20 – Definitions

(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)

The following definitions apply for purposes of these guidelines only:

Abuse includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between "fraud" and "abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

Act refers to the Social Security Act.

Appeal (Part C Plan): Any of the procedures that deal with the review of adverse organization determinations on the health care services an enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service as defined in 42 C.F.R. § 422.566(b). These procedures include reconsideration by the MA Plan and, if necessary, an independent review entity, hearings before Administrative Law Judges (ALJs), review by the Medicare Appeals Council (MAC), and judicial review.

Appeal (Part D Plan): Any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in 42 C.F.R. §423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity (IRE), Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

Cost Plan is a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) with a cost-reimbursement contract under section 1876(h) of the Act (See 42 C.F.R. §417.1, §423.4). Cost Plan sponsors may contract to offer prescription drug benefits under the Part D program. (See, 42 C.F.R. §423.4.)

Data Analysis is a tool for identifying coverage and payment errors, and other indicators of potential FWA and noncompliance.

Deemed Provider or Supplier means a provider or supplier that has been accredited by a national accreditation program (approved by CMS) as demonstrating compliance with certain conditions.

DHHS is the Department of Health and Human Services. CMS is the agency within DHHS that administers the Medicare program.

DOJ is the Department of Justice.

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. (See, 42 C.F.R. §, 423.501).

Employee(s) refers to those persons employed by the sponsor or a First Tier, Downstream or Related Entity (FDR) who provide health or administrative services for an enrollee.

Enrollee means a Medicare beneficiary who is enrolled in a sponsor's Medicare Part C or Part D plan.

External Audit means an audit of the sponsor or its FDRs conducted by outside auditors, not employed by or affiliated with, and independent of, the sponsor.

FDR means First Tier, Downstream or Related Entity.

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MAO 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. (See, 42 C.F.R. § 423.501).

Formulary means the entire list of Part D drugs covered by a Part D plan and all associated requirements outlined in Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 6.

Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347.

FWA means fraud, waste and abuse.

Governing Body means that group of individuals at the highest level of governance of the sponsor, such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control the sponsor in the best interest of the organization and its enrollees. As used in this chapter, governing body does not include C-level management such as the Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, etc., unless persons in those management positions also serve as directors or trustees or otherwise at the highest level of governance of the sponsor.

GSA means General Services Administration.

Internal Audit means an audit of the sponsor or its FDRs conducted by auditors who are employed by or affiliated with the sponsor.

Medicare is the health insurance program for the following:

- People 65 or older,
- People under 65 with certain disabilities, or
- People of any age with End-Stage Renal Disease (ESRD) (permanent kidney failure requiring dialysis or a kidney transplant).

Monitoring Activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

NBI MEDIC means National Benefit Integrity Medicare Drug Integrity Contractor (MEDIC), an organization that CMS has contracted with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program. The NBI MEDIC's primary role is to identify potential FWA in Medicare Parts C and D.

OIG is the Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.

Pharmacy Benefit Manager (PBM) is an entity that provides pharmacy benefit management services, which may include contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs. Some sponsors perform these functions in-house and do not use an outside

entity as their PBM. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies. A PBM is often a first tier entity for the provision of Part D benefits.

PDP means Prescription Drug Plan.

Related Entity means 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. (See, 42 C.F.R. §423.501).

Special Investigations Unit (SIU) is an internal investigation unit responsible for conducting investigations of potential FWA.

Sponsor refers to the entities described in the Introduction to these guidelines.

TrOOP (True Out of Pocket) Costs are costs that an enrollee must incur on Part D covered drugs to reach catastrophic coverage. (These incurred costs are defined in regulation at §423.100 and Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 5, section 30). In general, payments counting toward TrOOP include payments by enrollee, family member or friend, Qualified State Pharmacy Assistance Program (SPAP), Medicare's Extra Help (low income subsidy), a charity, manufacturers participating in the Medicare coverage gap discount program, Indian Health Service, AIDS Drug Assistance Programs, or a personal health savings vehicle (flexible spending account, health savings account, medical savings account). Payments that do NOT count toward TrOOP include Part D premiums and coverage by other insurances, group health plans, government programs (non-SPAP), workers' compensation, Part D plans' supplemental or enhanced benefits, or other third parties, drugs purchased outside the United States, and over-the counter drugs and vitamins.

Waste is the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.