



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

Fallon Health contracts with a number of vendors and providers to perform services that Fallon is obligated to perform or provide under its contracts with the Centers for Medicare & Medicaid Services (CMS). However, this delegation of functions does not release Fallon Health from overseeing all activities and maintaining ultimate responsibility.

### Frequently Asked Questions

<b>1</b>	<p><b>What are first tier, downstream and related entities (FDR)?</b></p> <p>A <b>first tier entity</b> 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. §§ <a href="#">422.500</a> and <a href="#">423.501</a>).</p> <p>A first tier entity may then contract with a <b>downstream entity</b> 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. §§ <a href="#">422.500</a> and <a href="#">423.501</a>).</p> <p>Fallon may also delegate its functions to an organization that is <b>related</b> to Fallon by common ownership or control (See <a href="#">Medicare Managed Care Manual (MMCM) Chapter 11 §110</a>; <a href="#">MMCM Chapter 21 §§ 20 &amp; 40</a>; <a href="#">42 CFR §§ 422.2</a> and <a href="#">422.500(b)</a>).</p>	
<b>2</b>	<p><b>Our company is not a provider of healthcare services. Why has Fallon Health determined that we are a first tier entity?</b></p> <p>In <a href="#">Chapter 21 §40, of the MMCM</a>, CMS indicates that it is the responsibility of Medicare Advantage plans, like Fallon, to identify contracted entities that are FDRs 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 exclusion screenings, annual Medicare Compliance and Fraud Waste and Abuse trainings, and compliance policies, are not limited to payors or providers of health care services. They also apply to organizations that provide administrative services as provided in <a href="#">42 C.F.R. §§ 422.2</a> and <a href="#">422.500</a>; <a href="#">MMCM Chapter 11 §§100.4,100.5, 110</a>.</p>	

3	<p><b>Why does Fallon Health monitor and audit the activities of our company that relate to Fallon business?</b></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 <a href="#">MMCM Chapter 21 §40</a>; <a href="#">42 CFR §422.504(i)(1)</a>. 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>	
4	<p><b>What are some examples of the monitoring and auditing of first tier entities that Fallon Health performs?</b></p> <p>The most recent example is Fallon Health’s 2018 First Tier Entity 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.</p> <p>First tier entities must also screen all employees, providers, vendors and board members prior to hire/contract execution, and monthly thereafter against the OIG List of Excluded Individuals and Entities (LEIE) and the System for Awards Management (SAM).</p> <p>Additionally, first tier entities are required to provide periodic reports to Fallon on their delegated activities to ensure satisfactory performance. <a href="#">42 C.F.R. §422.504(i)</a>.</p>	
5	<p><b>How can I find more information about Fallon Health’s Medicare compliance program for FDRs?</b></p> <p>Please check out our website, <a href="http://fallonhealth.org/Government-Programs-Vendors.aspx">fallonhealth.org/Government-Programs-Vendors.aspx</a>, send an email to <a href="mailto:ComplianceBlast@fallonhealth.org">ComplianceBlast@fallonhealth.org</a> or contact Kasey Ciolfi, Medicare Regulatory Affairs Manager, at 508-368-9514.</p>	