

guidance to industry on the implementation of the fee provisions of section 107 of the FDA Food Safety Modernization Act of 2011 (FSMA) (Pub. L. 111-353). Section 107 of FSMA amended section 743 of the Federal Food, Drug, and Cosmetic Act to provide FDA with the authority to collect fees related to food. In the **Federal Register** of August 1, 2011 (76 FR 45820), FDA published a notice establishing fee rates for FY 2012 for domestic and foreign facility reinspections, recall orders, and importer reinspections. On October 1, 2011, FDA will begin implementation of the fee provisions of section 107 of FSMA. The guidance document is intended to provide answers to common questions that might arise about the new fee provisions and FDA's plans for their implementation in FY 2012.

This guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because the fee provisions of FSMA are currently being implemented, and guidance is needed to help effectuate the implementation. The guidance provides information necessary for affected persons to understand the implementation of these FSMA fee provisions. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the guidance document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: September 30, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number: **OIG-1204-N**]

Proposed Revision of Performance Standards for State Medicaid Fraud Control Units

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and opportunity for comment.

SUMMARY: This notice seeks comment on an OIG proposal to revise standards for assessing the performance of the State Medicaid Fraud Control Units (MFCUs or Units). This proposal would replace and supersede standards published on September 26, 1994 (59 FR 49080).

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on December 5, 2011.

ADDRESSES: In commenting, please refer to the file code **OIG-1204-N**. Because of staff and resource limitations, OIG cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Office of Inspector General, Office of Congressional and Regulatory Affairs, Department of Health & Human Services, Attention: **OIG-118-N**, Room 5541, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to

be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Office of Inspector General, Department of Health & Human Services, Cohen Building, Room 5541, 330 Independence Avenue, SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-1343.

We do not accept comments by FAX transmission. All submissions received must include the agency name and docket number for this **Federal Register** document. All comments, including attachments and other supporting materials received, are subject to public disclosure.

FOR FURTHER INFORMATION CONTACT:

Richard B. Stern, OIG Office of Evaluation and Inspections, (202) 619-0480.

Patrice S. Drew, Office of External Affairs, (202) 619-1368.

SUPPLEMENTARY INFORMATION:

I. Background

The mission of the MFCUs, as established in Federal statute, is to investigate and prosecute Medicaid provider fraud and patient abuse and neglect. The States are responsible for operation of the MFCUs and receive reimbursement for a percentage of their costs from the Federal Government. Under section 1903(a)(6) of the Social Security Act (Act), States are reimbursed for 90 percent of their costs for the first 3 years of an MFCU's operation and 75 percent for subsequent years. All MFCUs are currently reimbursed at 75 percent of the costs of operating a certified MFCU.

OIG is delegated authority under 1903(q) and 1903(a)(6) of the Act to certify and annually recertify Units as eligible for Federal Financial Participation (FFP), and to reimburse States for costs incurred in operating an MFCU. Through the certification and recertification process, OIG ensures that the Units meet the requirements for FFP set forth in section 1903(q) of the Act and in OIG regulations found at 42 CFR part 1007. The performance standards set forth in this guidance document constitute the standards that OIG will apply in determining the effectiveness of State Units in carrying out MFCU required functions. As part of the recertification process, OIG reviews

reports from the Units, obtains information from other Federal and State agencies, and conducts periodic onsite reviews.

Under 1903(q), an MFCU must be a "single, identifiable entity of the State government" and be "separate and distinct" from the State Medicaid agency. The Unit must be an office of the State Attorney General's office, another State government office with statewide prosecutorial authority, or operate under a formal arrangement with the State Attorney General's office. The MFCU must investigate and prosecute Medicaid fraud cases, under State law, on a statewide basis. OIG regulations also require MFCUs to enter into agreements with the State Medicaid agency to ensure the referral of suspected provider fraud cases.

Under the statute, a MFCU must also have procedures for investigating and prosecuting (or referring for prosecution) allegations of patient abuse and neglect in Medicaid-funded facilities. A MFCU may also investigate and prosecute abuse and neglect in "board and care" facilities, such as assisted living facilities, even if such facilities do not receive Medicaid payments. Finally, the statute and regulations require that MFCUs be composed of a team of attorneys, auditors, and investigators.

Under section 1902(a)(61) of the Act, as added by Public Law 103-66, section 13625 (1994), all States must operate MFCUs unless they demonstrate to the Secretary of HHS that they can operate without a Unit. Currently, 49 States and the District of Columbia have established MFCUs and 1 State, North Dakota, operates without a MFCU after receiving permission from HHS in 1994. Under section 1902(a)(61), States must operate a MFCU that effectively carries out the functions and requirements described in 1903(q), as determined in accordance with standards established by the Secretary of HHS. The guidance proposed in this **Federal Register** notice sets forth the performance standards OIG will consider in determining whether State MFCUs are effectively carrying out their statutory functions under 1903(q).

These standards amend and update performance standards that were initially published in 1994. The performance standards have been used by OIG as part of the certification process to assess whether a MFCU is operating effectively. Where OIG determines there are deficiencies in meeting the standards, OIG will work with the Unit to improve performance. OIG may also make recommendations for improvement and will monitor the

Unit's implementation of any such recommendations. Ultimately, a Unit that is continuously not operating effectively could be designated as a high-risk grantee and OIG may make a separate determination regarding the Unit's certification status under section 1903(q). Based on our experience in overseeing the MFCUs since 1994, we are proposing in this notice to revise the standards.

II. Standards for Assessing MFCU Performance

Performance Standard 1—Compliance With Requirements

A Unit conforms with all applicable statutes, regulations, and policy directives, including:

A. Section 1903(q) of the Social Security Act, containing the basic requirements for operation of a MFCU;

B. OIG regulations for operation of a MFCU contained in 42 CFR part 1007;

C. Other Federal regulations and policies applicable to the Medicaid program, including grant administration requirements at 45 CFR part 92 and Federal cost principles at 2 CFR part 225;

D. OIG policy transmittals as maintained on the OIG Web site; and

E. Other applicable conditions of the State's award.

Performance Standard 2—Staffing

A Unit maintains reasonable staff levels and office locations in relation to the State's Medicaid program expenditures and in accordance with staffing allocations approved in its budget. In meeting this standard, the following performance indicators will be considered:

A. The Unit employs the number of staff that is included in the Unit's budget estimate as approved by OIG.

B. The Unit employs a total number of professional staff, including attorneys, auditors, and investigators, that is commensurate with the State's total Medicaid program expenditures and that enables the Unit to effectively investigate and prosecute (or refer for prosecution) the volume of case referrals and workload for both Medicaid fraud and patient abuse and neglect.

C. The Unit employs a mix and number of attorneys, auditors, investigators, and other professional staff, that is both commensurate with the State's total Medicaid program expenditures and that allows the Unit to effectively investigate and prosecute (or refer for prosecution) the volume of case referrals and workload for both Medicaid fraud and patient abuse and neglect.

D. The Unit employs a number of support staff in relation to its overall size that allows the Unit to operate effectively.

E. Office locations are distributed throughout the State, and are adequately staffed, commensurate with the volume of case referrals and workload for each location.

Performance Standard 3—Policies and Procedures

A Unit establishes written policies and procedures for its operations and ensures that staff are familiar with, and adhere to, policies and procedures. In meeting this standard, the following performance indicators will be considered:

A. The Unit has written guidelines or manuals that contain current policies and procedures, consistent with these performance standards, for the investigation and prosecution of Medicaid fraud and patient abuse and neglect.

B. The Unit adheres to current policies and procedures in its operations.

C. Procedures include a process for referring cases, when appropriate, to Federal and State agencies. Referrals to State agencies, including the State Medicaid agency, should identify whether further investigation or other administrative action is warranted, such as the collection of overpayments.

D. Written guidelines and manuals are readily available to all Unit staff, either online or in hard copy.

E. Policies and procedures address training standards for Unit employees.

Performance Standard 4—Maintaining Adequate Referrals

A Unit takes steps to maintain an adequate volume and quality of referrals from the single State Medicaid agency and other sources. In meeting this standard, the following performance indicators will be considered:

A. The Unit takes steps, such as the development of operational protocols, to ensure that the State Medicaid agency and other agencies refer to the Unit all suspected provider fraud cases.

B. Consistent with 42 CFR 1007.9(g), the Unit provides timely written notice to the State Medicaid agency when referred cases are accepted or declined for investigation.

C. The Unit provides periodic feedback to the State Medicaid agency and other referral sources on the adequacy of both the volume and quality of its referrals.

D. The Unit provides timely information to the State Medicaid agency when the Medicaid agency

requests information on the status of MFCU investigations, including when the Medicaid agency requests quarterly certification pursuant to 42 CFR 455.23(d)(3)(ii).

E. The Unit takes steps to ensure that the State Long Term Care Ombudsman and other officials and agencies refer to the Unit suspected patient abuse and neglect cases.

F. The Unit takes steps, through public outreach or other means, to encourage the public to refer cases to the Unit.

Performance Standard 5—Maintaining a Continuous Case Flow

A Unit takes steps to maintain a continuous case flow and to complete cases in an appropriate timeframe based on the complexity of the cases. In meeting this standard, the following performance indicators will be considered:

A. Supervisors approve the opening and closing of all investigations.

B. Supervisors review the progress of cases as part of a performance management system and take action as necessary to ensure that each stage of an investigation and prosecution is completed in an appropriate timeframe.

C. Delays to investigations and prosecutions are supported and justified based on resource constraints or other exigencies.

Performance Standard 6—Case Mix

A Unit's case mix, as practicable, covers all significant provider types and includes a mix of fraud and patient abuse and neglect cases. In meeting this standard, the following performance indicators will be considered:

A. The Unit seeks to have a mix of cases from all significant provider types in the State.

B. For those States that rely substantially on managed care entities for the provision of Medicaid services, the Unit includes a commensurate number of managed care cases in its mix of cases.

C. The Unit seeks to allocate resources among provider types based on levels of Medicaid expenditures or other risk factors. Special Unit initiatives may focus on specific provider types.

D. As part of its case mix, the Unit at all times maintains a substantial number of patient abuse and neglect cases.

Performance Standard 7—Maintaining Case Information

A Unit maintains case files in an effective manner and develops a case management system that allows efficient access to case information and other performance data. In meeting this

standard, the following performance indicators will be considered:

A. Supervisory reviews are conducted periodically, consistent with MFCU policies and procedures, and are noted in the case file.

B. Case files include all relevant facts and information and justify the opening and closing of the cases.

C. Significant documents, such as charging documents and settlement agreements, are included in the file.

D. Interview summaries are written in a timely manner, as defined by MFCU policies and procedures.

E. The Unit has an information management system that manages and tracks case information from initiation to resolution.

F. The Unit has an information management system that allows for the reporting of aggregate case information.

Performance Standard 8—Performance Outcome and Measurement

A Unit has a process for monitoring and measuring the outcome of cases. In meeting this standard, the following performance indicators will be considered when determining how effectively the Unit detects, investigates and prosecutes (or refers for prosecution) Medicaid fraud and patient abuse and neglect:

A. The Unit maintains a performance management system or relies upon the State's performance management system as it applies to the Unit.

B. If establishing its own performance system, the Unit develops performance outcomes, such as the following:

1. The number of cases opened and closed and the reason that cases are closed.

2. The length of time taken to determine whether to open a case referred by the State Medicaid agency or other referring source.

3. The number, age, and types of cases in the Unit's inventory/docket.

4. The number of referrals received by the Unit and the number of referrals to other agencies made by the Unit.

5. The dollar amount of overpayments identified.

6. The number of cases criminally prosecuted by the Unit or referred to others for prosecution, the number of individuals or entities charged, and the number of pending prosecutions.

7. The number of criminal convictions and the number of civil judgments.

8. The dollar amount of fines, penalties, and restrictions ordered in a criminal case; the dollar amount of recoveries and the types of relief obtained through civil judgments or pre-filing settlements.

9. Non-case specific work of the Unit which enhances the Unit's mission,

such as training activities for provider groups and other public integrity or law enforcement offices; outreach and training for State and county social service agencies; liaison meetings with managed care organizations; and publication of fraud alerts or other information for areas within the Unit's jurisdiction.

C. The Unit establishes annual performance goals for each identified outcome.

D. The Unit annually evaluates whether it has achieved its goals.

E. If the Unit maintains a strategic plan, the Unit aligns performance outcomes and goals with the plan.

Performance Standard 9—Cooperation With Federal Authorities on Fraud Cases

A Unit cooperates with OIG and other Federal agencies in the investigation and prosecution of Medicaid and other health care fraud. In meeting this standard, the following performance indicators will be considered:

A. The Unit communicates on a regular basis with the OIG Office of Investigations (OI) and other Federal agencies investigating or prosecuting health care fraud in the State.

B. The Unit cooperates and, as appropriate, coordinates with OI and other Federal agencies on cases being pursued jointly, cases involving the same suspects or allegations, and cases that have been referred to the Unit by OI or another Federal agency.

C. The Unit makes available, upon request by Federal investigators and prosecutors, all information in its possession concerning provider fraud or fraud in the administration of the Medicaid program.

D. For cases that require the granting of "extended jurisdiction" to investigate Medicare or other Federal health care fraud, the Unit seeks permission from OI or other relevant agencies under procedures as set by those agencies.

E. For cases that have significant civil fraud potential, the Unit investigates and prosecutes such cases under State authority or refers such cases to OIG or the U.S. Department of Justice.

F. The Unit transmits to OIG, for purposes of program exclusions under section 1128 of the Act, all pertinent information on MFCU convictions within 30 days of sentencing, including charging documents, plea agreements, and sentencing orders.

G. The Unit reports qualifying cases to the Healthcare Integrity & Protection Databank or successor data bases.

Performance Standard 10—Program Recommendations

A Unit makes statutory or programmatic recommendations, when warranted, to the State government. In meeting this standard, the following performance indicators will be considered:

A. The Unit, when warranted and appropriate, makes statutory recommendations to the State legislature to improve the operation of the Unit, including amendments to the enforcement provisions of the State code.

B. The Unit, when warranted and appropriate, makes other regulatory or administrative recommendations regarding program integrity issues to the State Medicaid agency and to other agencies responsible for Medicaid operations or funding.

C. The Unit monitors actions taken by the State legislature and the State Medicaid or other agencies in response to recommendations.

D. The Unit reports program recommendations to OIG.

Performance Standard 11—Agreement With Medicaid Agency

A Unit periodically reviews its Memorandum of Understanding (MOU) with the single State Medicaid agency to ensure that it reflects current practice, policy, and legal requirements. In meeting this standard, the following performance indicators will be considered:

A. The MOU reflects current policy and practice by both the Unit and the State Medicaid agency.

B. The MOU meets current Federal legal requirements as contained in law or regulation, including 42 CFR § 455.21, "Cooperation with State Medicaid fraud control units," and 42 CFR 455.23, "Suspension of payments in cases of fraud."

C. The MOU is consistent with current Federal and State policy, including any policies issued by OIG or the Centers for Medicare & Medicaid Services (CMS).

D. Consistent with Performance Standard 4, the MOU establishes a process to ensure the receipt of an adequate volume and quality of referrals to the Unit from the State Medicaid agency.

E. The MOU incorporates by reference the *CMS Performance Standard for Referrals of Suspected Fraud from a Single State Agency to a Medicaid Fraud Control Unit*.

Performance Standard 12—Fiscal Control

A Unit exercises proper fiscal control over Unit resources. In meeting this standard, the following performance indicators will be considered:

A. The Unit director, or the director's designee, approves and signs the Unit's budget and estimated expenditures.

B. The Unit director, or the director's designee, approves and signs all fiscal and administrative reports concerning Unit expenditures.

C. The Unit maintains an equipment inventory that is updated on a regular basis to reflect all property under the Unit's control.

D. The Unit maintains an effective time and attendance system.

E. The Unit applies generally accepted accounting principles in its control of Unit funding.

F. The Unit employs a financial system in which all funds are assigned to individual accounts according to their source and all expenditure items can be traced to the original funding stream and account.

Performance Standard 13—Training

A Unit maintains an annual training plan for all professional disciplines. In meeting this standard, the following performance indicators will be considered:

A. The Unit maintains a training plan for each professional discipline that includes an annual minimum number of training hours and that is at least as stringent as required for professional certification.

B. The Unit ensures that professional staff complies with its training plans and maintains records of the staff's compliance.

C. Professional certifications are maintained for all staff, including continuing education requirements.

D. The Unit participates in training offered by OIG, CMS, and other MFCUs, as funding permits.

E. Through cross-training or by other means, Unit staff receive training on the role and responsibilities of the State Medicaid agency and other law enforcement partners.

Daniel R. Levinson,

Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Submission for OBM Review; Comment Request; New Proposed Collection, Environmental Science Formative Research Methodology Studies for the National Children's Study**

SUMMARY: Under the provisions of Section (3507(a)(1)(D)) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for reinstatement of approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23603-23605, and allowed 60 days for public comment. Two written comments and two verbal comments were received. The verbal comments expressed support for the broad scope of the study. The written comments were identical and questioned the cost and utility of the study. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Environmental Science Formative Research Methodology Studies for the National Children's Study (NCS). *Type of Information Request:* New. *Need and Use of Information Collection:* The Children's Health Act of 2000 (Pub. L. 106-310) states:

(a) **PURPOSE.**—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) **IN GENERAL.**—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.