Medicare Managed Care Manual
Chapter 21 – Compliance Program Guidelines
And
Prescription Drug Benefit Manual
Chapter 9 – Compliance Program Guidelines

(Chapter 21 – Rev. 110, 01-11-13)
(Chapter 9 – Rev. 16, 01-11-13)

50.6.6 – Monitoring and Auditing FDRs

(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors are responsible for the lawful and compliant administration of the Medicare Parts C and D benefits under their contracts with CMS, regardless of whether the sponsor has delegated some of that responsibility to FDRs. The sponsor must develop a strategy to monitor and audit its first tier entities to ensure that they are in compliance with all applicable laws and regulations, and to ensure that the first tier entities are monitoring the compliance of the entities with which they contract (the sponsors' "downstream" entities). Sponsors must also monitor any related entities to ensure those entities are compliant with all applicable laws and regulations.

Sponsors must include in their work plan the number of first tier entities that will be audited each year and how the entities will be identified for auditing. It is a best practice for sponsors to conduct a number of on-site audits.

Sponsors must conduct specific monitoring of first tier entities to ensure they fulfill the compliance program requirements. When a sponsor has a large number of first tier entities, making it impractical and/or cost prohibitive to monitor or audit all first tier entities for all compliance program requirements, the sponsor may perform a risk assessment to identify its highest risk first tier entities, then select a reasonable number of first tier entities to audit from the highest risk groups. Monitoring of first tier entities for compliance program requirements must include an evaluation to confirm that the first tier entities are applying appropriate compliance program requirements to downstream entities with which the first tier contracts.

When FDRs perform their own audits, it is a best practice for sponsors to obtain a summary of the audit work plan and audit results that relate to the services the FDR performs. Examples of reports that sponsors should receive and review as part of their FDR monitoring and auditing efforts include, but are not limited to:

- **Payment Reports** that detail the amount paid by both the sponsor and the enrollee; in addition, payment reports identifying the provider, the enrollee and a description of the drug (including dosage and amount) or service provided. These reports should be used to identify over and under payments, duplicate payments, timely payments, and pricing aberrances, and to help verify correct pricing;

- **Drug Utilization Reports** that identify the number of prescriptions filled by a particular enrollee and in particular, numbers of prescriptions filled for suspect classes of drugs, such as narcotics, to identify possible therapeutic abuse or illegal activity by an enrollee. Enrollees with an abnormal number of prescriptions or

prescription patterns for certain drugs should be identified in reports. Likewise, Drug Utilization Management reports from FDRs may be a useful tool in identifying FWA;

- **Provider Utilization Reports** that identify the number and types of visits and services submitted for payment to identify possible spikes and/or irregularities such as a provider submitting claims for services that would not normally be performed by the provider's specialty;

- **Prescribing and Referral Patterns by Physician Reports** that identify the number of prescriptions and referrals written by a particular provider and typically focus on a class or particular type of drug, such as narcotics, or a specific type of DME, such as scooters. These reports should be generated to identify possible prescriber and referral/provider, pharmacy fraud and DME fraud; and

- **Geographic ZIP Reports** that identify possible doctor shopping schemes or script mills by comparing the geographic location (ZIP code) of the patient to the location of the provider that wrote the prescription and should include the location of the dispensing pharmacy. These reports should generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (for example, 30 miles). "Normal distance" should take into account where the enrollee resides (i.e., enrollees in rural areas would typically have longer trips to a doctor or pharmacy than enrollees living in urban areas).

When corrective action is needed, sponsors must ensure that corrective actions are taken by the entity. Although first tier entities may perform their own internal auditing, the sponsor remains obligated to perform its' own auditing of first tier entities.