DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

SMDL #08-003

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Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) is issuing this State Medicaid Director Letter to strengthen the integrity of the Medicaid program and help States reduce improper payments to providers. This letter specifically:

(1) Clarifies CMS policy with respect to States' obligations to screen for excluded individuals and entities prior to and during provider enrollment;

(2) Reminds States of the obligation to report to the Health and Human Service Office of Inspector General (OIG) both convictions related to the Medicaid program and sanctions imposed by the State Medicaid Agency on Medicaid providers; and

(3) Reminds States of the consequences set forth in Federal laws and regulations for failure to prevent Medicaid participation by excluded individuals and entities.

Background

The OIG excludes individuals and entities from participation in Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and all Federal health care programs (as defined in section 1128B(f) of the Social Security Act (the Act)) based on the authority contained in various sections of the Act, including sections 1128, 1128A, 1156, and 1892.

When the OIG has excluded a provider, Federal health care programs (including Medicaid and SCHIP programs) are prohibited from paying for any items or services furnished, ordered, or prescribed by excluded individuals or entities until the provider has been reinstated by the OIG (42 CFR section 1001.1901). The only exception is when the OIG has waived the exclusion of an individual or entity. *See* sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act; and 42 CFR section 1001.1801. No State may waive such an exclusion, in whole or in part. Only the OIG has the authority to waive an exclusion that it has imposed. If a State believes that waiver of an exclusion is appropriate, it may submit a written request for such a waiver to the OIG (42 CFR section 1001.1801).

Additionally, section 1932(d)(1) of the Act prohibits managed care organizations (MCOs) and primary care case managers (PCCMs) from knowingly having a director, officer, partner, or person with a beneficial ownership of more than 5 percent of the entity's equity who is debarred, suspended, or excluded, or from having an employment, consulting, or other agreement with an

individual or entity for the provision of items and services that are significant and material to the entity's obligations under its contract with the State where the individual or entity is debarred, suspended, or excluded. Section 438.610 of the Federal managed care regulations extends the prohibition to prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) (42 CFR section 438.610.) If a State finds that an MCO, PCCM, PIHP, or PAHP has a noncompliant relationship, the State must notify the Secretary of the noncompliance. The State may not renew or extend its agreement with the noncompliant entity unless the Secretary provides to the State and to Congress a written statement describing compelling reasons to renew or extend the agreement. Additional administrative sanctions applicable to MCEs are set forth in 42 CFR section 438.700 *et seq*.

Policy Clarification
States must determine whether current providers, managed care entities (MCEs) (i.e., MCOs, PCCMs, PIHPs, and PAHPs),[*] providers applying to participate in the Medicaid program, and individuals with an ownership or control interest in the provider entity or MCE are excluded individuals or entities. Since Federal regulations prohibit payment for items or services furnished by excluded individuals and entities, it is imperative that this first line of defense in combating fraud and abuse be conducted accurately, thoroughly, and routinely.

Previous Guidance
In a State Medicaid Director Letter issued on March 17, 1999, and in a follow-up State Medicaid Director Letter issued on May 16, 2000, CMS described the OIG's authority to exclude persons based on actions taken by State Medicaid Agencies.

In the State Medicaid Director Letter dated May 16, 2000, CMS reminded States that the Medicare/Medicaid Sanction-Reinstatement Report, formerly known as HCFA Publication 69 and now replaced by the Medicare Exclusion Database, discussed below, is a vital resource for ascertaining and verifying whether a provider is excluded and should not be receiving payments. The guidance also stated that the payment prohibition applies to any MCO contracting with an excluded party.

State Obligations Concerning Excluded Individuals and Entities
Federal statutes and regulations clearly prohibit States from paying for items or services furnished, ordered or prescribed by excluded persons. States typically do screen for excluded providers prior to and after enrollment. However, not all States attempt to determine whether an excluded individual has an ownership or control interest, as defined below, in an entity that is a Medicaid provider. Federal regulations at 42 CFR section 1002.3 require States to report to OIG information regarding individuals that have ownership or control interests in provider entities and who have been convicted of a criminal offense as described in sections 1128(a) and 1128(b)(1), (2), or (3) of the Act, that have had civil monetary penalties imposed under section 1128A of the Act, or that have been excluded from participation in Medicare or any of the State

[*] While this *State Medicaid Director Letter* uses the term "managed care entity" to refer briefly to MCOs, PIHPs, PAHPs, and PCCMs, States should not confuse this abbreviation with the statutory definition of managed care entity which only refers to MCOs and PCCMs. *See* section 1932(a)(1)(B) of the Act.

health care programs, within 20 business days after the date the agency receives the information. If appropriate, OIG may permissively exclude the provider under section 1128(b)(8) of the Act and under 42 CFR section 1001.1001.

General Rules

- States should solicit information from providers about individuals with ownership or control interests in the provider entity.
- In accordance with the rules set forth in this letter, States should search the Medicare Exclusion Database (MED) or the OIG List of Excluded Individuals/Entities (LEIE) database by the names of any individual, entity, or individual with ownership or control interest in any provider entity providing services for which payment is made under the Medicaid program or seeking to participate in the Medicaid program, including through a fee-for-service delivery system or through the State's managed care program or other waiver program.
- States should review provider enrollment eligibility upon enrollment or reenrollment.
- States should search the MED or the OIG Web site monthly to capture exclusions and reinstatements that have occurred since the last search.
- States should search the exclusions database for both in-State providers and out-of-State providers seeking to participate in the program.
- States should not process a provider's disclosure information that does not appear complete or does not include information on individuals with ownership or control interests in the provider entity, including managing employees, until the State verifies the accuracy and completeness of the information.
- States should report to OIG any exclusion information that is disclosed to them by a provider about an individual who has or had an ownership or control interest in a provider entity or who is a managing employee of a provider entity within 20 business days after receipt of such information.
- States must notify the OIG promptly if the State Medicaid Agency has taken any action on the provider's application for participation in the Medicaid program.
- States should notify the OIG promptly of any administrative action the State takes to limit a provider's participation in the Medicaid program that might lead to an exclusion.

Ownership and Control Interests

An individual is considered to have an ownership or control interest in a provider entity if it has direct or indirect ownership of 5 percent or more, or is a managing employee (e.g., a general manager, business manager, administrator, or director) who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity as defined in section 1126(b) of the Act and under 42 CFR section 1001.1001(a)(1).

States must actively solicit information regarding individuals with ownership or control interests in provider entities from providers because providers may not independently disclose the identity of owners or managing employees on the disclosure document. State data files should capture these important data elements so that an automated comparison of exclusions against a provider file that includes the names of individuals with ownership or control interests in provider entities

can be accomplished easily during regular monthly searches and at any time providers submit new disclosure information to the State. While States may delegate many provider enrollment or credentialing functions to MCEs for the managed care program and to the States' contractors for Home and Community-Based Services (HCBS) and other waiver programs, the State remains responsible for ensuring that it does not pay an excluded provider for Medicaid health care items or services. States that delegate managed care and waiver program provider enrollment and credentialing to their MCEs and HCBS waiver contractors must mandate that the MCEs and HCBS waiver contractors search the exclusions database with the same frequency as the State for fee-for-service providers. MCEs and HCBS waiver contractors should search for providers, provider entities, and individuals with ownership or control interests in the provider entities.

Under Federal regulations at 42 CFR section 1002.3(a), providers entering into or renewing a provider agreement must disclose to the State Medicaid Agency the identity of any excluded individual with an ownership or control interest in the provider entity. The State Medicaid Agency then must notify the OIG of this information within 20 business days after the date the agency receives the information and must notify the OIG promptly if the State Medicaid Agency has taken any action on the provider's application for participation in the Medicaid program. 42 CFR section 1002.3 (b)(2). The OIG, in its discretion and under statutory and regulatory authority, may exclude that entity.

Convictions and Administrative Sanctions

Under 42 CFR section 1002.230, each State, either through its State Medicaid Agency or its Medicaid Fraud Control Unit (MFCU), must notify the OIG of convictions related to the delivery of items or services under the Medicaid program within 15 days after the conviction if the State agency was involved in the investigation or prosecution of the case, or within 15 days after the State agency learns of the conviction if the agency was not involved in the investigation or prosecution of the case. Such a report should include all the necessary documentation to support an exclusion action by the OIG.

Additionally, under 42 CFR section 1002.3, the State agency must notify the OIG of any disclosures made by providers with regard to the ownership or control by a person that has been convicted of a criminal offense described under sections 1128(a) and 1128(b)(1), (2), or (3) of the Act, or that has had civil money penalties or assessments imposed under section 1128A of the Act. *See* 42 CFR section 1001.1001(a)(1). The State Medicaid Agency must notify the OIG of this information within 20 business days after the date it receives the information. 42 CFR sections 455.106(b)(1) and 1002.3.

States are required under 42 CFR sections 455.106(b)(2) and 1002.3(b)(3) to notify the OIG promptly of any administrative action it takes to limit participation of a provider in the Medicaid program. Reporting these criminal and administrative actions is critical to timely implementation of exclusions of persons who have defrauded health care programs or harmed patients. Currently in some States there are significant delays in reporting of such actions. Such

delays jeopardize the government's ability to protect the Federal health care programs and their beneficiaries from untrustworthy persons.

Where to Look for Excluded Parties

Medicare Exclusion Database

In 2002, HCFA Publication 69 was replaced by a new system of record called the Medicare Exclusion Database (MED). The MED was developed to collect and retrieve information that aided in ensuring that no payments are made to excluded individuals and entities for services furnished during the exclusion period. Two of the information sources used in populating the MED are the OIG Exclusion file and the Social Security Administration. MED files contain a variety of identifiable and general information including name, Social Security Number (SSN), employer identification number, Uniform Provider Identification Number, National Provider Identifier, address, exclusion type, and reinstatement date, if applicable. The five MED files are e-mailed to States every month. These files contain the month's new exclusions, new reinstatements, cumulative exclusions, cumulative reinstatements and non-MED data. MED files are also available through CMS' Application Portal.

List of Excluded Individuals/Entities

The OIG maintains the LEIE, a database that provides information about parties excluded from participation in Medicare, Medicaid, and all other Federal health care programs. The LEIE Web site is located at http://oig.hhs.gov/fraud/exclusions/listofexcluded.html and is available in two formats. The on-line search engine identifies currently excluded individuals or entities. When a match is identified, it is possible for the searcher to verify the accuracy of the match using a SSN or Employer Identification Number (EIN). The downloadable version of the database may be compared against State enrollment files. However, unlike the on-line format, the downloadable database does not contain SSNs or EINs.

When to Look for Excluded Parties

States should review provider enrollment eligibility whenever an individual or entity submits an application for enrollment or reenrollment in the program. Additionally, States should conduct searches on both in-State providers and out-of-State providers about which the State Medicaid Agency would not have received notice of exclusion. States should conduct the searches monthly via the MED or the OIG Web site to capture exclusions and reinstatements that have occurred since the last search.

Reminder of Consequences of Paying Excluded Providers

The CMS informed States in the State Medicaid Director Letter dated May 16, 2000, that under section 1903(i)(2) of the Act CMS shall make no payments to States for any amount expended for items or services (other than an emergency item or service not provided in a hospital emergency room) furnished under the plan by an individual or entity while being excluded from participation. This includes Medicare, Medicaid, SCHIP, and all Federal health care programs (as defined in section 1128B(f) of the Act) based on the authority contained in various sections of the Act, including sections 1128, 1128A, 1156, and 1892. Any such payments actually

claimed for Federal financial participation (FFP) constitute an overpayment under section 1903(d)(2)(A) of the Act and are unallowable for FFP.

Further, States may not seek Federal reimbursement for payments to providers that have not provided required ownership and control disclosures, or other disclosures regarding business transactions, under 42 CFR sections 455.104 and 455.105. States may deny enrollment to a provider whose owner, agent, or managing employee has been convicted of a criminal offense relating to Medicare, Medicaid, or title XX programs. Moreover, States may deny enrollment or terminate a provider's enrollment if the State determines the provider did not fully disclose required criminal conviction information, under 42 CFR section 455.106(c).

Conclusion

We know you share our commitment to combating fraud and abuse and understand that provider enrollment is the first line of defense in this endeavor. If we strengthen our efforts to identify excluded parties, the integrity and quality of the Medicaid program will be improved, benefiting Medicaid beneficiaries and taxpayers across the country.

If you have any questions or would like any additional information on this guidance, please direct your inquiries to Ms. Claudia Simonson, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Medicaid Integrity Group, Division of Field Operations, 233 North Michigan Avenue, Suite 600, Chicago, IL 60601 or claudia.simonson@cms.hhs.gov. Thank you for your assistance in this important endeavor.

Sincerely,

/s/

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