

HOMETOWN HEALTH POLICY		Current Version Effective Date:	05/01/19
Title:	Oversight of Delegated Entities	Next Review Date:	05/01/20
Category:	Compliance	Creation Date:	02/26/07
Number:	Hometown.HCP.010	Revision History: 10/25/12 12/01/17 04/18/15 04/27/18 08/19/16 04/20/19 04/28/17	
Author:	Manager of Compliance		

Scope: Hometown Health Compliance Policies & Procedures apply to the following individuals and entities:

- 1) All persons (management, staff, contractors, vendors) affiliated with Hometown Health and Hometown Health Management Corporation (“staff”);
- 2) All members of the Board of Directors (“Board”), officers and managers of Hometown Health and Hometown Health Management Corporation;
- 3) First-tier, downstream and related entities (“FDR”) as defined by the Centers for Medicare and Medicaid Services (“CMS”), as set forth in Hometown Health’s policies & procedures and standard of work and/or work aids; and
- 4) Delegated entities as defined by URAC standards, as set forth in Hometown Health’s policies & procedures and standard of work and/or work aids.

Purpose: The purpose of HOMETOWN.HCP.010 is to outline the oversight activities of FDR and delegated entities that perform delegated administrative and health care functions on behalf of Hometown Health.

Policy: This policy applies to any delegated entity to which administrative or health care functions have been delegated to be performed on behalf of Hometown Health. This policy covers all lines of business.

In this policy and procedure, the term “FDR” refers to those entities that meet the Centers for Medicare and Medicaid Services (CMS) definition of the term. Delegated entity refers to those entities that meet URAC definition of the term.

Hometown Health requires compliance with all federal and state laws, CMS guidance, CMS contract provisions, URAC and other accreditation standards as applicable. Hometown Health also requires compliance with rules of the Internal Revenue Code to maintain its tax- exempt status.

I. Requirements

Prior to entering into a written contractual agreement with a FDR/Delegated entity, the Delegation Oversight Coordinator, or designee, will begin a pre-implementation audit of the entity’s ability to perform delegated functions according to industry standards and Hometown Health’s requirements. The criteria and processes may include an assessment of the potential entities’ policies and procedures, capacity to perform the functions described in the contract and a possible on-site visit. The audit and recommendation will be presented to the Delegation Oversight Workgroup and Compliance Committee.

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In the event of fraudulent, wasteful, abusive or egregious noncompliance, the contractual relationship with FDR/Delegated entity may be subject to further corrective action, including termination.

II. Approval of Criteria and Processes

Before selecting an entity, the criteria and processes should first be reviewed and approved by the responsible business owner and Hometown Health Delegation Oversight Workgroup. Approval should be documented in the Delegation Oversight Workgroup notes.

III. Pre-implementation Audit

Before entering into an agreement with an entity, the Delegation Oversight Coordinator will conduct a pre-implementation audit, as referenced in section I above. The criteria and processes will include an assessment to determine if the delegated entity is an FDR or Delegated entity as subject by Medicare compliance requirements and URAC, and will evaluate the entity's policies and procedures and capacity to perform the functions as described in the contract. Depending on the extent and significance of health plan functions, the pre-delegation review may be performed as a desk-top audit or conducted by an on-site visit.

***Note:** Prior to initial contracting and monthly thereafter, all entities/persons must be screened for sanctions and exclusions from Medicare in accordance with policy, Hometown.HCP.005 – OIG/GSA Exclusion Screening.

IV. Delegation Agreement

Hometown Health will sign a written agreement with the FDR/Delegated entity that is consistent with the delegation requirements outlined in the Medicare Managed Care Manual, Chapter 21 Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 Compliance Program Guidelines, the Medicare Advantage Contract Amendment (Rev. January 1, 2015) and URAC Health Plan CORE Standard CORE 6-9.

V. Delegation Oversight

A. For all entities/persons subject to this policy, the assigned business owner and/or Delegation Oversight Coordinator ("delegation oversight authority") will conduct a risk assessment on an annual basis. The delegation oversight authority will conduct auditing and/or monitoring on a daily, weekly, monthly, quarterly and/or annual basis.

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- B. Policies and Procedures - The delegation oversight authority will conduct a documented initial review, or more frequently as needed, of the FDR/Delegated entity’s written policies & procedures to assure continued compliance and to comply with the terms of the contract.
- C. Quality & Performance Activities - The delegation oversight authority will conduct a documented review annually or more frequently as needed, of the entity’s quality activities that are related to the functions in order to assure continued compliance and to comply with the applicable quality and performance standards of Hometown Health.
- D. Financial Incentives - As a part of the annual review, the delegation oversight authority will query the entity of any financial incentives, either in agreement between Hometown Health and the FDR/Delegated entity or within the entity’s relationships with its staff. If financial incentives exist, the delegation oversight authority (after consultation with the medical director, if necessary) will document whether the financial incentives compromises the quality of care provided to Hometown Health and Renown Health's members. If the incentives are found to compromise a members’ quality of care, the medical director will be alerted and will collaborate with staff to either terminate the contract or require the entity to remedy the issue.
- E. Oversight of Downstream Entities – If the delegated entity further delegates any part of the delegated function to a downstream entity or subcontractor, the delegated entity will provide sufficient oversight of the function to ensure compliance with this policy, the Medicare Managed Care Manual, Chapter 21 (“Compliance Program Guidelines”) and the Prescription Drug Benefit Manual, Chapter 9 (“Compliance Program Guidelines”).
- F. Reporting Issues to Delegation Oversight Authority – Upon identification of performance or compliance issues with the performance of the function by the FDR/Delegated entity, the delegated entity will report issues to the delegation oversight authority. The delegation oversight authority will require a corrective action plan to remediate the issue to include documentation of disciplinary action taken with responsible individuals.
- G. Delegated Entity Risk Assessment - In conjunction with the Hometown Health Delegation Oversight Workgroup, an objective risk assessment of each entity will be performed by the Delegation Oversight Coordinator to determine the extent to which the FDR/Delegated entity poses risk to Hometown Health and Renown Health, and:
 - 1. Evaluate the entity’s compliance with applicable Medicare Parts C and D program requirements, URAC accreditation standards, and Hometown Health policies and procedures;

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2. Ensure that FDR/Delegated entities are auditing and monitoring their downstream entities, imposing applicable program requirements, implementing corrective action, and monitoring adherence with corrective action;
3. Scored using a standardized methodology and the aggregate results of the risk assessment are according to high, medium and low risk;
4. Results of the risk assessment will be used to determine which Hometown Health entity will receive targeted audits, strategic monitoring activities and/or corrective action (*e.g.*, termination of the contractual relationship and entity arrangement);
5. The level of monitoring and auditing given to FDR/Delegated entities will depend on the risk rating assigned;
6. FDR/Delegated entities will be required to complete an annual compliance attestation where they attest to being compliant with CMS and URAC regulations/standards; and,
7. The risk rating assigned to the FDR/Delegated entity will be taken into consideration when developing the Audit Plan.

H. Delegation Oversight Workgroup

The Delegation Oversight Workgroup is charged with the routine and systematic evaluation of FDR/Delegated entities to ensure risk management of all entities. The Delegation Oversight Coordinator will act as Chair. Delegation oversight authority is responsible for reporting FDR/Delegation compliance concerns to the compliance department. The Delegation Oversight Coordinator will report Delegation Oversight Workgroup activities, along with monitoring and auditing activities to the Compliance Committee.

Delegation Oversight Workgroup responsibilities include:

1. Assurance and coordination of pre-implementation audit are conducted to determine entities operational capabilities to comply with Federal and State regulatory requirements;
2. Make final determination as to the risk ranking given to each FDR/Delegated entity;
3. Evaluation of ongoing FDR/Delegated performance;
4. Adherence to applicable policies and procedures;
5. Escalation of compliance findings to Compliance Manager and Compliance Committee;

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6. Ensuring Business Owner’s accountability of functions performed by FDR/Delegated entities;
7. Assigning risk levels and reporting on compliance issues concerning FDR/Delegated entities; and,
8. Acting on instances of non-compliance concerning the FDR/Delegated entities, including but not limited to the issuance of a Corrective Action Plan (CAP), mandating additional self-monitoring and reporting to be performed by the FDR/Delegated entity, and any request for documentation regarding the non-compliance.

VI. Effect of Medicare-deemed and URAC-accredited Status

Hometown Health must take into consideration the level and extent of delegation oversight activities as listed in this policy. The entities are to demonstrate, through verification of contract and/or accreditation documents, that they are a Medicare-deemed organization or have attained URAC accreditation status.

VII. Quasi-Delegation Involving Protected Information

While services performed by entities are not considered delegated health plan functions under this policy, if the relationship between Hometown Health and an entity involves the use and/or disclosure of PHI, ePHI, EHR, and PII, there must be a Business Associate Agreement.

VIII. Inquiries that relate to this Hometown Health Policy or matters that are not specifically addressed by this policy should be directed to Hometown Health Manager of Compliance.

IX. To monitor adherence to applicable laws, statutes and regulations, Hometown Health should conduct a periodic review and analysis to determine if there are any changes in its benefits, policies and management protocols which impact compliance.

X. To monitor adherence to applicable laws, statutes and regulations, Hometown Health should notify its entities of changes impacting compliance, including parity of health care services such as mental health and/or substance use disorder parity (“MHPAEI”), as applicable.

Definitions:

- **Auditing:** A formal review of compliance with a particular set of internal (e.g., policies and procedures) or external (e.g., laws and regulations) standards used as base measures, and are performed by someone with no vested interest in the outcomes or FDR being reviewed.

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- **Abuse:** Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare. It also includes beneficiary practices that result in unnecessary cost to the Medicaid program. (42 C.F.R. 455.2).
- **Centers for Medicare and Medicaid Services (“CMS”):** The federal agency that administers the Medicare program. CMS works to make sure that the beneficiaries in these programs are able to get high quality health care. (<https://cms.gov/>).
- **Delegated Entity:** Any party, including an agent or broker that enters into an agreement with a Qualified Health Plan (“QHP”) issuer to provide administrative services or healthcare services to qualified individuals, qualified employers, or qualified employees and their dependents. (45 C.F.R. 156.20).
- **Downstream Entity:** Any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA organization or Part D benefit, below the level of the arrangement between an MA organization or Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (42 C.F.R. 422.2, 423.4).
- **Electronic Protected Health Information (“ePHI”):** Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically as covered by the HIPAA Security Rule (45 C.F.R. Part 160 and Part 164).
- **Electronic Health Records (“EHR”):** An Electronic Health Record (“HER”) is an electronic version of a patient’s medical history that is maintained by the provider over time and may include all of the key administrative clinical data relevant to that persons care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. (www.cms.gov).
- **Entity:** Means all of Hometown Health and Renown Health’s FDRs, delegated entities, subcontractors and network providers.
- **First-Tier Entity:** Any party that enters into a written arrangement, acceptable to CMS, with the MA organization or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA organization or Part D program. (42 C.F.R. 422.2, 423.4).
- **Fraud:** A false representation of a material fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives another. (Paraphrasing Black’s Law Dictionary - <http://thelawdictionary.org/fraud/>).
- **Government Services Administration (“GSA”):** An independent agency of the United States government, it combines the Central Contractor Registration (CCR/FedReg), Online

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Representations & Certifications Application (ORCA) and the Excluded Parties List System (EPLS) into one main contractor database. This database was named System for Award Management or better known as the SAM registration.

- **Medicare Advantage (“MA” or “Part C”):** A Medicare program that provides additional choices among health plans. Those who subscribe to Medicare Parts A and B are eligible, except individuals who have End-Stage Renal Disease (“ESRD”) unless certain exceptions apply. Medicare Advantage Plans are also known as Medicare + Choice Plans.
- **Monitoring:** Includes surveillance activities conducted during the normal course of operations and which may not necessarily be independent of the business area being monitored (*e.g.*, self-reviews, peer reviews, etc.). Monitoring activities may occur to ensure corrective actions are being implemented and maintained effectively or when no specific problems have been identified to confirm ongoing compliance.
- **Office of Inspector General (“OIG”):** The department within the Department of Health & Human Services (“HHS”) tasked with enforcement of waste, fraud, and abuse efforts in Medicare, Medicaid and more than 100 other HHS programs. (<https://oig.hhs.gov>).
- **Prescription Drug Plan (“PDP” or “Part D”):** A Medicare program to assist with the cost of prescription drugs for individuals who are eligible beneficiaries to receive Medicare prescription drug coverage. There are two ways to obtain Medicare prescription drug coverage: 1) through a Medicare Prescription Drug Plan or 2) through Medicare Advantage Plan that includes drug coverage. These plans are offered by insurance companies and other private companies approved by Medicare.
- **Protected Health Information (“PHI”):** Individually identifiable health information, held, maintained or transmitted in any form or medium (electronic, oral or paper) by a covered entity or its subcontractors acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens) which include: identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer or health care clearinghouse; excluding certain educational and employment records. (Paraphrasing https://privacyruleandresearch.nih.gov/pr_07.asp).
- **Personally Identifiable Information (“PII”):** Data which relate to a natural person who can be identified from the data, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity.
- **Related Entity:** Any entity that is related to MA and/or Part D sponsor by common ownership or control.

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- **Risk Assessment:** The identification, measurement, and prioritization of likely relevant events or risks that may have material consequences on Hometown Health's ability to maintain compliance with program requirements.
- **Utilization Review Accreditation Commission ("URAC"):** URAC has been the independent leader in promoting health care quality through accreditation of organizations involved in medical care services. URAC accreditations, certifications, and designations address health care management, health care operations, health plans, pharmacy quality management, and providers. URAC's accreditation is recognized nationwide by state and federal regulators. URAC accreditation standards appear in legislation and regulation at the state and federal government. (www.urac.org).
- **Waste:** Occurs when poor or inefficient practices result in unnecessary healthcare expenditures to a Government program.

References:

- Federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b))
- Physician Self-Referral Statute (42 U.S.C. § 1395nn) ("Stark")
- Nevada Anti-Kickback Statute (Nevada Revised Statute 439B.420-.430)
- 42 CFR Parts 140 through 159 - Commercial insurance regulations relating to health care access
- 42 CFR Part 422 - MEDICARE ADVANTAGE PROGRAM
- 42 CFR Part 423 - Voluntary Medicare Prescription Drug Benefit
- Department of Health & Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare, Medicare Drug & Health Plan Contract Administration Group, HPMS Memorandum, "Release of the Medicare Advantage Contract Amendment," October 5, 2012
- Federal Register / Vol. 64, No. 219 / Monday, November 15, 1999 ("Department of Health and Human Services, Office of Inspector General, Publication of the OIG's Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plan")
- Medicare Advantage Contract Amendment (Rev. January 1, 2015), available at https://www.cms.gov/medicare/medicare-advantage/medicareadvantageapps/downloads/model_contract_amendment_10_05_12.pdf
- Medicare Managed Care Manual, Chapter 21 -Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 Compliance Program Guidelines
- Nevada Revised Statutes governing commercial insurance regulations in the state of Nevada, Title 57, Chapters 679A through 689C

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- U.S. Department of Justice, Criminal Division, Fraud Section, “Evaluation of Corporate Compliance Programs,” available at www.justice.gov/criminal-fraud/page/file/937501/download
- URAC Health Plan CORE Standard P-CORE 6 – Delegation Review Criteria
- URAC Health Plan CORE Standard P-CORE 7 – Delegation Review
- URAC Health Plan CORE Standard P-CORE 8 – Delegation Contracts
- URAC Health Plan CORE Standard P-CORE 9 – Delegation Oversight
- RENOWN.CCD.775 – Patient Privacy – Business Associates
- Hometown.HCP.005 – OIG/GSA Exclusion Screening

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