GOVERNMENT PROGRAMS COMPLIANCE OFFICER NEWSLETTER

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HEALTH CARE SERVICE CORPORATION



Message from Kim Green HCSC Government Programs Compliance Officer

Welcome to our second quarter newsletter for 2014!

In this edition, we are going to re-visit a topic introduced last year, First Tier, Downstream and Related Entities, or FDRs. Like our commercial business, the Government Programs Division has contracts with vendors to perform services as part of our Medicare Prescription Drug Part D and Medicare Advantage Part C plans. Some of the vendors simply perform support services, while others may have a larger role in the administration or delivery of Medicare Parts C and D benefits. Generally, those vendors involved in the administration or delivery of Parts C and D benefits are considered FDRs (e.g., Prime, Argus, TMG). Regardless of the functions delegated to a FDR, HCSC as the plan sponsor maintains the responsibility for ensuring its FDRs meet the requirements of the Medicare program and carry out the delegated functions in accordance with all CMS and State regulations. Furthermore, certain First Tier entity relationships may require additional upfront due diligence beyond executing a contract and Medicare Addendum. Performing a pre-delegation assessment, establishing routine monitoring and determining the need for an annual audit are examples of additional oversight that may be necessary.

Inside this newsletter, we will review how CMS defines FDRs, give examples of FDRs and discuss what is expected of Plan Sponsors that utilize FDRs in the administration or delivery of Parts C and D benefits.

Please do not hesitate to contact your business partners in the Government Programs Division (GPD) if you have any questions regarding the entities you are working with and the applicable oversight requirements.

As always, please remember that you are required to report any suspicious behavior or potential wrongdoing related to any government contract. You can report this information to your manager or our Medicare hotline number, which is listed below. As the Government Program's Compliance Officer, please know that you can always contact me directly at 312-653-5110. We encourage you to visit our website and submit any topics that you would like to hear about in future newsletters.

Kim Green

HCSC Government Programs Compliance Officer

Inside this issue:

FDR Defined	2
HCSC Process identifying FDRs	2
Additional Oversight	3
Examples of FDRs	3

Medicare Compliance Issues?

Contact HCSC Medicare Hotline 1.877.211.2290





Your 24/7 resource for questions about Medicare Part D or MAPD

FDR

First Tier, Downstream and Related Entity (FDR)

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MAO (Medicare Advantage Organizations) or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program. Example: Pharmacy Benefit Manager (PBM), Contracted Medical Groups or Agencies that sell Medicare products to members.

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a 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. Example: Pharmacies and Claims Processing firms.

Related Entity is any entity that is related to an MAO or Part D sponsor by common ownership or control and (1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation; (2) Furnishes services to Medicare enrollees under an oral or written agreement; or (3) Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period. Example: Plan sponsor is the parent company of its own in-house Pharmacy Benefit Manager (PBM).

HCSC Process for identifying FDRs

GPD has established processes to review the list of vendors performing services on behalf of HCSC specific to Part C and D. GPD is responsible for determining if a vendor should be considered a First Tier entity to HCSC or if they are simply performing support services on behalf of HCSC. The Legal Department, Government Programs Compliance (GPC) and Strategic Sourcing are consulted as necessary during the review process.

Below are a list of general guidelines which can be used to help determine whether an FDR status should be applied to the entity.

- Whether the function performed by the entity is something that is required of the MAO or Part D Plan Sponsor under its contract with CMS, the applicable federal regulations or CMS guidance;
- O To what extent the function directly impacts enrollees;
- To what extent the delegated entity has interaction with enrollees, either orally or in writing;
- Whether the delegated entity has access to beneficiary information or personal health information;
- Whether the delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from the MAO or Sponsor;
- The extent to which the function places the delegated entity in a position to commit health care fraud, waste or abuse; and
- The risk the entity could harm enrollees or otherwise violate Medicare Program requirements or commit fraud.

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Additional Oversight that First Tier Entity Relationships May Require:

Medicare Addendum

The Medicare Addendum contains flow down provisions relating to CMS requirements. A flow down provision is a contract provision by which the parties incorporate the terms of the general contract between the owner and the general contractor into the lower tier agreement. It may also be referred to as a pass-through or conduit clause. Flow down provisions help to ensure that the vendor's (FDR's) obligations to the contractor (HCSC) mirror the contractor's (HCSC) obligations to the owner (CMS).

Certificate of Compliance

The Certificate of Compliance references CMS requirements that the First Tier entity certifies its (as well as their FDRs) adherence to, and ongoing compliance with, the requirements cited in the document. The requirements cited include: Training, OIG Exclusion, Conflict of Interest, Record Retention, Fraud Waste & Abuse, and Offshoring. All of HCSC's First Tier entities are required to complete a Certificate of Compliance annually.

Routine Monitoring

The contracting organization, specifically the business process owners responsible for the vendor, should develop written procedures for routine monitoring and review of the functions delegated to the First Tier entity.

If you are a business area that contracts with FDRs, it is your responsibility to be well informed of the guidelines and regulations that must be adhered to by the FDR. If you have any questions regarding a FDR, please contact the Government Programs Division.

Examples of First Tier and Downstream Entities

