

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 2013!

In our last newsletter, we discussed FWA (Fraud, Waste and Abuse). In this edition, we are going to focus on the CMS acronym, FDR (First Tier, Downstream and Related entity). Like our commercial business, we have several contracted vendors who perform services as part of our Medicare Part D and Medicare Advantage contracts. Some of the vendors may perform support services and others may be responsible for the administration or delivery of Parts C and D benefits. Generally, those vendors involved in the administration or delivery of Parts C and D benefits are considered FDRs. Medicare program requirements apply to FDRs to whom the sponsor (HCSC/HISC/BlueLincs HMO) has delegated administrative or health care service functions relating to the sponsor's (HCSC/HISC/BlueLincs HMO) Medicare Parts C and D contracts. HCSC/HISC/BlueLincs HMO as the plan sponsor has the ultimate responsibility for making certain its FDRs meet the requirements of the Medicare program and carry out the delegated functions. Furthermore, if an FDR fails to meet CMS requirements, HCSC/HISC/BlueLincs HMO may incur regulatory fines or sanctions and in some instances the loss of a contract with CMS.

Inside this newsletter, you will identify how CMS defines FDRs, examples of FDRs and what is expected of an entity that is considered an FDR.

We hope that you will find this information useful. **Please do not hesitate to contact the government programs compliance staff if you have any specific questions regarding entities that you may be working with that may be considered an FDR.**

As always, please remember that you are required to report any suspicious behavior or potential wrongdoing related to any government contract. All calls to our hotline can be made anonymously and without fear of intimidation or retaliation.

Our Medicare and Fraud hotline numbers and email address are also included in this newsletter so that you may contact us should you have any questions or concerns. 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 general questions or news items that you would like to hear about in future newsletters.

Kim Green

HCSC Government Programs Compliance Officer

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Medicare Compliance Issues?

**Contact
HCSC Medicare Hotline
1.877.211.2290**



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

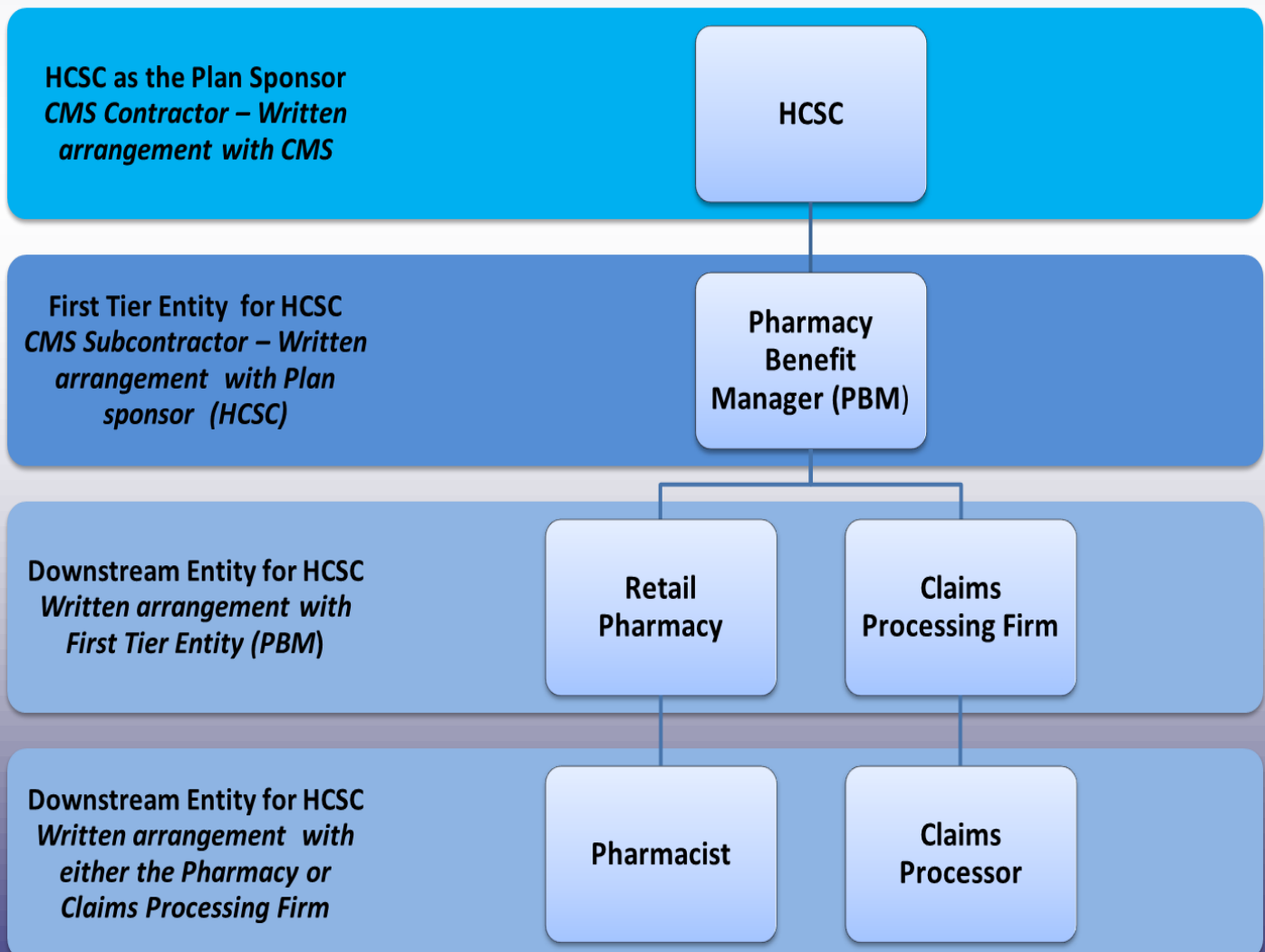
First Tier, Downstream and Related Entity (FDR)

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, 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).

First Tier and Downstream Example



HCSC Process for First Tier Entities

Determination of a First Tier Entity

HCSC has a Delegate Entity Committee that is comprised of Legal, Government Programs, Government Program Compliance and Medicare Operations. This committee meets on a regular basis to review the current list of first tier entities and to determine if a new entity should be considered a first tier entity or a support services vendor.

Each delegated entity is evaluated against the following set of criteria to 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 Medicare Advantage Organization (MAO) or Part D Plan Sponsor under its contract with CMS, the applicable federal regulations or CMS guidance;
- 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.

Please refer to Medicare Managed Care Manual, Chapter 21, Compliance Program Guidelines and the Prescription Drug Benefit Manual, Chapter 9, Compliance Program Guidelines at www.cms.gov for additional information.

First Tier Entity Requirements

All first tier entities are required to have a current Medicare Addendum in place as well as complete a Certificate of Compliance at time of contract and annually thereafter.

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. Such provisions state that the vendor is bound to the contractor (HCSC/HISC/BlueLincs HMO) in the same manner as the contractor (HCSC/HISC/BlueLincs HMO) is bound to the owner (CMS) in the prime contract. Flow down provisions help to ensure that the vendor's obligations to the contractor (HCSC/HISC/BlueLincs HMO) mirror the contractor's (HCSC/HISC/BlueLincs HMO) obligations to the owner (CMS).

Certificate of Compliance

In addition to meeting any operational function requirements detailed in the Statement of Work (SOW) or contract, all FDRs must meet certain compliance requirements. The Certificate of Compliance references requirements that are in accordance with CMS regulations. By completing this document, the submitter representing the first tier entity certifies that their entity/ organization as well as their first tier, downstream and related entities are in compliance with the requirements cited in the document.

The requirements referenced in the Certificate of Compliance are as follows:

- **Training and Education**

General Compliance Training - Employees (including temporary workers and volunteers) and governing body must, at a minimum, receive general compliance training within 90 days of initial hiring and annually thereafter.

Fraud, Waste and Abuse Training (FWA) - Employees (including temporary workers and volunteers) and governing body who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring and annually thereafter.

- **OIG/GSA Exclusion** The DHHS OIG List of Excluded Individuals and Entities (LEIE list) and the GSA Excluded Parties Lists System (EPLS) must be reviewed prior to the hiring or contracting of any new employee, temporary employee,

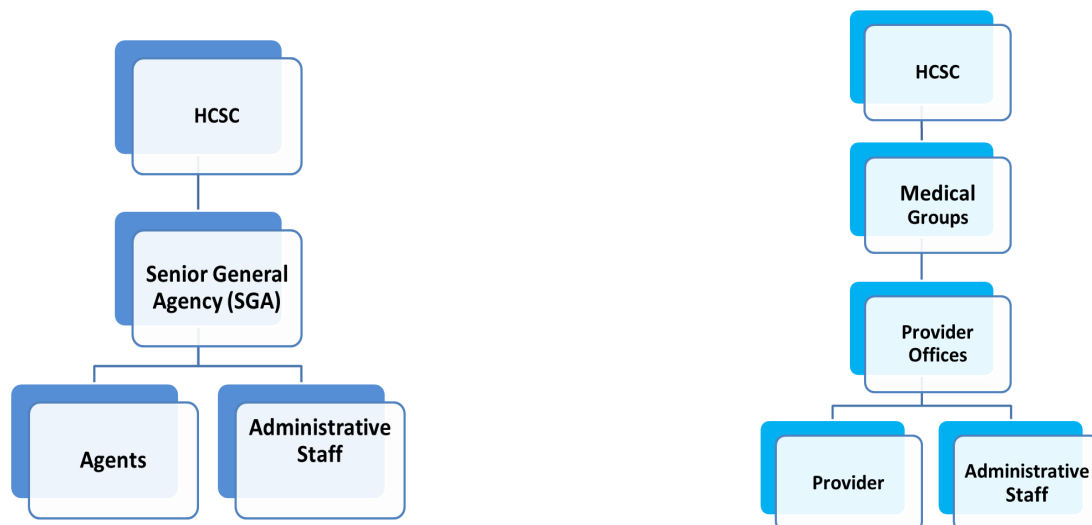
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Certificate of Compliance Requirements Continued

volunteer, consultant, governing body member, or FDR, and monthly thereafter, to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs.

- **Conflict of Interest** The entity's governing body and senior leadership must be screened for conflicts of interest through a certification, attestation or other means at time of hire and annually thereafter.
- **Standards of Conduct and Compliance Policies and Procedures** The FDR must distribute to its employees, contractors and/or subcontractors who support the Medicare business HCSC's Code of Business Ethics and Conduct and Compliance Policies and Procedures or the FDR's Standards of Conducts and Compliance Policies and Procedures. Distribution of the Standards of Conduct and Compliance Policies and Procedures must occur within 90 days of hire, when there are updates to the policies, and annually thereafter.
- **Record Retention** Supporting documentation for all the CMS requirements must be retained for ten years in addition to contract year.
- **Incidents of Suspected Non-Compliance Fraud, Waste and Abuse** Entity/Organization shall promptly investigate any potential and/or suspected incidents of non-compliance with laws, regulations, or fraud, waste, and abuse. The entity/organization must report any such incident to HCSC Government Programs Compliance Officer in a timely manner after entity/organization becomes aware of such incident.
- **Sponsor activities performed outside of the United States (Offshore Subcontracting)** All FDRs must obtain prior written consent from HCSC/HISC/BlueLincs HMO and complete HCSC's Offshore Attestation form in **advance of 30 days** of signing a contract if the FDR is engaged in offshore subcontracting that involves Medicare-related work. Many state specific Medicaid contracts prohibit offshore subcontracting.

Additional Examples of First Tier and Downstream Entities



Visit our website:
www.hisccompliance.com

If you have any news or questions that you would like included in the newsletter, please send an email to:
HISCCOMPLIANCE @ BCBSIL.COM

Fraud Hotline: Available 24/7

Report fraud issues anonymously

1-800-543-0867 – for Members

1-877-272-9741 – for Producers, Vendors & Providers

1-877-211-2290 – for Employees