



**Fallon Health’s Medicare Compliance Program Guidance for
first tier, downstream and related entities**

Fallon Health contracts with a number of individuals and entities to perform services that Fallon is obligated to perform or arrange under its contracts with the Centers for Medicare & Medicaid Services (CMS). These contracts impose upon Fallon the obligation to monitor the compliance efforts of its contractors.

Frequently Asked Questions

<p>1</p>	<p>What are first tier, downstream and related entities?</p> <p>Fallon Health enters into business relationships with vendors, providers and suppliers to perform certain administrative and healthcare functions that are the obligation of Fallon under agreements with CMS. These contractors are known as first tier entities.</p> <p>A first tier entity is defined by CMS as any party that enters into a written arrangement, acceptable to CMS, with Fallon, to provide administrative or healthcare services for Medicare eligible individuals under the Medicare Advantage or Part D programs (See 42 C.F.R. §§ 422.500 and 423.501).</p> <p>A first tier entity may then contract with a downstream entity to perform the functions that Fallon has delegated to the first tier entity. Downstream entities are defined as any party that enters into a written arrangement, acceptable to CMS with persons or entities involved with the Medicare Advantage or Part D benefit, below the level of the arrangement between Fallon Health and a first tier entity (See 42 C.F.R. §§ 422.500 and 423.501).</p> <p>Fallon may also delegate its functions to an organization that is related to Fallon by common ownership or control (See Medicare Managed Care Manual (MMCM) Chapter 11 §110; MMCM Chapter 21 §§ 20 & 40; 42 CFR §§ 422.2 and 422.500(b)).</p>	
<p>2</p>	<p>Our company is not a payor or provider of healthcare services, why has Fallon Health determined that we are a first tier entity?</p> <p>In Chapter 21 §40, of the MMCM, CMS indicates that it is the responsibility of Medicare Advantage plans, like Fallon, to identify contracted entities that are first tier, downstream or related entities (“FDR”) and which must comply with CMS requirements. Unless it is clear that an entity is or is not an FDR, the determination of FDR status requires an analysis of all of the facts and circumstances of the arrangement.</p> <p>CMS requirements, including monthly exclusions checks, as well as the annual Medicare Compliance and Fraud Waste and Abuse trainings, are not</p>	

	<p>limited to payors or providers of health care services. They also apply to organizations that provide administrative services as provided in 42 C.F.R. §§ 422.2 and 422.500; MMCM Chapter 11 §§100.4,100.5, 110.</p>	
<p>3</p>	<p>Why does Fallon Health monitor and audit the activities of our company that relate to Fallon business?</p> <p>Fallon maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements. Therefore, CMS has the right to hold Fallon accountable for the failure of a first tier entity to comply with Medicare program requirements MMCM Chapter 21 §40; 42 CFR §422.504(i)(1). As such, Fallon monitors and audits its first tier entities on an ongoing basis to ensure compliance with applicable Medicare laws, regulations and CMS subregulatory guidance.</p>	
<p>4</p>	<p>What are some examples of the monitoring and auditing of first tier entities that Fallon Health performs?</p> <p>In response to CMS requirements, Fallon Health has developed the Government Programs Vendor Compliance Annual Assessment. This assessment assists Fallon in evaluating the performance of a first tier entity against the requirements of its current contract with Fallon, as well as Fallon’s contracts with the Federal and State governments. Such contracts between Fallon and the first tier entities contain the provisions prescribed in 42 CFR §422.504(i) which require first tier entities to comply with Fallon’s contractual obligations to CMS.</p> <p>Fallon also monitors first tier entities to ensure that they have implemented Fraud Waste and Abuse safeguards to identify excluded providers and entities. MMCM Chapter 21 §50.6.8; 42 CFR §§ 422.752(a)(8);422.503(b)(4)(vi); and 1001.1901.</p> <p>First tier entities must perform excluded individuals and entity checks for all employees, managers and board members prior to hire, and vendors and contractors prior to contract execution, and monthly thereafter against the OIG List of Excluded Individuals and Entities (LEIE) and the System for Awards Management (SAM).</p> <p>First tier entities are also required to provide periodic reports to Fallon on their delegated activities to ensure satisfactory performance. 42 CFR §422.504(i).</p>	