



DIRECT CONTRACTING ENTITY COMPLIANCE PROGRAM TRAINING GUIDE

OVERVIEW

The Centers for Medicare & Medicaid Services (CMS) is the agency within the U.S. Department of Health and Human Services that is charged with administering the Medicare and Medicaid programs. A Medicare Direct Contracting Entity (DCE) is an entity composed of health care providers operating under a common legal structure, which accepts financial accountability for the overall quality and cost of medical care furnished to Medicare fee-for-service (FFS) Beneficiaries aligned to the entity.

CMS implemented the Global and Professional Direct Contracting Model (Model) under section 1115A of the Social Security Act, which authorizes CMS, through its Center for Medicare and Medicaid Innovation, to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while maintaining or improving the quality of Beneficiary care. The Model seeks to accomplish these goals through financial incentives, emphasis on beneficiary choice, strong monitoring to ensure Beneficiaries maintain access to care, and an emphasis on care delivery for Beneficiaries with complex, chronic, and serious illness.

Esse Health ACO LLC (the Company, or the DCE), as a DCE under contract with CMS, shall follow all rules, regulations, and requirements defined by CMS in its Global and Professional Direct Contracting Model Participation Agreement, which includes training its DC Participant Providers and Preferred Providers (herein, Providers) on the elements and expectations of its DCE Compliance Program. **You are expected to read and comply with the Compliance Program requirements described in this Training Guide, as well as all terms and conditions of your DCE Participation Agreement.**

Any questions about the Compliance Program or the contents of this Training Guide may be addressed to the DCE's Chief Compliance Officer, Erin Venable, at evenable@EHDce.com or (314) 209-3957.

PROVIDER COMPLIANCE

As a DCE Provider, you have agreed to adhere to all applicable DCE laws, regulations, and provisions of your DCE Participation Agreement (Agreement). The DCE is permitted to take remedial action against a Provider to address noncompliance with the terms of the Agreement or program integrity issues identified by CMS. It is your responsibility to know and understand these laws and provisions, and to ask for clarification if you have any questions about your responsibilities or how to comply.

Key elements are highlighted here for Provider awareness¹:

1. **COMPLIANCE.** The DCE arrangement expressly sets forth the Provider's obligation to comply with the applicable terms of the Agreement, including any provisions regarding the following: participant exclusivity; quality measure reporting and continuous care improvement objectives; Voluntary Alignment Activities; Marketing

¹ List of requirements is not all-inclusive; refer to Participation Agreement to review all responsibilities in detail.



Activities; Beneficiary freedom of choice; Benefit Enhancements and Beneficiary Engagement Incentives; participation in evaluation, shared learning, monitoring, and oversight activities; the DCE Compliance Plan; and audit and record retention requirements.

2. **MEDICARE PARTICIPATION.** Providers must be a Medicare-enrolled provider, must timely update their Medicare enrollment information in accordance with Medicare program requirements, and notify the DCE of any such changes within 30 days after the change.
3. **PROVIDER SANCTION OR EXCLUSION.** The DCE is required to notify CMS of any Provider under investigation or found to be sanctioned by the government or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges). Providers must notify the DCE within 7 days of becoming aware of any such investigation or sanction.
4. **PROVIDER TERMINATION.** Any Provider that has been terminated or removed from the DC Provider List (in accordance with CMS guidelines) may not engage in any DCE Activities, Marketing Activities, Voluntary Alignment Activities, Benefit Enhancements, or Beneficiary Engagement Incentives after the effective date of such termination.
5. **BENEFICIARY INDUCEMENTS.** Strict rules and conditions apply regarding participation in the Model, beneficiary referrals, and giving and receiving remuneration, inducements, or rewards. The DCE and its Providers may not provide gifts or other remuneration to Beneficiaries to induce them to receive, or continue to receive, items or services from the DCE or its Providers. Certain in-kind items or services may be permissible, only in accordance with the provisions of the Participation Agreement.
6. **PROVIDER HEALTH CARE DECISIONS.** The DCE and its Providers may not take any action to limit a Provider's ability to make decisions in the best interests of the Beneficiary, including the selection of devices, supplies and treatments used in the care of the Beneficiary. Providers must make Medically Necessary Covered Services available to Beneficiaries in accordance with applicable laws, regulations and guidance. Beneficiaries and their assignees retain their right to appeal claims determinations.
7. **CMS ALIGNMENT OF BENEFICIARIES to the DCE.** Providers may not, directly or indirectly, commit any act or omission, nor adopt any policy, that coerces or otherwise influences a Beneficiary's decision to complete or not complete a Voluntary Alignment Form or a MyMedicare.gov (or any successor site) designation. Providers must instruct Beneficiaries to contact the DCE for questions about how to make changes or how to designate a primary clinician. Providers may not inhibit Beneficiaries from exercising their freedom to obtain health services from providers and suppliers who are not DC Providers.
8. **MARKETING ACTIVITIES.** All Marketing Activities (as defined by CMS) must be conducted in accordance with the DCE's approved Marketing Plan and the rules outlined in the Participation Agreement.
 - Marketing Materials and Marketing Activities may require advance review and approval by CMS, and/or by the DCE, and may not be used until all required approvals are obtained.
 - Providers and other individuals or entities performing functions or services related to DCE Activities or Marketing Activities may not conduct communication or Marketing Activities targeted to Beneficiaries enrolled in Medicare Advantage or any other Medicare managed care plan.



- Marketing Activities may not be conducted outside the DCE Service Area, or in restricted areas of a health care setting.
 - Providers must not engage in any activities that could mislead or confuse a Beneficiary.
 - Providers must not claim the DCE is recommended or otherwise endorsed by CMS or that CMS recommends that the Beneficiary select a Provider as his/her main doctor, main provider, and/or the main place to receive care.
 - Providers must not state or imply that selecting a Provider as his/her main doctor, main provider, and/or main place of care removes a Beneficiary's freedom to choose to obtain health services from non-DC Providers and suppliers.
 - Discrimination against, or selectively targeting Beneficiaries based on race, ethnicity, national origin, religion, gender, sex, age, mental or physical disability, health status, receipt of health care, claims experience, medical history, genetic information, evidence of insurability, geographic location, or income, is strictly prohibited.
- **DATA PRIVACY, SECURITY, and RETENTION.** Providers must follow all applicable rules and requirements for the use and disclosure of health care information, and for maintaining data privacy, security, and confidentiality, in accordance with laws established by the Health Insurance Portability and Accountability Act (HIPAA). All data and information related to the provision of services under their DCE Participation Agreement (all books, contracts, records, documents, and other evidence) must be retained for a minimum of ten (10) years from the expiration or termination of the Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, or longer if circumstances (as defined by CMS and/or the DCE) a .

COMPLIANCE PROGRAM and REQUIREMENT TO COMPLY

The DCE is committed to promoting a corporate culture that encourages ethical conduct and compliance with all applicable Federal and State laws, regulations, all terms and provisions of the DCE Participation Agreement, and Company policies and procedures (collectively Laws). This commitment is embodied in the DCE's Compliance Plan (Plan). Plan elements, how the DCE complies with the Plan, and specific Provider responsibilities are described below.

1. Implementation of compliance standards, policies, and procedures to support the prevention, detection, and correction of activities or performance that are noncompliant with the regulatory, contractual, or operational agreements, policies, and procedures applicable to the Company.

- **CODE OF CONDUCT.** The DCE's Code of Conduct² describes the organization's principal policy regarding its expectations, responsibilities, requirements, and commitment to comply with all relevant Laws and to act and serve in an ethical manner.
- **INTEGRITY.** Each Provider should adhere to the spirit and language of the Compliance Program and the Code of Conduct and strive for excellence in performing all duties. Providers must maintain a high level of integrity in business conduct and avoid any conduct that could reasonably be expected to reflect adversely upon the integrity of Company or DCE parties.
- **CONFLICT OF INTEREST.** To protect the interests of the Company when it is contemplating entering into a transaction or arrangement that might benefit the private interest of a manager, officer, or senior leader,

² Access the Code of Conduct on the DCE Website



the Company has adopted a Conflict-of-Interest Policy that requires disclosure of potential conflicts, management, and corrective actions in case of violation.

- **FRAUD, WASTE, AND ABUSE.** To comply with the law and promote an atmosphere that is free from improper dealing, the Company's policy is to follow the Medicare fraud, waste, and abuse standards in all circumstances. Government health care fraud and abuse requirements prohibit, among other things, any person from offering or paying remuneration to a Medicare, a Medicaid or any other government-funded patients' referral source for making or recommending patient referrals and from making false claims for reimbursement. The following key federal fraud and abuse laws must be followed:
 - Physician Self-Referral (Stark) Law prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies.
 - Anti-Kickback Statute (AKS) prohibits a provider from intentionally (knowing and willfully) offering, paying, soliciting or receiving anything of value to induce or reward referral or generate reimbursable federal health care program business.
 - Civil Monetary Penalties Law (CMPL) prohibits offering "remuneration" to a Medicare beneficiary if you know or should know that doing so is likely to influence beneficiary selection of a particular provider.
 - False Claims Act (FCA) prohibits the knowing submission of false or fraudulent claims to the government. Even if medically necessary services are rendered and billed correctly, in the context of a Stark, AKS, or the CMPL violation, those claims are considered to be false and implicate the FCA.
- **NON-COMPLIANCE.** Any activity that results or may result in the violation of Laws, the Compliance Plan, Code of Conduct, or DCE activities or marketing activities, whether deliberate or unintentional, by either an internal or external individual/entity, may constitute a compliance problem and must be reported to the DCE.

2. Assigning responsibility to oversee compliance with those standards, policies, and procedures to individuals within the organization who have substantial control.

- The DCE appointed a Chief Compliance Officer (CCO) to direct and oversee the day-to-day implementation and operation of the Plan, and report to the governing body on Plan performance.
- The DCE Board established a Compliance Committee to advise the CCO in the Plan's implementation, and to oversee the effectiveness of Plan performance.

3. Communicating compliance and ethics standards to all associates.

- Compliance training is required for all DCE associates, including its Providers.
- Compliance and ethical standards are described in the DCE's Code of Conduct.
- Compliance Program Training Guide and Code of Conduct are readily available to Providers at all times via the DCE Website, or upon request to the CCO.
- Associates and Providers are expected to know and follow all applicable rules and expectations regarding DCE Medicare, general Compliance and Ethics, Information Security, Data Privacy, and Marketing Activities.



4. Establishing monitoring and auditing procedures to prevent and detect possible violations and evaluate the Plan's effectiveness.

- The DCE conducts various monitoring and audit activities to evaluate performance against compliance requirements, and to identify risks and/or any deficiencies requiring correction.
- The DCE is also subject to monitoring, auditing, and oversight by regulatory authorities. The government has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents, and other evidence of the DCE and its Providers that pertain to DCE activities.
- The DCE and its Associates, Providers, and other related entities are expected to fully comply with all DCE and regulatory monitoring and oversight requests and activities.

5. Establishing a system for individuals to report or seek guidance regarding potential or actual compliance violations, without fear of retaliation or intimidation.

- The DCE has a Hotline for any individual to report any compliance problem or concern, anonymously and confidentially if desired. The Hotline is accessed by calling **1-800-450-0068**, or online at **<https://lumeris.ethicspoint.com>**.
- Issues and concerns may also be reported by contacting the CCO in person, by telephone, or via e-mail.³
- The Company prohibits retaliation or intimidation against any individual making a good faith report of a known or suspected compliance violation or cooperating in any investigation or inquiry. Such individuals shall not be disciplined, or discriminated or retaliated against, even if the report is determined to be false.

6. Establishing disciplinary/corrective action mechanisms to fairly and consistently respond to violations or failure to detect or report a violation.

- The CCO ensures that appropriate disciplinary/corrective action is taken, including, without limitation, reporting of violations promptly to government authorities and/or appropriate law enforcement agency(ies) if warranted, and the imposition of appropriate disciplinary/ corrective action in accordance with Company policies and procedures.
- The type and severity of disciplinary action will depend on the particular facts and circumstances. Serious deviations can result in termination of employment or contract.

7. Establishing reasonable steps to respond appropriately to detected violations and prevent recurrence.

- All reported compliance concerns or those identified in the course of self-evaluations or audits, including concerns of possible fraud or misconduct, are investigated promptly, in accordance with Company policies and procedures.

³ Chief Compliance Officer: Erin Venable at evenable@EHdce.com or (314) 209-3957.



- If, upon review, it is determined that the Company has been noncompliant in some regard, the Company will promptly take all appropriate actions required under the circumstances. The actual response will vary depending on the unique circumstances, but in all cases, steps will be taken to ensure future compliance.

PROVIDER COMPLIANCE RESPONSIBILITIES – SUMMARY

1. Follow all provisions of the DCE Participation Agreement, the DCE's Code of Conduct, and applicable policies & procedures in performing all DCE functions and services, including those specified in the Provider Compliance section of this document (above).
2. Participate in all applicable monitoring and/or audit activities, as requested or required.
3. Maintain books, contracts, records, documents, and other evidence of DCE functions and services performed, for a period of ten (10) years from the final date of the agreement period, or from the date of completion of any audit, evaluation, or inspection, whichever is later, and provide/allow access to any such documentation to the government and/or DCE if requested.
4. Promptly report any issues or concerns of non-compliance with Laws, DCE Participation Agreement, Code of Conduct, and applicable policies & procedures, using the reporting methods described herein.
5. Contact the CCO with any questions or concerns about the Compliance Program or your responsibilities for compliance with the Program.