

**§ 438.604 Data that must be certified.**

(a) *Data certifications.* When State payments to an MCO or PIHP are based on data submitted by the MCO or PIHP, the State must require certification of the data as provided in § 438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Additional certifications.* Certification is required, as provided in § 438.606, for all documents specified by the State.

**§ 438.606 Source, content, and timing of certification.**

(a) *Source of certification.* For the data specified in § 438.604, the data the MCO or PIHP submits to the State must be certified by one of the following:

(1) The MCO's or PIHP's Chief Executive Officer.

(2) The MCO's or PIHP's Chief Financial Officer.

(3) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PIHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of the data.

(2) To the accuracy, completeness and truthfulness of the documents specified by the State.

(c) *Timing of certification.* The MCO or PIHP must submit the certification concurrently with the certified data.

**§ 438.608 Program integrity requirements.**

(a) *General requirement.* The MCO or PIHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate

the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision for internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PIHP's contract.

**§ 438.610 Prohibited affiliations with individuals debarred by Federal agencies.**

(a) *General requirement.* An MCO, PCCM, PIHP, or PAHP may not knowingly have a relationship of the type described in paragraph (b) of this section with the following:

(1) An individual who is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in non-procurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

(b) *Specific requirements.* The relationships described in this paragraph are as follow:

(1) A director, officer, or partner of the MCO, PCCM, PIHP, or PAHP.

(2) A person with beneficial ownership of five percent or more of the MCO's, PCCM's, PIHP's, or PAHP's equity.

(3) A person with an employment, consulting or other arrangement with the MCO, PCCM, PIHP, or PAHP for the provision of items and services that are significant and material to the

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MCO's, PCCM's, PIHP's, or PAHP's obligations under its contract with the State.

(c) *Effect of Noncompliance.* If a State finds that an MCO, PCCM, PIHP, or PAHP is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

(d) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (c)(2) or (c)(3) of this section is taken in consultation with the Inspector General.

**Subpart I—Sanctions**

**§ 438.700 Basis for imposition of sanctions.**

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines whether an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient,

except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) A State determines whether an MCO, PIHP, PAHP or PCCM has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines whether—

(1) An MCO has violated any of the other requirements of sections 1903(m) or 1932 of the Act, and any implementing regulations;

(2) A PCCM has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act and any implementing regulations;

(3) For any of the violations under paragraphs (d)(1) and (d)(2) of this section, only the sanctions specified in § 438.702, paragraphs (a)(3), (a)(4), and (a)(5) may be imposed.

**§ 438.702 Types of intermediate sanctions.**

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management for an MCO as provided in § 438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.