Policy:	HH.2027
Title:	**Annual Risk Assessment (FDR)**
Department:	Office of Compliance
Section:	Delegation Oversight
CEO Approval:	*/s/ Michael Hunn 12/07/2023*
Effective Date:	05/01/2014
Revised Date:	11/01/2023
Applicable to:	☒ Medi-Cal ☒ OneCare ☐ PACE ☐ Administrative

I. PURPOSE

This policy describes the Annual Risk Assessment process conducted by CalOptima Health's Delegation Oversight Department to identify First Tier, Downstream, and Related Entities (FDRs) specific functional areas vulnerable to potential compliance risk. Such areas are documented in CalOptima Health's risk assessment, which will influence the development of CalOptima Health's FDR's audit and monitoring work plan.

II. POLICY

A. CalOptima Health maintains ultimate responsibility for adhering to and otherwise fully complying with its contract with the Centers for Medicare & Medicaid Services (CMS) and/or the Department of Health Care Services (DHCS). CalOptima Health is required to establish and implement an effective system of routine monitoring and identification of compliance risks.

B. At least annually, the Delegation Oversight Department is responsible for completing an Annual Risk Assessment to develop its FDR audit and monitoring work plan that ensures CalOptima Health's regulatory obligations are met. In assessing risk, the Delegation Oversight Department shall consider the following:

1. Statutory, regulatory, and contractual standards;
2. CalOptima Health's policies and procedures;
3. Business impact on Member care; and
4. Past compliance issues.

C. CalOptima Health shall, through contract or appropriate written arrangements, require the FDRs to conduct risk assessments, at least annually, and ongoing monitoring and audit of the Downstream Entities with which they contract to ensure compliance. CalOptima Health shall retain the right to conduct its own risk assessments and ongoing monitoring and audit of the Downstream Entities to ensure compliance.

D. The Delegation Oversight Department shall stay current with all regulatory communication and guidance from the Regulatory Agencies.

E. The Delegation Oversight Department shall present Annual Risk Assessment results and the proposed FDR audit and monitoring work plan to both the Delegation Oversight Committee (DOC) and the Compliance Committee for review and approval by the end of the calendar year to be effective for the following year.

III. PROCEDURE

A. The Delegation Oversight Department shall undertake a discovery process of the FDRs, consisting of a document review to determine how regulatory, statutory, contractual, and CalOptima Health policy requirements are implemented; the operational effectiveness, and how the practices and the documentation support compliance. The analysis component of the Annual Risk Assessment is based on the evaluation of the FDRs' performance during the previous calendar year, including but not limited to ongoing monitoring and auditing results and focused reviews when applicable.

1. In the event that the FDR is a new delegate, the Delegation Oversight Department shall audit the FDR to collect baseline data in accordance with CalOptima Health Policy GG.1619: Delegation Oversight.

B. The Delegation Oversight Department shall consider the following information as it applies to FDRs, as part of the Annual Risk Assessment process:

1. A particular area identified by a Regulatory Agency as problematic through enforcement actions that may impact CalOptima Health, including but not limited to, National Committee for Quality Assurance (NCQA) status;

2. Regulatory audit findings;

3. CalOptima Health monitoring and audit findings;

4. Regulatory notices of non-compliance;

5. A completed questionnaire by the following CalOptima Health departments: (i) Regulatory Affairs and Compliance, (ii) Quality Improvement, (iii) Grievance and Appeals Resolution Services, (iv) Privacy, (v) Fraud, Waste & Abuse, and (vi) the business owner to provide knowledge of issues or trends being identified throughout CalOptima Health.

6. Accuracy of FDR encounter data submissions, coding, medical loss ratio (MLR) reported data, and other areas that may impact CalOptima Health payments (e.g., MLR, Hierarchical Condition Category (HCC) risk scores), if applicable;

7. Whether there is a Corrective Action Plan (CAP) in effect, and if so, its relative risk for the non-compliance area; and

8. Whether the First Tier Entities (FTEs) are applying appropriate compliance program requirements to the Downstream Entities with which they contract, conducting risk assessments, at least annually, and performing ongoing monitoring and auditing of such Downstream Entities to ensure compliance.

C. The Delegation Oversight Department shall rely on data gathered using the Annual Risk Assessment, and conduct baseline risk assessment audits evaluating file reviews, data collected from ongoing monitoring and auditing results and number of CAPs issued during the review period.

   1. The Delegation Oversight Department shall compile the data and rank the risks based on the greatest impact on delegated operations and quality health care delivery to CalOptima Health Members.

D. The Delegation Oversight Department shall present the FDR risk assessment results and proposed audit and monitoring work plan to the DOC and subsequently to the Compliance Committee for approval.

E. The Delegation Oversight Department shall re-evaluate the work plan based on internal changes for approval (e.g., staffing, and organizational structure changes, audit results, monitoring results) and external changes (e.g., regulatory changes, marketplace changes, Regulatory Agency audit results).

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

A. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
B. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
C. CalOptima Health Contract for Health Care Services
D. CalOptima Health Compliance Plan
E. CalOptima Health Policy GG.1619: Delegation Oversight
F. Health Network Service Agreement
G. Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines
H. Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines
I. Title 42, Code of Federal Regulations (C.F.R.), §455.2
J. Welfare and Institutions Code §14043.1(a)

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

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

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	05/01/2014	MA.9117	Annual Risk Assessment	OneCare
Revised	11/01/2014	MA.9117	Annual Risk Assessment	OneCare
Revised	09/01/2015	MA.9117	Annual Risk Assessment	OneCare OneCare Connect PACE
Effective	09/01/2015	HH.2027	Annual Risk Assessment	Medi-Cal
Revised	12/01/2016	HH.2027	Annual Risk Assessment (Delegate)	Medi-Cal OneCare OneCare Connect
Retired	12/01/2016	MA.9117	Annual Risk Assessment	OneCare OneCare Connect PACE
Revised	12/07/2017	HH.2027	Annual Risk Assessment (Delegate)	Medi-Cal OneCare OneCare Connect PACE
Revised	12/06/2018	HH.2027	Annual Risk Assessment (Delegate)	Medi-Cal OneCare OneCare Connect PACE
Revised	12/05/2019	HH.2027	Annual Risk Assessment (Delegate)	Medi-Cal OneCare OneCare Connect PACE
Revised	12/03/2020	HH.2027	Annual Risk Assessment (FDR)	Medi-Cal OneCare OneCare Connect PACE
Revised	12/20/2021	HH.2027	Annual Risk Assessment (FDR)	Medi-Cal OneCare OneCare Connect PACE
Revised	12/31/2022	HH.2027	Annual Risk Assessment (FDR)	Medi-Cal OneCare PACE
Revised	11/01/2023	HH.2027	Annual Risk Assessment (FDR)	Medi-Cal OneCare

IX. GLOSSARY

Term	Definition
Abuse	Actions that may, directly or indirectly, result in unnecessary costs to a CalOptima Health program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from Fraud, because the distinction between "Fraud" and "Abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.
Annual Risk Assessment Tool	A tool utilized to stratify (high, medium, low) audit results and corrective actions issued to identify specific CalOptima Health functional areas vulnerable to potential Compliance risk.
Centers for Medicare & Medicaid Services (CMS)	The federal agency within the United States Department of Health and Human Services (DHHS) that administers the Federal Medicare program and works in partnership with state governments to administer Medicaid programs.
Compliance Committee	That committee designated by the Chief Executive Officer (CEO) to implement and oversee the Compliance Program and to participate in carrying out the provisions of the Compliance Plan. The composition of the Compliance Committee shall consist of Executive staff that may include, but is not limited to, the: Chief Executive Officer; Chief Medical Officer; Chief Operating Officer; Chief Financial Officer; Chief Compliance Officer; and Chief Human Resources Officer.
Corrective Action Plan (CAP)	A plan delineating specific identifiable activities or undertakings that address and are designed to correct program deficiencies or problems identified by formal audits or monitoring activities by CalOptima Health, the Centers of Medicare & Medicaid Services (CMS), Department of Health Care Services (DHCS), or designated representatives. FDRs and/or CalOptima Health departments may be required to complete CAPs to ensure compliance with statutory, regulatory, or contractual obligations and any other requirements identified by CalOptima Health and its regulators.
Delegation Oversight Committee (DOC)	CalOptima Health's Delegation Oversight Committee (DOC) is a subcommittee of the Compliance Committee and is responsible for overseeing the delegated and internal activities of CalOptima Health.
Department of Health Care Services (DHCS)	The California Department of Health Care Services, the State agency that oversees California's Medicaid program, known as Medi-Cal.
Department of Managed Health Care (DMHC)	The California Department of Managed Health Care that oversees California's managed care system. DMHC regulates health maintenance organizations licensed under the Knox Keene Health Care Service Plan Act of 1975, Health & Safety Code, Sections 1340 *et seq.*
Downstream Entity	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 the 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.
FDR	Means First Tier, Downstream or Related Entity, as separately defined herein.

Term	Definition
First Tier Entity (FTE)	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.
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).
Member	A beneficiary enrolled in a CalOptima Health program.
Regulatory Agencies	For the purposes of this policy Regulatory Agencies include Centers for Medicare and Medicaid Services (CMS), Department of Health Care Services (DHCS), Department of Managed Health Care (DMHC), Health and Human Services Office of Inspector General (OIG) and Office of Civil Rights (OCR).
Related Entity	Any entity that is related to CalOptima Health by common ownership or control and that: performs some of CalOptima Health's management functions under contract or delegation; furnishes services to Members under an oral or written agreement; or leases real property or sells materials to CalOptima Health at a cost of more than $2,500 during a contract period.
Waste	The overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to a CalOptima Health Program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.