Policy:	HH.2022
Title:	**Record Retention and Access**
Department:	Office of Compliance
Section:	Regulatory Affairs & Compliance
CEO Approval:	*/s/ Michael Hunn 11/19/2024*
Effective Date:	06/01/2013
Revised Date:	11/07/2024
Applicable to:	☒ Medi-Cal ☒ OneCare ☒ PACE ☐ Administrative

I. PURPOSE

This policy establishes the requirements for CalOptima Health and its First Tier, Downstream, and Related Entities (FDRs) to retain and make available premises, contracts, books, documents, records, financial statements, equipment, computers, or other electronic systems, in accordance with federal and state regulations for the purpose of any audit, or investigation, of a CalOptima Health program.

II. POLICY

A. CalOptima Health and its FDRs shall retain and make available contracts, books, documents, records, and financial statements, in accordance with the provisions of this Policy. These documents include, but are not limited to, the following:

1. Data relating to Medicare utilization and costs;
2. Reinsurance costs;
3. Low-income subsidy payments;
4. Risk corridor costs;
5. Bid calculations;
6. Rebate information;
7. Medical Records;
8. Medical charts and prescription files;
9. Records related to/supporting Health Network Medical Loss Ratio (MLR) calculations;
10. Hierarchical Condition Categories (HCC) and risk adjustment records;
11. Encounter data;
12. Member Grievance and Appeal records;

13. Base data as defined in Title 42, Code of Federal Regulations (C.F.R.), Section 438.5(c);

14. Data, information, and documentation specified in Title 42, C.F.R., Sections 438.604, 606, 608, and 610; and

15. Other documentation pertaining to medical and non-medical services rendered to Members.

16. Documentation of disciplinary actions for a period of ten (10) years at a minimum, including date of and description of violation, date of investigation, findings and date and description of disciplinary action.

B. An FDR shall retain and make available all of its premises, facilities, equipment, contracts, books, documents, records, encounter data (for a period of at least ten (10) years), computers and other electronic systems pertaining to the goods and services provided to Members, available to CalOptima Health and any authorized state and federal agencies or contractors, as described in Section II.C. 1-9 of this Policy, or their designees, for inspections, evaluations, examinations, copying, monitoring and auditing.

1. If DHCS, CMS, or the HHS Inspector General determines there is a reasonable possibility of fraud or similar risk, DHCS, CMS, or the HHS Inspector General may inspect, evaluate, and audit an FDR at any time.

2. Upon resolution of a full investigation of Fraud, DHCS reserves the right to suspend or terminate the FDR from participation in the Medi-Cal program; seek recovery of payments made to the FDR; impose other Sanctions provided under the State Plan, and direct CalOptima Health to terminate its agreement with the FDR due to Fraud.

C. Authorized state and federal agencies reserve the right to monitor all aspects of CalOptima Health's operations, including its FDRs, for compliance with the provisions of the CalOptima Health Contract with DHCS for Medi-Cal and applicable federal and state laws and regulations. Monitoring activities will include, but are not limited to, inspection and auditing of facilities, management systems and procedures, and books and records as deemed appropriate by the Director of DHCS, at any time, pursuant to 42 CFR 438.3(h). The monitoring activities will be either announced or unannounced.

III. PROCEDURE

A. CalOptima Health and its FDRs shall provide an authorized entity with the requested and required access to premises, contracts, books, documents, records, financial statements, equipment, computers, or other electronic systems at any time during normal business hours for audit, monitoring, and other investigative activities.

B. CalOptima Health and its FDRs shall maintain and make available all records and documents for a minimum of ten (10) years from the final date of the Contract Period, or from completion of any audit or investigation, whichever is later.

1. If there is a termination, dispute, or allegation of Fraud, or similar fault, document retention requirements for CalOptima Health and its FDRs may be extended to ten (10) years from the date of any resulting final resolution of the termination, dispute, or allegation of Fraud, or similar fault.

C. CalOptima Health shall retain and make available all of its premises, facilities, equipment, contracts, books, documents, records, encounter data (for a period of at least ten (10) years and in

accordance with CalOptima Health's Document Retention Schedule), computers and other electronic systems pertaining to the goods and services provided to Members, to any authorized state and federal agencies or contractors for inspections, evaluations, examinations or copying, monitoring and auditing including, but not limited to:

a. Centers for Medicare & Medicaid Services (CMS);

b. Department of Managed Health Care (DMHC);

c. Department of Health Care Services (DHCS);

d. The U.S. Department of Health and Human Services (HHS) Office of the Inspector General ;

e. The Bureau of Medi-Cal Fraud

f. The Comptroller General;

g. Department of Justice;

h. The U.S. Government Accountability Office (GAO)

i. Authorized State agencies, or their duly authorized representatives or designees, including DHCS's External Quality Review Organization (EQRO) contractor; and

j. Any Quality Improvement Organization (QIO) or accrediting organizations, including NCQA, their designees and other representatives of regulatory or accrediting organizations.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

A. CalOptima Health Compliance Plan
B. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
C. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
D. CalOptima Health's Document Retention Schedule
E. CalOptima Health PACE Program Agreement Department of Health Care Services (DHCS) All Plan Letter (APL) 23-006: Delegation and Subcontractor Network Certification
F. Medicare Managed Care Manual, Chapter 21
G. Medicare Prescription Drug Benefit Manual, Chapter 9
H. Title 42, Code of Federal Regulations (C.F.R.), §422.504(d)(2), §438.230(c), §438.3(h), §438.604, §606, §608, §438.3(u); and §610

VI. REGULATORY AGENCY APPROVAL(S)

Date	Regulatory Agency	Response
07/12/2013	Department of Health Care Services (DHCS)	Approved as Submitted
01/19/2022	Department of Health Care Services (DHCS)	File and Use

VII. BOARD ACTION(S)

Date	Meeting
12/01/2016	Regular Meeting of the CalOptima Board of Directors
12/07/2017	Regular Meeting of the CalOptima Board of Directors
12/06/2018	Regular Meeting of the CalOptima Board of Directors
12/05/2019	Regular Meeting of the CalOptima Board of Directors
12/03/2020	Regular Meeting of the CalOptima Board of Directors
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	06/01/2013	HH.2022	Record Retention and Access	Medi-Cal OneCare
Revised	09/01/2015	HH.2022	Record Retention and Access	Medi-Cal
Revised	12/01/2016	HH.2022	Record Retention and Access	Medi-Cal OneCare OneCare Connect PACE
Revised	12/07/2017	HH.2022	Record Retention and Access	Medi-Cal OneCare OneCare Connect PACE
Revised	12/06/2018	HH.2022	Record Retention and Access	Medi-Cal OneCare OneCare Connect PACE
Revised	12/05/2019	HH.2022	Record Retention and Access	Medi-Cal OneCare OneCare Connect PACE
Revised	12/03/2020	HH.2022	Record Retention and Access	Medi-Cal OneCare OneCare Connect PACE
Revised	12/20/2021	HH.2022	Record Retention and Access	Medi-Cal OneCare OneCare Connect PACE
Revised	12/31/2022	HH.2022	Record Retention and Access	Medi-Cal OneCare PACE
Revised	09/01/2023	HH.2022	Record Retention and Access	Medi-Cal OneCare PACE
Revised	11/07/2024	HH.2022	Record Retention and Access	Medi-Cal OneCare PACE

IX. GLOSSARY

Term	Definition
Appeal	Medi-Cal: A review by CalOptima Health of an adverse benefit determination, which includes one of the following actions: 1. A denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for Medical Necessity, appropriateness, setting, or effectiveness of a Covered Service; 2. A reduction, suspension, or termination of a previously authorized service; 3. A denial, in whole or in part, of payment for a service; 4. Failure to provide services in a timely manner; or 5. Failure to act within the timeframes provided in 42 CFR 438.408(b). OneCare: As defined at 42 CFR §422.561 and §423.560, the procedures that deal with the review of adverse initial determinations made by the plan on health care services or benefits under Part C or D the enrollee believes he or she is entitled to receive, including a delay in providing, arranging for, or approving the health care services or drug coverage (when a delay would adversely affect the health of the enrollee) or on any amounts the enrollee must pay for a service or drug as defined in 42 CFR §422.566(b) and §423.566(b). These appeal procedures include a plan reconsideration or redetermination (also referred to as a level 1 appeal), a reconsideration by an independent review entity (IRE), adjudication by an Administrative Law Judge (ALJ) or attorney adjudicator, review by the Medicare Appeals Council (Council), and judicial review. PACE: A Member's action taken with respect to the PACE organization's noncoverage of, modification of, or nonpayment for, a service including denials, reductions or termination of services, as defined by federal PACE regulation 42 CFR Section 460.122.
Contract Period	For purposes of this policy, this timeframe is the First Tier, Downstream, and Related Entities' (FDR's) contract duration with the Department of Health Care Services (DHCS).
Covered Service	Medi-Cal: Those health care services, set forth in W&I sections 14000 et seq. and 14131 et seq., 22 CCR section 51301 et seq., 17 CCR section 6800 et seq., the Medi-Cal Provider Manual, the California Medicaid State Plan, the California Section 1115 Medicaid Demonstration Project, the contract with DHCS for Medi-Cal, and DHCS APLs that are made the responsibility of CalOptima Health pursuant to the California Section 1915(b) Medicaid Waiver authorizing the Medi-Cal managed care program or other federally approved managed care authorities maintained by DHCS. Covered Services do not include: 1. Home and Community-Based Services (HCBS) program as specified in the DHCS contract for Medi-Cal Exhibit A, Attachment III, Subsections 4.3.15 (Services for Persons with Developmental Disabilities), 4.3.20 (Home and Community-Based Services Programs) regarding waiver programs, 4.3.21 (In-Home Supportive Services), and Department of Developmental Services (DDS) Administered Medicaid Home and

Term	Definition
	Community-Based Services Waiver. HCBS programs do not include services that are available as an Early and Periodic Screening, Diagnosis and Treatment (EPSDT) service, as described in 22 CCR sections 51184, 51340 and 51340.1. EPSDT services are covered under the DHCS contract for Medi-Cal, as specified in Exhibit A, Attachment III, Subsection 4.3.11 (Targeted Case Management Services), Subsection F4 regarding services for Members less than twenty-one (21) years of age. CalOptima Health is financially responsible for the payment of all EPSDT services; 2. California Children's Services (CCS) as specified in Exhibit A, Attachment III, Subsection 4.3.14 (California Children's Services), except for Contractors providing Whole Child Model (WCM) services; 3. Specialty Mental Health Services as specified in Exhibit A, Attachment III, Subsection 4.3.12 (Mental Health Services); 4. Alcohol and SUD treatment services, and outpatient heroin and other opioid detoxification, except for medications for addiction treatment as specified in Exhibit A, Attachment III, Subsection 4.3.13 (Alcohol and Substance Use Disorder Treatment Services); 5. Fabrication of optical lenses except as specified in Exhibit A, Attachment III, Subsection 5.3.7 (Services for All Members); 6. Direct Observed Therapy for Treatment of Tuberculosis (TB) as specified in Exhibit A, Attachment III, Subsection 4.3.18 (Direct Observed Therapy for Treatment of Tuberculosis); 7. Dental services as specified in W&I sections 14131.10, 14132(h), 14132.22, 14132.23, and 14132.88, and EPSDT dental services as described in 22 CCR section 51340.1(b). However, CalOptima Health is responsible for all Covered Services as specified in Exhibit A, Attachment III, Subsection 4.3.17 (Dental) regarding dental services; 8. Prayer or spiritual healing as specified in 22 CCR section 51312; 9. Educationally Necessary Behavioral Health Services that are covered by a Local Education Agency (LEA) and provided pursuant to a Member's Individualized Education Plan (IEP) as set forth in Education Code section 56340 et seq., Individualized Family Service Plan (IFSP) as set forth in California Government Code (GC) section 95020, or Individualized Health and Support Plan (IHSP). However, CalOptima Health is responsible for all Medically Necessary Behavioral Health Services as specified in Exhibit A, Attachment III Subsection 4.3.16 (School-Based Services); 10. Laboratory services provided under the State serum alpha-feto-protein-testing program administered by the Genetic Disease Branch of California Department of Public Health (CDPH); 11. Pediatric Day Health Care, except for Contractors providing Whole Child Model (WCM) services; 12. State Supported Services; 13. Targeted Case Management (TCM) services as set forth in 42 USC section 1396n(g), W&I sections 14132.48 and 14021.3, 22 CCR sections 51185 and 51351, and as described in Exhibit A, Attachment III, Subsection 4.3.11 (Targeted Case Management Services). However, if Members less than twenty-one (21) years of age are not eligible for or accepted by a Regional Center (RC) or a local government health program for TCM services, CalOptima Health must ensure access to

Term	Definition
	comparable services under the EPSDT benefit in accordance with DHCS APL 23-005; 14. Childhood lead poisoning case management provided by county health departments; 15. Non-medical services provided by Regional Centers (RC) to individuals with Developmental Disabilities, including but not limited to respite, out-of-home placement, and supportive living; 16. End of life services as stated in Health and Safety Code (H&S) section 443 et seq., and DHCS APL 16-006; and 17. Prescribed and covered outpatient drugs, medical supplies, and enteral nutritional products when appropriately billed by a pharmacy on a pharmacy claim, in accordance with DHCS APL 22-012. OneCare: Those medical services, equipment, or supplies that CalOptima Health is obligated to provide to Members under the Centers of Medicare & Medicaid Services (CMS) Contract, or Care Coordination, or Coordination of Care as defined in the state Medicaid Agency Contract. PACE: Those items and services provided by CalOptima Health under the provisions of Welfare and Institutions Code, section 14132 and the California State Plan, except those services specifically excluded under Exhibit E, Attachment 1 of the CalOptima Health PACE contract, state law, or the California State Plan.
Department of Health Care Services (DHCS)	Medi-Cal: The single State department responsible for the administration of the Medi-Cal Program, California Children's Services (CCS), Genetically Handicapped Persons Program (GHPP), and other health related programs as provided by statute and/or regulation. OneCare: The single State Department responsible for administration of the Medi-Cal program, California Children Services (CCS), Genetically Handicapped Persons Program (GHPP), Child Health and Disabilities Prevention (CHDP), and other health related programs. PACE: The single State Department responsible for administration of the federal Medicaid (referred to as Medi-Cal in California) Program.
Department of Managed Health Care (DMHC)	The State agency responsible for administering the Knox-Keene Health Care Service Plan Act of 1975.
Downstream Entity	Medi-Cal: Any party that enters into a written arrangement, acceptable to DHCS and/or CMS, with persons or entities involved with a CalOptima Health Program benefit, below the level of arrangement between CalOptima Health and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. OneCare: Any party that enters into an acceptable written arrangement below the level of the arrangement between a Medicare Advantage (MA) organization (and contract applicant) and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of health and/or administrative services.

Term	Definition
External Quality Review	The analysis and review by the External Quality Review Organization (EQRO) of aggregated information on quality, timeliness, and access to the health care services that CalOptima Health, its Subcontractor, its Downstream Subcontractor, or its Network Provider furnishes to Members.
External Quality Review Organization (EQRO)	An organization that meets the competence and independence requirements set forth in 42 CFR section 438.354, and performs EQR and other EQR–related activities as set forth in 42 CFR section 438.358 pursuant to its contract with DHCS.
First Tier, Downstream, and Related Entities (FDR)	First Tier, Downstream or Related Entity, as separately defined herein. For the purposes of this policy, the term FDR includes delegated entities, contracted providers, Health Networks, Physician Medical Groups, Physician Hospital Consortia, and Health Maintenance Organizations.
First Tier Entity	Medi-Cal: Any party that enters into a written arrangement, acceptable to DHCS and/or CMS, with CalOptima Health to provide administrative services or health care services to a Member under a CalOptima Health Program. OneCare: Any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program.
Fraud	An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law, in accordance with Title 42 Code of Federal Regulations section 455.2, Welfare and Institutions Code section 14043.1(i).
Grievance	Medi-Cal: Any expression of dissatisfaction about any matter other than an Adverse Benefit Determination (ABD), and may include, but is not limited to the Quality of Care or services provided, aspects of interpersonal relationships with a Provider or CalOptima Health's employee, failure to respect a Member's rights regardless of whether remedial action is requested, and the right to dispute an extension of time proposed by CalOptima Health to make an authorization decision. A complaint is the same as Grievance. An inquiry is a request for more information that does not include an expression of dissatisfaction. Inquiries may include, but are not limited to, questions pertaining to eligibility, benefits, or other CalOptima Health processes. If CalOptima Health is unable to distinguish between a Grievance and an inquiry, it must be considered a Grievance. OneCare: An expression of dissatisfaction with any aspect of the operations, activities or behavior of a plan or its delegated entity in the provision of health care items, services, or prescription drugs, regardless of whether remedial action is requested or can be taken. A grievance does not include, and is distinct from, a dispute of the appeal of an organization determination or coverage determination or an LEP determination. PACE: A complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished, as defined by the federal PACE regulation 42 CFR Section 460.120.
Hierarchical Coding Categories (HCC)	A risk-adjusted model developed by CMS to adjust Medicare payments to health care plans for the health expenditure risk of Members.

Term	Definition
Medical Loss Ratio (MLR)	Medi-Cal: The percentage calculated by dividing the Health Network's total medical costs paid on behalf of CalOptima Health Members by the total revenue received from CalOptima Health. Health Network medical costs would include payments to physicians (i.e., capitation, fee-for-service, or salary), medical groups/Independent Practice Associations (IPAs), hospitals, labs, ambulance companies, and other providers of service. PACE: The Allowed Medical Expenses for the covered services provided to enrollees under the Contract divided by the amount of Medi-Cal managed care Net Capitation Payments or revenues recorded by CalOptima Health PACE, by county.
Medically Necessary or Medical Necessity	Medi-Cal: Reasonable and necessary Covered Services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I Code 14059.5(a) and Title 22 CCR Section 51303(a). Medically Necessary services shall include Covered Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity. For Members under twenty-one (21) years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) standard of medical necessity set forth in Section 1396dI(5) of Title 42 of the United States Code, as required by W&I Code 14059.5(b) and W&I Code Section 14132(v). Without limitation, Medically Necessary services for Members under twenty-one (21) years of age include Covered Services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support or maintain the Member's current health condition. CalOptima Health shall determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the child. OneCare: Reasonable and necessary medical services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I Code 14059.5(a) and Title 22 CCR Section 51303(a). Medically Necessary services includes Medi-Cal Services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity. PACE: Reasonable and necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness, or injury.

Term	Definition
Medical Record	Medi-Cal: The record of a Member's medical information including but not limited to, medical history, care or treatments received, test results, diagnoses, and prescribed medications. OneCare: A medical record, health record, or medical chart in general is a systematic documentation of a single individual's medical history and care over time. The term 'Medical Record' is used both for the physical folder for each individual patient and for the body of information which comprises the total of each patient's health history. Medical records are intensely personal documents and there are many ethical and legal issues surrounding them such as the degree of third-party access and appropriate storage and disposal. PACE: Written documentary evidence of treatments rendered to plan Members.
Member	Medi-Cal: A Medi-Cal eligible beneficiary as determined by the County of Orange Social Services Agency, the California Department of Health Care Services (DHCS) Medi-Cal Program, or the United States Social Security Administration, who is enrolled in the CalOptima Health program. OneCare: A beneficiary enrolled in a CalOptima Health OneCare Program. PACE: Any Eligible Medi-Cal Beneficiary who has enrolled in CalOptima Health PACE's plan in accordance with the provisions of California Code of Regulations title 22, section 53420.
National Committee for Quality Assurance (NCQA)	Medi-Cal: An organization responsible for the accreditation of managed care plans and other health care entities and for developing and managing health care measures that assess the Quality of Care and services that Members receive. OneCare: An independent, not-for-profit organization dedicated to assessing and reporting on the quality of managed care plans, managed behavioral healthcare organizations, preferred provider organizations, new health plans, physician organizations, credentials verification organizations, disease management programs and other health-related programs. PACE: A non-profit organization committed to evaluating and publicly reporting on the quality of managed care plans.
Quality Improvement Organization (QIO)	An organization comprised of practicing doctors and other health care experts under contract to the federal government to monitor and improve the care given to Medicare enrollees. A QIO reviews Complaints raised by enrollees about the quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, Medicare managed care plans, and ambulatory surgical centers. A QIO also reviews continued stay denials for enrollees receiving care in acute inpatient hospital facilities as well as coverage terminations in Skilled Nursing Facilities, Home Health Agencies, and Comprehensive Outpatient Rehabilitation Facilities.

Term	Definition
Related Entity	Any entity that is related to the Medicare Advantage organization by common ownership or control and: 1. Performs some of the Medicare Advantage organization's management functions under contract or delegation; 2. Furnishes services to Medicare enrollees under an oral or written agreement; or 3. Leases real property or sells materials to the Medicare Advantage organization at a cost of more than two thousand five hundred dollars ($2,500) during a contract period.