decides that it is not in the best interest of the patient to treat the individual as the patient's representative [45 C.F.R. §164.502(g)(5)(i)]
- B. Exceptions to granting access. The following are reasons that state entities can deny patients access to their health information:

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1. The state entity does not have the patient's health information as part of their designated record set. If this is the case, the state entity must notify the patient in writing that it does not maintain the patient's health information.
 2. Health information compiled in anticipation of a civil, criminal, or administrative action or proceeding, and not otherwise made confidential (*State entities are encouraged to discuss each request with their legal counsel*).
[45 C.F.R. §164.524(a)(1)(ii)]
 3. Denial of patient access without opportunity for review of request. A state entity may deny a patient access without providing the patient an opportunity for review in the following circumstances (*State entities should confer with their legal counsel for these certain exceptions*):
 - a. Health information that was obtained from a third party, other than the health care provider, under a promise of [confidentiality](#) and the access requested would likely identify the source.
[45 C.F.R. §164.524(a)(2); CA Health and Safety Code §11845.5(c)(4)]
 4. Denial of patient access with right to review of denial. A state entity may deny a patient access if the patient is given the right to have denials reviewed under the following circumstances:
 - a. A licensed health care professional determined that access could endanger the life or physical safety of the patient or another person.
[45 C.F.R. §164.524(a)(3)(i)]
 - b. The requested health information references another person (other than a health care provider) and a licensed health care professional has determined that access is reasonably likely to cause substantial harm to that other person.
[45 C.F.R. §164.524(a)(3)(ii)]
 - c. The request is made by the patients' representative, and a licensed health care professional has determined that access is reasonably likely to cause substantial harm to the patient or another person.
[45 C.F.R. §164.524(a)(3)(iii)]
- C. Laboratory records. State entities are responsible to provide patients access to their laboratory results within 15 days. When the patient requests access to lab results, and:
1. The state entity has no access to a physician to review the request, the state entity must comply with the request of the patient.
 2. The state entity has access to a physician to review, the laboratory results must be reviewed prior to release to the patient.

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[CA Civil Code §§56.10 –56.11;CA Health and Safety Code §120980(f), §120990, and §123148]

D. Administrative responsibilities. State entities that are covered entities, business associates, [health care clearinghouses](#), health care providers, health care plans, or hybrid entities have the following administrative responsibilities regarding health information access requests:

1. Policy and Procedure. State entities are responsible to implement policies and procedures for:
 - a. Providing access for the patient (or patient representative) to the patient's health information.
 - b. Non-discrimination in the transmittal of x-rays, or other patient records. A health care provider may establish reasonable conditions, including a reasonable deposit fee, to ensure the return of the original x-rays transmitted to another health care provider, provided the conditions do not discriminate on the basis of, or in a manner related to, the license of the provider to which the x-rays are transmitted.

[CA Health and Safety Code §§123110-123149.5]

2. Include in Notice of Privacy Practices (NPP). The NPP must provide information that describes how a patient can request access in writing to health information, and how to request a review of denial of access. *[45 C.F.R. §164.520(b)(iv)(C), and §164.524]*
3. Verify identity. State entities are responsible to require reasonable verification of identification prior to permitting inspection or copying of patient records. This requirement shall not be used oppressively or discriminatorily to hinder or delay compliance with these provisions (see *SHIPM Chapter 3, Verification of Identity*).
4. Document. A state entity is responsible to develop and implement policies and procedures regarding the following:
 - a) What is included in the designated record sets, and that patients may access the designated record sets
 - b) The titles of the persons or offices responsible for receiving and processing patient requests for access.

[45 C.F.R. §164.524(e)]

5. Retain Documents. Documentation relating to requests for access must be retained for six (6) years from the date of its creation or the date when it last was in effect, whichever is later.

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IV. References

45 C.F.R.

- §160.306
- §164.502(b)(4)(C)
- §164.502(g)(1)
- §164.502(g)(3)
- §164.502(g)(5)(i)
- §164.504(e)(2)(ii)(E)
- §164.504(f)(2)(ii)(E)
- §164.524(a)(1) – (e)
- §164.530(a)(1)(ii)
- §164.530(d)

CA Civil Code

- §§56.10 – 56.11
- §56.106
- §§1798.30 – 1798.44

CA Health and Safety Code

- §11845.5(c)(4)
- §§120110(c), and (h)
- §120980(f)
- §120990
- §§12300 – 12349.5
- §123110
- §123110(c)
- §123115

CA Welfare and Institutions Code

- §5328(b), (j), (k), and (d)
- §5328.04

5 United States Code §552a

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 2 – Authorizations

SHIPM Chapter 2 – Mental Health Records

SHIPM Chapter 2 – Psychotherapy Notes

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SHIPM Chapter 2 – Patient’s (Personal) Representative

SHIPM Chapter 3 – Verification of Identity

SHIPM Chapter 5 – Amendments

SHIPM Chapter 5 – Notice of Privacy Practices

SHIPM Chapter 5 – Restriction for Self-Pay and Confidential Communication

VI. Attachments

None

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Chapter: 5 – Patient Rights		
Section: 5.5.0 – Restriction for Self-Pay and Confidential Communication		
5.5.1 – Restriction for Self-Pay and Confidential Communication		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

I. Purpose

To provide guidance regarding the requirements to address a [patient's](#) right to restrict disclosure of their [health information](#) and the obligation to address a patient's request to receive confidential communications.

II. Policy

Patients have a right to request [privacy](#) protection for health information including the restriction of uses or [disclosures](#) and/or a request to receive communications by alternative means or at alternative locations.

III. Implementation Specifics

A. Patients have the right to restrict the use and disclosure of their own health information when they have self-paid for services. [State entities](#) are responsible to comply with a patient's request that health information not be disclosed to a [health care plan](#) for [payment](#) or [health care operations](#) *only* if the health information is related to services that have been paid out-of-pocket in full, either by the patient, or by another person on the patient's behalf.

[45 C.F.R. §164.522(a), and §164.522(b)]

1. A state entity *must* honor the patient's restriction request *if* either are met:
 - a. The disclosure is for the purpose of carrying out payment or health care operations
 - b. The disclosure is not otherwise required by law

[45 C.F.R §164.522(a), and §164.510(b)]

2. Restriction requests should be in writing. If the patient cannot or will not submit the request in writing, the [workforce](#) member receiving the request should document the request in writing.
3. A state entity is not obligated to restrict the use of health information under any of the following circumstances:

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- a. If the patient was informed in advance and had the opportunity to agree, object, or restrict the sharing of health information.

[45 C.F.R. §164.510]

- b. When an [authorization](#) is not required

[45 C.F.R. §164.512]

4. Denial of restriction request. A state entity can deny the requested restriction if the request is related to services that were not paid for in full by the patient or on the patient's behalf.

[45 C.F.R. §164.522(a)]

5. Exceptions to restricted use and disclosure of health information. Exceptions include [psychotherapy notes](#), information compiled for use in civil, criminal or administrative actions, and information that is subject to prohibition by the Clinical Laboratory Improvements Amendments.

Please contact your organization's legal office prior to developing or implementing operational policies and procedures to comply with this section of the implementation specifics.

[42 C.F.R. §493]

6. Termination of restriction. A state entity may terminate a restriction *if* either of the following occurs:

- a. The patient requests the termination in writing
- b. The patient agrees to or requests the termination orally and a workforce member documents the request

[45 C.F.R. §164.522]

B. Confidential communications.

1. State entities must accommodate any reasonable request by a patient to receive confidential communications from a state entity regarding health information by alternative means or at alternative locations provided that all the following conditions are satisfied:

- a. The request is provided in writing
- b. An alternative address or other method of contact is provided
- c. When appropriate, information as to how payment, if any, will be handled

[45 C.F.R. §164.522]

2. A patient is not required to provide an explanation for the request and the request cannot be denied solely because an explanation was not given. State entities may not ask for an explanation from the patient as to why the request is being made.

[45 C.F.R. §164.522]

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3. State entities are responsible to develop a process to ensure the appropriate patient address and/or phone number is recorded in the system or medical record and is used when communicating with the patient.

[45 C.F.R. §164.522]

C. Documentation. State entities are responsible to do all the following:

1. Document all requests for health information use or disclosure restriction, or confidential communication
2. Document the reason for a denial of request for restriction or confidential communication
3. Maintain correspondence and associated documentation related to patient requests for restriction or confidential communications, including denials, in the patient's medical record, in accordance with the records retention policy (*for a minimum of six (6) years*)

[45 C.F.R. §164.522(b), and §164.530(j)]

IV. References

42 C.F.R. §493

45 C.F.R.

- §164.510
- §164.512
- §164.522
- §164.530(j)

V. Related Policies

SHIPM Chapter 1 – CalOHII Authority

SHIPM Chapter 4 – Business Associates

VI. Attachments

None

SHIPM Definitions

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SHIPM Definitions		
Review Date: 06/01/2016	Revision Date: 06/01/2016	Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Term	Definition
Access	<p><u><i>IT related:</i></u> The ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. [source: 45 C.F.R. §134.304]</p> <p><u><i>Non-IT related:</i></u> The right of an individual, or his or her patient representative, to inspect and/or obtain a copy of the individual's health information. [source: 45 C.F.R. §164.524]</p>
Addressable [security]	<p>There are two classes of security safeguards - <i>required</i> and <i>addressable</i>. Addressable safeguards allow an organization to determine what is reasonable and appropriate, considering the likely contribution to protecting health information for that specific organization. The organization must either implement the requirement, or document why the requirement would not be appropriate and implement an equivalent alternative safeguard measure [source: 45 C.F.R. §164.306(d)(3)]</p>
Administrative Safeguards [security]	<p>Administrative actions and policies and procedures to manage the selection, development, implementation, and maintenance of security measures to protect electronic health information, and to manage the conduct of the covered entity's or business associate's workforce in relation to the protection of that health information. [source: 45 C.F.R. §164.306(d)(3)]</p>
Agents	<p>A person or business authorized to act on another's behalf. [source: Agents defined http://www.thesaurus.com/]</p>
AIDS	<p>Acquired Immunodeficiency Syndrome (AIDS). A disease of the immune system characterized by increased susceptibility to opportunistic infections, to certain cancers and to neurological disorders. [source: AIDS defined www.thesaurus.com]</p>
Authentication	<p>The corroboration that a person is the one claimed. [source: 45 C.F.R. §164.304]</p>
Authorization	<p><u><i>IT related:</i></u> the act of granting a user, program, process or device access to information assets after proper identification and authentication are obtained. [source: CA CIO website http://www.cio.ca.gov/OIS/Government/definitions.asp]</p> <p><u><i>Non-IT related:</i></u> a detailed document signed and dated by the patient that grants permission for the covered entity to use or disclose health information, for specified purposes. [source: 45 C.F.R. §164.508]</p>

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Term	Definition
Availability	The reliability and accessibility of information assets to authorized personnel in a timely manner. [source: CA CIO website ; and 45 C.F.R. §164.304]
Breach	The unauthorized acquisition, access, use or disclosure of unsecured health information in a manner not permitted, which compromises the security or privacy of the health information. [source: 45 C.F.R. §164.402; CA Civil Code §1798.82]
Business Associate (BA)	Is a person or entity that performs certain functions or activities that involve the use or disclosure of health information on behalf of, or provides services to, a covered entity. A member of the covered entity's workforce is not a Business Associate. [source: 45 C.F.R. §160.103]
Business Associate Agreement (BAA)	A contract between a HIPAA covered entity and a HIPAA business associate (BA). The contract protects health information in accordance with HIPAA guidelines. [source: 45 C.F.R. §164.504(e)]
CA	A two-letter abbreviation used to represent California. [source: USPS website http://pe.usps.gov/text/pub28/28apb.htm]
Confidentiality	A security and privacy principle that works to ensure that information is not disclosed to unauthorized persons. [source: CA CIO website http://www.cio.ca.gov/OIS/Government/definitions.asp ; and 45 C.F.R. §164.304]
Covered Entity	The following individuals or organizations that directly handle health information or Personal Health Records (PHRs): <ul style="list-style-type: none"> • A Health Plan • A Health Care Clearinghouse • A Health Care Provider who transmits any health information in electronic form in connection with a standard transaction covered by HIPAA. [source: 45 C.F.R. §160.103]
Covered Functions	Functions performed by a covered entity that makes the entity a health care provider, health plan, or health care clearinghouse under the HIPAA Administrative Simplification Rules. [source: HHS National Institutes of Health website http://privacyruleandresearch.nih.gov/dictionary.asp (paraphrased)]

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Term	Definition
De-identified Information	<p>Information that has been redacted such that any identifying information has been removed and there is no reasonable basis to believe that the information can be used to re-identify the patient.</p> <p><i>This process of de-identification mitigates privacy risks to patients and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research and other endeavors.</i></p> <p>[source: HHS website http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification; and 45 C.F.R. §164.514(a) (paraphrased)]</p>
Designated Record Set	<p>A group of records maintained by, or for a covered entity that may include patient medical and billing records; the enrollment, payment, claims, adjudication, and cases or medical management record systems maintained by or for a Health Plan; or information used in whole or in part to make care-related decisions. [source: 45 C.F.R. §164.501]</p>
Developmental Services Records	<p>All information and records obtained in the course of providing intake, assessment, and services covered under Division 4.1, Division 4.5, Division 6, or Division 7 of the Welfare and Institutions Code to persons with developmental disabilities.</p> <p>[source: CA Welfare and Institutions Code §4514]</p>
Direct Treatment Relationship	<p>A treatment relationship between a patient and a health care provider that is not an indirect treatment relationship. [source: 45 C.F.R. §164.501]</p> <p><i>(Indirect Treatment Relationship: A relationship between a patient and a health care provider, where the provider:</i></p> <ul style="list-style-type: none"> • <i>delivers health care to the patient based on the orders of another health care provider</i> • <i>typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides services or products or reports to the patient.)</i>
Disability Rights California	<p>The disability rights protection and advocacy agency for the State of California, authorized by federal and state regulations. The agency is further described on its website at Disability Rights California www.disabilityrightscalifornia.org.</p> <p>[source: 45 U.S.C. §15043(a), and §10805; CA Welfare and Institutions Code §4903]</p>
Disclose	<p>The release, disclosure, transfer, dissemination, or to otherwise communicate all or any part of any record orally, in writing, or by electronic or any other means to any person or entity. [source: 45 C.F.R. §164.103; CA Civil Code §1798]</p>

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Term	Definition
Electronic Data Interchange (EDI)	The electronic exchange, via information systems, of business data in standard electronic formats between business partners. [source: EDI website http://www.edibasics.com]
Electronic Health Record	An electronic record of health information on a patient that is created, gathered, managed, and consulted by authorized health care providers and staff. [source: EHR defined http://www.hipaa.com/the-definition-of-electronic-health-record/]
Employer	Any person or organization acting directly to engage the services of members of a workforce, or indirectly in the interest of a person or group engaging the services of members of a workforce, in relation to an employee benefit plan; and includes a group or association of employers acting for an employer in such capacity. [source: ERISA - 29 U.S.C. §1002(5)]
Encryption	Rendered unusable, unreadable, or indecipherable to an unauthorized person through a security technology or methodology generally accepted in the field of information security. [source: CA Civil Code 1798.82]
Fundraising	The process of gathering voluntary contributions of money or other resources, by requesting donations from individuals, businesses, charitable foundations, or governmental agencies. [source: Fund raising defined: http://en.wikipedia.org/wiki/Fundraising (paraphrased)]
Genetic Information	<p>Information about any of the following:</p> <ul style="list-style-type: none"> • a patient’s genetic tests; • the patient’s family members’ genetic tests; • the manifestation of a disease or disorder in family members of such a patient; <i>or</i> • any request for or receipt of genetic services or participation in clinical research which includes genetic services by the patient or any family member of the patient. <p>Genetic information includes:</p> <ul style="list-style-type: none"> • information about the fetus of a patient or family member who is pregnant; <i>and</i> • any embryo legally held by a patient or family member utilizing an assisted reproductive technology. <p><i>Genetic services as used in the definition of “genetic information” means: a genetic test, genetic counseling, or education.</i> [source: HIPPA Final Rule https://www.hipaa.com/hipaa-final-rule-genetic-information-nondiscrimination-act-gina-definitions/]</p>

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Term	Definition
Group Health Plan	<p>A program that, directly or through insurance or reimbursement, provides services and goods paid for as medical care to employees or their dependents, <i>and</i>:</p> <ul style="list-style-type: none"> • Has 50 or more participants, <i>or</i> • Is administered by an entity other than the employer that established and maintains the plan <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • <i>employer-provided health insurance or HMO participation</i> • <i>union-sponsored health plans</i> • <i>multi-jurisdictional public employee health plans</i> • <i>employer-coalition reimbursement plans</i> • <i>a health insurance issuer or HMO providing health care good and services to the group health plan</i> <p>[source: 45 C.F.R. §160.103; 29 U.S.C. §1002(1); 42 U.S.C. §§300gg-91(a)(1)]</p>
Health Care Clearinghouse	<p>A public or private entity, including a billing service, repricing company, community health management information system or community health information system, and “value-added” networks and switches, that does either of the following functions:</p> <ul style="list-style-type: none"> • Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a HIPAA compliant transaction. • Receives a HIPAA compliant transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity. <p>[source: 45 C.F.R. 164.103]</p>
Health Care Component	<p>The part(s) (or component(s)) of a hybrid entity that perform functions covered by HIPAA. [source: 45 C.F.R. §164.103, and §164.105(a)]</p>

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Term	Definition
Health Care Operations	<p>Activities relating to covered functions of a business associate, health care clearinghouse, health care plan, health care provider or hybrid entity. Including, but not limited to:</p> <ul style="list-style-type: none"> • Conducting quality assessment and improvement activities; patient safety activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment • Licensing and accreditation • Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities • Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care • Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs • Business planning and development • Business management and general administrative activities of the entity. <p>[source: 45 C.F.R. §164.501; CA Civil Code §56.10(c)]</p>

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Term	Definition
Health Care Plan or Health Plan	<p>An individual or group plan that provides, or pays the costs of, medical care and includes the following, singly or in:</p> <ul style="list-style-type: none"> • a group plan, a health insurance issuer, a health care service plan • an HMO • Part A, B or D of the Medicare program, or a supplemental policy thereof • a long-term care policy excluding a nursing home fixed indemnity policy, • an employee welfare benefit plan • a healthcare program for uniformed services, a veterans health care program • an Indian Health Services program • the Federal Employees Health Benefits Program • an approved state child health plan • a Medicare Advantage program • a high risk pool established under state law to provide health insurance coverage or comparable coverage • any other individual or group plan or combination of individual or group plans that provides or pays for the cost of medical care <p>[source: 45 C.F.R. §160.103; CA Civil Code §56.05]</p>
Health Care Provider	<p>Any person or organization that furnishes, bills, or is paid for health care in the normal course of business.</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • <i>Doctors</i> • <i>Clinics</i> • <i>Psychologists</i> • <i>Dentists</i> • <i>Chiropractors</i> • <i>Nursing Homes</i> • <i>Pharmacies</i> <p><i>Health Care Providers must comply with HIPAA, only if they transmit health information electronically in connection with a HIPAA covered transaction.</i></p> <p>[source: 45 C.F.R. §160.102, and §160.103]</p>

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Term	Definition
Health Care Services	<p>Care, services or supplies related to the health of a patient. It includes, but is not limited to:</p> <ul style="list-style-type: none"> • Preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, of functional status, of an individual or that affects the structure or function of the body; and • Sale of dispensing of a drug, device, equipment, or other item in accordance with a prescription. [source: 45 C.F.R. §160.103]
Health Information	<p>Any name in combination with any other information related to the provision of health care that can lead a person to reasonably identify the patient.</p> <p><i>This SHIPM definition incorporates and synthesizes State of CA and federal definitions, including:</i></p> <ul style="list-style-type: none"> • <i>Protected Health Information</i> • <i>Electronic Health information</i> • <i>Individually Identifiable Health Information</i> • <i>Personal Information</i> • <i>Medical Information</i> • <i>Confidential and Private information</i> <p><i>Special note: Health Information as used in the SHIPM does not include information and records covered by other federal or state laws regarding substance abuse treatment records, mental/behavioral health records, developmental services records, HIV, genetic information.</i></p> <p><i>See policies covering Specially Protected Information for these rules.</i></p> <p>[source: 45 C.F.R. §160.103; CA Civil Code §56.05, and §1798.3]</p>
Health Information Exchange (HIE)	<p>The capability to electronically move health information among disparate health care information systems, and maintain the meaning of the information being exchanged.</p> <p><i>The goal of HIE is to facilitate access to, and retrieval of, clinical data to provide safe, timely, efficient, effective, equitable and patient-centered care.</i></p> <p>[source: Health Information Exchange http://www.himss.org/library/health-information-exchange]</p>
Health Information Organization (HIO)	<p>An organization that oversees and governs the exchange of health information among stakeholders within a defined geographic area, for improving health and care in that community.</p> <p>[source: HIMSS website http://www.himss.org/library/health-information-exchange]</p>

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Term	Definition
Health Oversight Activities	<p>The oversight of the health care system (whether public or private), as well as government benefit programs, entities subject to government regulatory programs and entities subject to civil rights laws. These oversight activities include:</p> <ul style="list-style-type: none"> • Audits • Civil, administrative or criminal investigations • Inspections • Licensure or disciplinary action • Civil, administrative or criminal proceedings or actions <p>[source: 45 C.F.R. §164.512(d)(1) (<i>paraphrased</i>)]</p>
Health Oversight Agency	<p>A person, or entity, at any level of the federal, state, local, or tribal government that oversees the health care system or requires health information to determine eligibility, or compliance, or to enforce civil rights laws.</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • State health professional licensure agencies • Department of Justice and their civil rights enforcement activities • State Medicaid fraud control units • Food and Drug Administration • State licensing boards to the extent granted authority under state law <p>[source: 45 C.F.R. §164.501 (<i>paraphrased</i>)]</p>
HIV/AIDS Test Results	<p>The results of any clinical test, laboratory or otherwise, used to identify HIV and/or AIDS, a component of HIV and/or AIDS, or antibodies or antigens to HIV. [source: CA Health and Safety Code §120775(c)]</p>
Human Immunodeficiency Virus (HIV)	<p>A variable retrovirus that invades and inactivates helper T cells of the immune system and is a cause of AIDS and AIDS-related complex. [source: HIV defined http://dictionary.reference.com/browse/HIV]</p>
Hybrid Entity	<p>A single legal entity that is:</p> <ul style="list-style-type: none"> • A business associate, health care clearinghouse, health care plan, or health care provider whose business activities include both HIPAA covered and non-covered functions; <i>and</i> • That designates the HIPAA covered health care components and creates adequate “firewalls” between covered and non-covered healthcare components in accordance with the law. <p><i>Example of a hybrid entity:</i> <i>A state entity that provides health care and health care oversight functions</i> [source: 45 C.F.R. §164.103]</p>

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Term	Definition
Implementation	<p>The act of fulfillment, or carry out. To put into effect according to or by means of a definite plan or procedure.</p> <p><i>Implementation also includes initializing and complying with policies and procedures, as well as maintaining them.</i></p> <p>[source: Implementing defined http://dictionary.reference.com/browse/implementing]</p> <p>For policies and procedures (P&Ps) – Implementation includes training all workforce members on the specifics of the policies and procedures, complying with all requirements in the SHIPM, and maintaining P&Ps by reviewing and revising as business practices and/or regulations change.</p> <p>[source: CalOHII Authority]</p>
Incidental Disclosure	<p>A secondary disclosure that cannot reasonably be prevented, is limited in nature, and occurs as a result of another use or disclosure that is permitted.</p> <p><i>For example, a health care professional calling out a patient's name in a crowded waiting room.</i></p> <p>[source: HHS website http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/incidentalusesanddisclosures.html]</p>
Individually Identifiable Health Information	<p>Information that is a subset of health information, including demographic information, collected from a patient, <i>and</i>:</p> <ul style="list-style-type: none"> • is created or received by a health care provider, health plan, employer or health care clearinghouse, <i>and</i> • relates to past, present, or future physical or mental health or condition of a patient; or the past, present, or future payment for the provision of health care to a patient, <i>and</i> <ul style="list-style-type: none"> ○ that identifies the patient, <i>or</i> ○ with respect to which there is a reasonable basis to believe the information can be used to identify the patient <p>[source: 45 C.F.R. §160.103]</p>
Institutional Review Board (IRB) / Privacy Board	<p>An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. IRBs have the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.</p> <p>[source: HHS website http://www.hhs.gov/ohrp/archive/irb/irb_chapter1.htm; and 45 C.F.R. §§164.512(i)(i)(A) - (B)]</p>
Integrity	<p>The property that data or information has not been altered or destroyed in an unauthorized manner. [source: 45 C.F.R. §164.304]</p>

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Term	Definition
Law Enforcement Official	<p>An officer or employee of any agency or authority of the United States, a state, a territory, a political subdivision or a state or territory, or an Indian tribe, who is empowered by law to:</p> <ul style="list-style-type: none"> • Investigate or conduct an official inquiry into a potential violation of law, or • Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law. <p>[source: 45 C.F.R. §164.103]</p>
Limited Data Set	<p>Health information that excludes the following direct identifiers of the patient, or of relatives, employers, or household members of the patient:</p> <ul style="list-style-type: none"> • Names • Postal address information, other than town or city, state, and zip code • Telephone and Fax numbers • Electronic Mail addresses • Social Security numbers • Medical record numbers • Health Plan beneficiary numbers • Account numbers • Certificate / License numbers • Vehicle identifiers and serial numbers, including license plate numbers • Device identifiers and serial numbers • Web Universal Resource Locators (URLs) • Internet Protocol (IP) address numbers • Biometric identifiers, including finger and voice prints • Full face photographic images and any comparable images <p>[source: 45 C.F.R. §164.514(e)(2)]</p>
Look-back	<p>A study of persons exposed to a disease, from whom specimens – e.g., sera, epidemiologic, demographic or other related data, is examined retrospectively to determine whether they are currently infected.</p> <p>[source: Look-back Program defined http://medical-dictionary.thefreedictionary.com/look-back+program]</p>
Marketing	<p>A communication about a product or service that encourages recipients of the communication to purchase or use the product or service. The entity may receive financial remuneration in exchange for making the communication. [source: 45 C.F.R. §164.501]</p>

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Term	Definition
Mental Health Records	<p>Information and records related to all involuntary treatment; all voluntary treatment at a state or local hospital, developmental center, psychiatric hospital or unit, obtained in the course of providing services under the following provisions of California’s Welfare and Institutions Code:</p> <ul style="list-style-type: none"> • Division 4 and 5 (concerning mental health services) • Division 6 (concerning voluntary admissions to state hospitals) • Division 7 (concerning psychiatric services in county hospitals) <p>[source: CA Civil Code §56.104; CA Welfare and Institutions Code §5328]</p>
Mental Health Professional	<p>Licensed professional, or social worker with a master’s degree in social work, responsible for providing patient services under the following provisions of California’s Welfare and Institutions Code:</p> <ul style="list-style-type: none"> • Division 4 and 5 (concerning mental health services) • Division 6 (concerning voluntary admissions to state hospitals) • Division 7 (concerning psychiatric services in county hospitals) <p>[source: CA Welfare and Institutions Code §5328]</p>
Minimum Necessary	<p>The amount of information, to the extent necessary, to accomplish the intended purpose of a use, disclosure or request.</p> <p>[source: 45 C.F.R. §164.502(b), and §164.514(d)]</p>
Mobile Devices	<p>Portable computing devices that can connect by cable, telephone wire, wireless transmission, or via any internet connection to an IT infrastructure and/or data systems.</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • Laptops • Cellular smart phones • Personal digital assistants • Blackberries • Tablet personal computers • Portable hard drives <p>[source: CA CIO website http://www.cio.ca.gov/OIS/Government/definitions.asp]</p>
Multiple Covered Functions	<p>Those functions of a covered entity that operationally designate the entity as any combination of the following under the HIPAA Administrative Simplification Rules: health care provider, health plan, or health care clearinghouse.</p> <p>[source: National Governors Association document http://www.nga.org/files/live/sites/NGA/files/pdf/FACTSHIPAAHYBRID.pdf, (paraphrased)]</p>

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Term	Definition
Patient	<p>Any natural person who is receiving health care services from a health care provider and to whom the health information pertains.</p> <p><i>This SHIPM definition combines terms from:</i></p> <ul style="list-style-type: none"> • HIPAA – Person and Individual • CMIA (CA Civil Code §56.10) – Enrollee and Patient • IPA (CA Civil Code §1798) – Individual and Person <p>[source: 45 C.F.R. §160.103; CA Civil Code §56.05, and §1798.3]</p>
Patient's Representative	<p>A person who:</p> <ul style="list-style-type: none"> • Has the authority under law to make health care decisions for another person, <i>or</i> • Has the authority to administer the estate of a deceased person (including execution administrator) <p><i>An individual should not be treated as the patient's representative, if:</i></p> <ul style="list-style-type: none"> • <i>There is a reasonable belief that the individual has or will abuse/neglect/treat the patient with violence, <u>and</u></i> • <i>May endanger the patient if the information is provided to the individual, <u>and</u></i> • <i>It would not be in the best interest of the patient to treat the individual as the patient's representative</i> <p>[source: HHS website http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/personalreps.html; and 45 C.F.R. §164.502(g)]</p>
Payment	<p>The activities undertaken by:</p> <ul style="list-style-type: none"> • A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan (except as prohibited under §164.502(a)(5)(i)); <u>or</u> • A health care provider or health plan to obtain or provide reimbursement for the provision of health care. <p>[source: 45 C.F.R. §164.501; CA Civil Code §56.10(c)]</p>
Pharmaceutical Company	<p>Any company or business (including its agents or representatives) that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. [source: 45 C.F.R. §160.103]</p>
Physical Safeguards <i>[security]</i>	<p>The physical measures designed to protect personnel; to prevent unauthorized access to equipment, installations, material, and documents; and to safeguard them against unauthorized access, damage and theft. [source: CA CIO website http://www.cio.ca.gov/OIS/Government/definitions.asp]</p>

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Term	Definition
Plan Sponsor	<p>The person or organization that arranges to provide health care goods and services for a group of participants by establishing or maintaining a group health plan (GHP).</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • <i>An employer in the case of a GHP established or maintained by a single employer for the benefit of employees or their dependents;</i> • <i>An employee organization (including unions or guilds) in the case of a group health plan established or maintained by an employee organization;</i> • <i>An association, joint board of trustees, or similar group of representatives of the parties in the case of a GHP established and maintained by two or more parties (including multiple employers, or an employer and an employee organization).</i> <p>[source: 29 U.S.C. §1002(16)(B)]</p>
Privacy	<p>The right of individuals and organizations to control the collection, storage, and dissemination of information about themselves. [source: CA CIO website http://www.cio.ca.gov/OIS/Government/definitions.asp#p]</p>
Professional Judgment	<p>The analysis and conclusions of a licensed medical, mental health, or developmental disabilities service provider regarding the use and disclosure of health information and its impact on the patient.</p> <p><i>Examples of professional judgment include:</i></p> <ul style="list-style-type: none"> • <i>Whether the patient’s representative should have access to the health information</i> • <i>Whether another person who is in the facility, or might come to the facility, could reasonably cause harm or danger to the patient</i> • <i>Whether disclosing the patient’s location within the facility implicitly would give information about the patient’s condition</i> • <i>Whether it is necessary or appropriate to give information about patient status to family and friends</i> <p>[source: 45 C.F.R. §164.502, §164.510, §164.514, and §164.524]</p>
Program	<p>Synonymous with “Substance Abuse Treatment Program” - An individual, entity, or identified unit within a general medical facility providing, or publically claiming to provide, alcohol or drug abuse diagnosis, treatment or referral for treatment; or medical personnel or other staff in a general medical care facility whose primary function is to provide alcohol or drug abuse diagnosis, treatment or referral for treatment.</p> <p>[source: 42 C.F.R. §2.11]</p>

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Term	Definition
Psychotherapy Notes	<p>Notes recorded (in any medium) by a mental health professional documenting or analyzing the contents of conversation during a private or group, joint or family counseling session and that are separated from the rest of the individual's medical record.</p> <p><i>Note: Medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and summary information (diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date) are NOT considered psychotherapy notes.</i></p> <p>[source: 45 C.F.R. §164.501]</p>
Public Health Authority	<p>An agency or authority of the United States government, a state, a territory, a political subdivision of a state or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency.</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • State and local health departments, • Food and Drug Administration (FDA), • Centers for Disease Control and Prevention, • Occupational Safety and Health Administration (OSHA) <p>[source: 45 C.F.R. §164.501]</p>
Research	<p>A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.</p> <p>[source: 45 C.F.R. §164.501]</p>
Security	<p>The administrative, physical and technical safeguards in, or protecting, an information system. [source: 45 C.F.R. §164.304]</p>
Security Incident	<p>An occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits or that constitutes a violation or imminent threat of violation of security policies, security procedures or acceptable use policies. [source: CA CIO website http://www.cio.ca.gov/OIS/Government/definitions.asp; and 45 C.F.R. §164.304]</p>
Specially Protected Health Information	<p>Any information regarding a patient's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional that requires special protections under the law, including substance abuse treatment records, mental health records, psychotherapy notes, behavioral health records, HIV, AIDS, and genetic information. [American Health Information Management Association website http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_016464.hcsp?dDocName=bok1_016464 (paraphrased)]</p>

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Term	Definition
State Entity	State departments, boards, commissions, programs, and other organizational units of the executive branch of state government. [source: CA Health and Safety Code §130302]
Substance Abuse Treatment Program	Synonymous with “Program” - An individual, entity, or identified unit within a general medical facility providing, or publically claiming to provide, alcohol or drug abuse diagnosis, treatment or referral for treatment; or medical personnel or other staff in a general medical care facility whose primary function is to provide alcohol or drug abuse diagnosis, treatment or referral for treatment. [source: 42 C.F.R. §2.11]
Substance Abuse Treatment Records	Any information that: <ul style="list-style-type: none"> • Identifies a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; • Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972; or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 2974 (or is obtained prior to this date and maintained by such a treatment program after this date as part of an ongoing treatment episode which extends past this date); <i>and</i> • Is for the purpose of treating alcohol or drug abuse, making a diagnosis for this treatment, or making a referral for this treatment. This includes patient alcohol and drug abuse treatment records as referenced in applicable state law. [source: 42 C.F.R. part 2 §2.12(a)(1); CA Civil Code §56.30(i)]
Substance Abuse Regulations	Federal regulations found in the “Confidentiality of Alcohol and Drug Abuse Patient Records regulations.” [source: 42 C.F.R. part 2 §2.12]
Technical Safeguards	The technology and policy and procedures in use that protect and control access to electronic health information. [source: 45 C.F.R. §164.304]

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Term	Definition
Telehealth	<p>The mode of delivering health care services and public health via telecommunications system(s) and technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at one location and the health care provider is at another site without the physical presence of the patient.</p> <p><i>Telehealth includes:</i></p> <ul style="list-style-type: none"> • <i>Real-time interactions between a patient and a health care provider</i> • <i>Transmission of patient health information to the health care provider, or</i> • <i>Medical advice provided by means of telephonic communications between a patient and a health care provider in which the health care professional's primacy function is to provide the patient a telephonic assessment, evaluation or advice to the patient's questions regarding his or her medical care or treatment, or that of a family member.</i> <p>[source: CA Business and Professions Code §2290.5(a); CA Health and Safety Code §1348.8(c)]</p>
Transactions and Code Sets (TCS)	<p>The collective name given to federal regulations standardizing and administratively simplifying the process, procedures and data elements used to electronically capture, store, and move health information.</p> <p><u>Transactions</u> are electronic exchanges involving the movement of information between parties for health care purposes.</p> <p><u>Code sets</u> are groups of codes used to categorize diagnoses, procedures, medical equipment and medications, and used in all transactions.</p> <ul style="list-style-type: none"> • <i>HCPCS (Ancillary Services/Procedures)</i> • <i>CPT-4 (Physicians Procedures)</i> • <i>CDT (Dental Terminology)</i> • <i>ICD-9 (Diagnosis and hospital inpatient Procedures)</i> • <i>ICD-10 (As of October 1, 2015)</i> • <i>NDC (National Drug Codes)</i> • <i>National Identifiers: Patient, Provider, Payer/Health Plan, Employer</i> <p>[source: HHS website http://www.hhs.gov/ocr/privacy/hipaa/administrative]</p>
Treatment	<p>The provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another. [source: 45 C.F.R. §164.501]</p>

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Term	Definition
Treatment Relationship	<p>One of two methods by which a health care provider delivers health care services to a patient:</p> <p>1. <i>Indirect</i> is a relationship between an individual and a health care provider in which:</p> <ul style="list-style-type: none"> • The health care provider delivers health care services or products to the patient based on the orders of another health care provider, <i>and</i> • The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the patient. <p>2. <i>Direct</i> is a relationship between a health care provider and a patient that is not an indirect treatment relationship (i.e., the provider delivers health care services or products to a patient based on professional judgment and personal observation). [source: 45 C.F.R. §164.501]</p>
Underwriting	<p>Activities related to the measurement of risk exposure and the creation, renewal or replacement of a contract for health insurance benefits.</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • <i>determinations of eligibility,</i> • <i>determinations of the cost of premiums,</i> • <i>determinations of the applicability of exclusion for a preexisting condition</i> <p>[source: 42 U.S.C. §1320(d)(9)]</p>
Unsecured health information	<p>Health information <u>not</u> rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the federal Health and Human Services Agency (HHS) in guidance.</p> <p><i>Only encryption and destruction consistent with National Institute of Standards and Technology (NIST) guidelines renders health information unusable, unreadable, or indecipherable to unauthorized persons, in which case notification is not required in the event of a breach.</i> [source: 45 C.F.R §§164.400-160.414]</p>
Whistleblower	<p>A workforce member who alleges wrong-doing or conduct by his/her organization of the sort that violates the law, regulation, executive order, rule of court, unsafe working conditions, SAM, state contracting manual, or gross mismanagement; and is reported to an authority (internally or externally) to investigate, discover or correct the problem. [source: 5 U.S.C. §2302(b)(8) (<i>paraphrased</i>); CA Labor Law §1102.5]</p>

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Term	Definition
Workforce	Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate. [source: 45 C.F.R. §160.103]
Workstation	An electronic device that performs computing functions and stores electronic media in its immediate environment (e.g., desktop computer, laptop computer, mobile devices or any other computing device). [source: 45 C.F.R. §164.304]