



Policy: HH.3022
Title: **Business Associate Agreements**
Department: Office of Compliance
Section: Privacy

CEO Approval: /s/ Michael Hunn 11/13/2024

Effective Date: 12/20/2021
Revised Date: 11/07/2024

Applicable to: ☒ Medi-Cal
☒ OneCare
☒ PACE
☒ Administrative

I. PURPOSE

This policy establishes guidelines related to CalOptima Health's Business Associate Agreements (BAA) with individuals or entities who are considered Business Associates.

II. POLICY

- A. As part of any Services Agreement where a Business Associate performs a service or function on behalf of CalOptima Health, CalOptima Health shall execute a BAA, in addition to the Service Agreement, that meets the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and the Department of Health Care Services (DHCS) Contract.
- B. CalOptima Health shall not Disclose, transmit or share PHI with an individual or business that performs a service or function using CalOptima Health member PHI without an executed BAA.
- C. CalOptima Health shall only contract with individuals or businesses that meet the requirements outlined in CalOptima Health's BAA template.
- D. CalOptima Health's Provider Contracting and/or Vendor Management Departments, as applicable, shall use CalOptima Health's BAA template, unless prior written approval is given by the Information Security Officer, Privacy Officer and Legal Counsel to use the proposed Business Associate's template based on the proposed Business Associate's template meeting all of the HIPAA Privacy and Security requirements.
- E. Any proposed edit or modification to the BAA requested by the proposed Business Associate shall be reviewed by the Vendor Management or Contracting Departments, as applicable, and must be approved by the appropriate CalOptima Health staff (e.g., CalOptima Health Security Officer, Privacy Officer, and Legal Counsel, as appropriate) before executing the BAA.
 - 1. CalOptima Health cannot accept any revisions to the BAA that conflict with the DHCS Contract or the underlying Service Agreement.
 - 2. CalOptima Health cannot accept any revisions that would allow the Business Associate to Use or Disclose PHI in a manner that would violate the HIPAA Privacy and Security requirements.
- F. If the Business Associate requires access to CalOptima Health member PHI in order to perform the function or service provided in the Service Agreement on behalf of CalOptima Health, and the

Business Associate refuses to sign the BAA, CalOptima Health may not disclose any CalOptima Health member PHI to the Business Associate and cannot contract with the Business Associate for the services.

- G. The CalOptima Health Privacy Officer, in collaboration with Information Technology Services, will maintain and update the BAA template based on statutory, regulatory and/or DHCS Contract changes.
 - 1. Any new BAA templates (or amendments) must include specified core elements and requirements in accordance with Title 45, Code of Federal Regulations, Sections 164.502 (e)(1-2) and 164.504 (e)(1-2), which shall include, but not be limited to, the following provisions:
 - a. Use and Disclosure;
 - b. Minimum Necessary Requirement;
 - c. Use Appropriate Safeguards;
 - d. Reporting of Any Unauthorized Use or Disclosure;
 - e. Subcontractor Requirements;
 - f. Right of Access;
 - g. Right of Amendment;
 - h. Right to an Accounting of Disclosures;
 - i. Books and Records Available;
 - j. Termination; and
 - k. Effect of Termination.
 - 2. Updates to the BAA templates (or amendments) must be submitted to the Legal Counsel for review.
- H. CalOptima Health reserves the right to automatically amend BAAs at any time when such modifications are necessary to comply with changes in:
 - 1. Applicable laws;
 - 2. CalOptima Health's contracts with government regulators; or
 - 3. In any requirements and conditions with which CalOptima must comply pursuant to its federally-approved Section 1915(b) waiver ("Regulatory Change").
- I. CalOptima Health's BAA will require that its Business Associates comply with privacy laws that provide for more restrictive protections than HIPAA.

III. PROCEDURE

A. Assessing potential Business Associate Relationships

1. Prior to issuing a Request for Proposal (RFP) or negotiating or entering into an underlying Service Agreement with an individual or business, the Provider Contracting or Vendor Management Department, in collaboration with the Contract Owner and the Privacy Officer, will determine whether a Business Associate relationship exists.
 - a. Examples of Business Associates include, but are not limited to individuals or entities that:
 - i. Create, receive, maintain, or transmit PHI for claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing;
 - ii. Provide legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for CalOptima Health, where the provision of the service involves the Disclosure of PHI to the individual or entity;
 - iii. Are a Health Information Organization/Exchange, E-prescribing Gateway, or that provide data transmission services with respect to PHI to CalOptima Health and that requires access on a routine basis to such PHI including, but not limited to cloud providers; and/or
 - iv. Are providers of personal health records to individuals on behalf of CalOptima Health.
 - b. Examples of individuals and entities that are not considered Business Associates:
 - i. Workforce members, such as employees, interns and CalOptima Health volunteers.
 - ii. Treatment providers, unless they are providing administrative services (which involve PHI) on behalf of CalOptima Health in addition to providing Member care.
2. The information Disclosed to the Business Associate by CalOptima Health must be restricted to the minimum amount necessary to enable the Business Associate to perform the function or provide the services for which CalOptima Health has contracted with the BA.

B. Maintenance of the BAA

1. The CalOptima Health Contracting and Vendor Management Departments shall maintain a current inventory of BAAs within the contract management system managed by the respective department.
2. The CalOptima Health Contracting and Vendor Management Departments shall be responsible for ensuring Business Associates have signed the most current (DHCS- approved) version of the BAA template.
3. The CalOptima Health Contracting and Vendor Management Departments shall be responsible for obtaining the required signatures for all BAAs and maintaining the original signed BAA and

any amendments and/or addendums thereto within the contract management system managed by the respective department.

4. CalOptima Health may terminate any BAA and applicable Service Agreement when patterns of material breaches or violations of the BAA or Service Agreement occur, or where reasonable measures to remediate non-compliant issues are unsuccessful in accordance with those agreements.
5. The BAA shall remain in effect throughout the term of any associated Service Agreement and shall extend beyond the termination of any Service Agreement(s) until such time as all the PHI provided by CalOptima Health to the BA, or created or received by the Business Associate on behalf of CalOptima Health, is destroyed or returned to CalOptima Health as specified in the Service Agreement and outlined in the BAA.
6. Whenever a Service Agreement that included a BAA expires by its own terms or is terminated before the end of its term, the Contracting or Vendor Management Department, as applicable, must obtain written certification from the Business Associate that all PHI received from or created or received by the Business Associate has either been returned, destroyed, or otherwise accounted for in accordance with the terms of the Service Agreement.
7. The Business Associate shall comply with the disposition of PHI requirements as specified in the BAA Template section 15.

C. Regulatory Amendments to the BAA

1. CalOptima Health will promptly notify its Business Associates, in writing, of any Regulatory Change in accordance with applicable federal and/or state requirements. CalOptima Health will require its Business Associates to comply with the new Regulatory Change requirements within thirty (30) days of the effective date of the Regulatory Change, unless otherwise instructed by a CalOptima Health government regulator.

D. CalOptima Health's BAA will require that Business Associates comply with applicable laws that provide more protections to Member Medical Information.

1. CalOptima Health requires that businesses described in California Civil Code, Section 56.06 that maintain Member electronic Medical Information comply with the following requirements regarding Sensitive Services:
 - a. Limit access privileges to information systems containing Medical Records related to Gender Affirming Care, abortion, abortion-related services, and contraception ("Restricted Information") only to persons authorized to access that specified information,
 - b. Prevent disclosure, access, transfer, transmission, or processing (and provide the ability to automatically disable access) of Restricted Information by other persons and entities outside of California; and
 - c. Segregate restricted information from the rest of the Member's records.
2. CalOptima Health will also require that contractors that maintain Member Medical Information do not cooperate with any inquiry or investigation by, or provide Medical Information to, any

individual, agency, or department from another state or, to the extent permitted by federal law, to a federal law enforcement agency regarding Abortion Services, unless the request for Medical Information is authorized under California Civil Code, Section 56.110.

IV. ATTACHMENT(S)

- A. Business Associate Disposition of Protected Health Information Form
- B. Business Associate Retention of Protected Health Information Form
- C. CalOptima Health Business Associate Agreement Template

V. REFERENCE(S)

- A. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
- B. CalOptima Health PACE Program Agreement
- C. Title 45, Code of Federal Regulations §160.103
- D. Title 45, Code of Federal Regulations §164.502 (a)(1-4) & (e)(1-2)
- E. Title 45, Code of Federal Regulations §164.504 (e)(1-2)
- F. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage

VI. REGULATORY AGENCY APPROVAL(S)

Date	Regulatory Agency	Response
02/04/2022	Department of Health Care Services (DHCS)	Approved as Submitted

VII. BOARD ACTION(S)

Date	Meeting
12/20/2021	Special Meeting of the CalOptima Board of Directors
11/07/2024	Regular Meeting of the CalOptima Health Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	12/20/2021	HH.3022	Business Associate Agreements	Medi-Cal OneCare OneCare Connect PACE Administrative
Revised	12/31/2022	HH.3022	Business Associate Agreements	Medi-Cal OneCare PACE Administrative
Revised	09/01/2023	HH.3022	Business Associate Agreements	Medi-Cal OneCare PACE Administrative

Action	Date	Policy	Policy Title	Program(s)
Revised	11/01/2023	HH.3022	Business Associate Agreements	Medi-Cal OneCare PACE Administrative
Revised	11/07/2024	HH.3022	Business Associate Agreements	Medi-Cal OneCare PACE Administrative

IX. GLOSSARY

Term	Definition
Business Associate (BA)	<p>Has the meaning given such term in Section 160.103 of Title 45, Code of Federal Regulations. A person or entity who:</p> <ol style="list-style-type: none"> 1. On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or 2. Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in §164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person. <p>A covered entity may be a business associate of another covered entity.</p> <p>Business associate includes:</p> <ol style="list-style-type: none"> 1. A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information. 2. A person that offers a personal health record to one or more individuals on behalf of a covered entity. 3. A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.
Business Associate Agreement (BAA)	<p>A covered entity's contract or other written arrangement with its business associate, which includes the elements specified at 45 CFR 164.504(e).</p>

Term	Definition
Contract Owner	The one individual within CalOptima Health with ultimate responsibility for the relationship between CalOptima Health and the Delegated Entity. Contract Owner responsibilities include, but are not limited to, initial contact, procurement, negotiation of contract terms, compliance remediation, on-going entity relations, site closings, hours of operations, etc. The Contract Owner is the individual with responsibility for ensuring that the documentation regarding the relationship between CalOptima Health and the Delegated Entity is complete and accurate.
DHCS Contract	The written instrument between CalOptima Health and the Department of Health Care Services (DHCS) pursuant to which CalOptima Health is obligated to arrange and pay for the provision of Covered Services to Members in the Service Area.
Covered Entity	A health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a transaction covered by Title 45, Code of Federal Regulations, Part 160.
Disclosure	Has the meaning given such term in section 160.103 of Title 45, Code of Federal Regulations including the following: the release, transfer, provision of access to, or divulging in any other manner of information outside of the entity holding the information.
Electronic Protected Health Information (EPHI)	Has the meaning given such term in Section 160.103 of Title 45, Code of Federal Regulations. Individually identifiable health information that is transmitted by Electronic Media or maintained in Electronic Media
Gender Affirming Care	Medically necessary health care or gender affirming mental health care that respects the gender identity of the patient, as experienced and defined by the patient, and may include, but is not limited to: <ol style="list-style-type: none"> 1. Interventions to suppress the development of endogenous secondary sex characteristics; 2. Interventions to align the patient's appearance or physical body with the patient's gender identity; and 3. Interventions to alleviate symptoms of clinically significant distress resulting from gender dysphoria, as defined in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition. Welfare and Institutions Code § 16010.2(b).
Health Insurance Portability and Accountability Act (HIPAA)	The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, was enacted on August 21, 1996. Sections 261 through 264 of HIPAA require the Secretary of the U.S. Department of Health and Human Services (HHS) to publicize standards for the electronic exchange, privacy and security of health information, and as subsequently amended.

Term	Definition
Medical Information	Has the meaning in Civil Code § 56.05(j): Any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental health application information, Reproductive or Sexual Health Application Information, mental or physical condition, or treatment. For purposes of this definition, "Individually Identifiable" means that the Medical Information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the identity of the individual. For purposes of this definition, "Reproductive or Sexual Health Application Information" means information about an individual's reproductive health, menstrual cycle, fertility, pregnancy, pregnancy outcome, plans to conceive, or type of sexual activity collected by a reproductive or sexual health digital service, including, but not limited to, information from which one can infer someone's pregnancy status, menstrual cycle, fertility, hormone levels, birth control use, sexual activity, or gender identity. Civ. Code § 56.05(q).
Member	A beneficiary enrolled in a CalOptima Health program.
Payment	Has the meaning in Title 42 of the Code of Federal Regulations, Section 164.501, including: activities carried out by CalOptima Health including: <ol style="list-style-type: none"> 1. Determination of eligibility, risk adjustments based on Member health status and demographics, billing claims management, and collection activities; 2. Review of health care services regarding medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; and 3. Utilization review activities including pre-certification, preauthorization, concurrent, or retrospective review of services.
Protected Health Information (PHI)	Has the meaning in 45 Code of Federal Regulations Section 160.103, including the following: individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. This information identifies the individual or there is reasonable basis to believe the information can be used to identify the individual. The information was created or received by CalOptima Health or Business Associates and relates to: <ol style="list-style-type: none"> 1. The past, present, or future physical or mental health or condition of a Member; 2. The provision of health care to a Member; or 3. Past, present, or future Payment for the provision of health care to a Member

Term	Definition
Sensitive Services	All health care services related to mental or behavioral health, sexual and reproductive health, sexually transmitted infections, substance use disorder, gender affirming care, and intimate partner violence, and includes services described in Family Code, Sections 6924, 6925, 6926, 6927, 6928, 6929, and 6930, and Health and Safety Code, Sections 121020 and 124260, obtained by a patient at or above the minimum age specified for consenting to the service, in accordance with California Civil Code, Section 56.05(s).
Service Agreement	A service agreement is a written agreement whereby a Business Associate agrees to provide services to CalOptima Health, and the Business Associate creates, receives, maintains, uses or transmits Protected Health Information in order to provide those services.
Treatment	Has the meaning in 42 Code of Federal Regulations Section 164.501, including: activities undertaken on behalf of a Member including the provision, coordination, or management of health care and related services; the referral to, and consultation between, health care Providers; and coordination with third parties for services related to the management of the Member's health care benefits.
Use	Has the meaning given such term in Section 160.103 of Title 45, Code of Federal Regulations. The sharing, employment, application, utilization, examination, or analysis of the PHI within an entity that maintains such information.
Workforce	Has the meaning in 45 Code of Federal Regulations Section 160.103 Workforce means 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.