gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf or by sending an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 159 to identify the guidance you are requesting.

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Richard Keller, on behalf of Bruno Independent Living Aids, Inc., for wheelchair elevator devices (commonly known as inclined platform lifts and vertical platform lifts), classified under 21 CFR 890.3930.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of 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.

Dated: May 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–13224 Filed 5–31–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number OIG–1204–N2]

Revision of Performance Standards for State Medicaid Fraud Control Units

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice sets forth OIG guidance regarding standards OIG will apply in assessing the performance of State Medicaid Fraud Control Units (MFCU or Unit). These standards replace and supersede standards published on September 26, 1994 (59 FR 49080). OIG will apply these standards in certifying and recertifying each Unit and to determine if a Unit is effectively and efficiently carrying out its duties and responsibilities.

DATES: *Effective Date:* These standards are effective on June 1, 2012.

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.

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 a 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 a 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 Federal regulations found at 42 CFR part 1007. The performance standards set forth in this guidance document constitute the standards that OIG applies 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), a 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 or 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, according to the laws of the State in which with MFCU operates. Federal regulations also require MFCUs to enter into agreements with the State Medicaid agency to ensure the referral of suspected provider fraud cases.

Under 1903(q), 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, 1903(q) 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 § 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. Consistent with this section, this notice establishes the performance standards OIG will consider in determining whether State MFCUs are effectively carrying out their statutory functions under 1903(q).

II. OIG Development and Use of These Standards

These standards amend and update performance standards that were initially published in 1994 (59 FR 49080). The standards provide guidance to MFCUs regarding how OIG will exercise its discretion in assessing a Unit's performance and, as such, do not require OIG to use formal notice-and-comment procedures. Nevertheless, on October 6, 2011, we published proposed revisions to the 1994 performance standards (76 FR 62074) to invite MFCUs and other interested parties to review and comment on our approach. We received seven sets of comments, all of which we have carefully considered. In addition, we met with one commenter, the National Association of Medicaid Fraud Control Units (the Association), which submitted extensive comments on each of the standards. We accepted many of the commenters' suggestions and recommendations and revised the standards accordingly.

One topic raised in comments by the Association was the use of statistics in assessing MFCU performance. Under the 1994 standards, Standard 7 stated that ''[a] Unit should have a process for monitoring the outcome of cases. In meeting this standard, the Unit's monitoring of the following case factors and outcomes will be considered [including numbers of arrests, convictions, overpayments, and civil

recoveries].'' In the 2011 proposed revision to the standards, OIG proposed that MFCUs design performance management systems that include performance goals and outcomes for case- and non-case work. The Association objected strongly to the draft standard, both because the development of performance management systems could be seen as a new mandate for many MFCUs as well as a perception that OIG was relying too heavily on statistical measures for assessing performance.

We agree with the Association that an exclusive reliance on case outcomes in evaluating performance is not appropriate for the Units. However, we also believe that the 1994 version of Standard 7 did not provide OIG an effective means to evaluate performance without further guidance on how MFCUs would systematically monitor outcomes. We have therefore eliminated a separate standard for the monitoring of case outcomes and have combined elements of the proposed standard with new Standard 7, ''Maintaining Case Information.''

While they are not included in these standards, we continue to believe that MFCUs, as an effective practice, should consider developing management systems or processes for monitoring and measuring the outcome of cases, for the purpose of improving performance. One way to accomplish this would be for MFCUs to monitor and measure the timeliness of their handling of key stages of the process or of similar types of cases. For example, a MFCU could review and monitor the length of time between the receipt of a referral and when the matter is accepted or declined for investigation. Another approach would be to monitor and measure the time spent in investigating a particular type of provider, such as pharmacies.

We believe that, in addition to monitoring and measuring of case outcomes, the Units should consider monitoring their own engagement in non-case activities that would improve performance. These activities may include, for example, training and outreach designed to increase referrals of fraud and patient abuse and neglect; liaison with program integrity staff, managed care organizations, and other law enforcement agencies to increase fraud referrals; and liaison on patient abuse and neglect matters with licensing and certification agencies, the State Long Term Care Ombudsman, or adult protective services offices.

As noted by the Association, OIG, consistent with Performance Standard 7, reviews statistical information provided by the MFCUs both for the purpose of analyzing MFCU operations and to provide information to the public about MFCU activities. In doing so, we emphasize that OIG does not intend that MFCUs be evaluated solely on the basis of statistical information. MFCUs are subject to various legal authorities and organizational constraints and, therefore, comparisons between two or more MFCUs based on statistical outcomes should be undertaken with caution.

Consistent with OIG's reliance on a variety of information sources in assessing performance, the performance standards themselves are an important oversight tool that aids OIG in assessing information on each of the topic areas covered by the standards. This information is important in recertifying the MFCUs and in evaluating whether a MFCU is operating effectively.

When OIG determines that a MFCU is deficient in meeting one or more standards, OIG will provide technical assistance or make recommendations for improvement. Ultimately, a Unit that continues to operate in an ineffective manner 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).

The revised standards, reflecting public comments, are set forth below. These standards may be further revised in future years based on experience gained in the oversight of the Units.

III. 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. Regulations for operation of a MFCU contained in 42 CFR part 1007;

C. 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. Terms and conditions of the notice of the grant 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. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

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 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) an appropriate volume of case referrals and workload for both Medicaid fraud and patient abuse and neglect.

C. The Unit employs an appropriate 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) an appropriate 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. To the extent that a Unit maintains multiple office locations, such 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. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

A. The Unit has written guidelines or manuals that contain current policies and procedures, consistent with these performance standards, for the investigation and (for those Units with prosecutorial authority) 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 or suspension of payments.

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 State Medicaid agency and other sources. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

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

B. 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.

C. The Unit provides timely information to the State Medicaid or other agency when the Medicaid or other 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).

D. For those States in which the Unit has original jurisdiction to investigate or prosecute patient abuse and neglect cases, the Unit takes steps, such as the development of operational protocols, to ensure that pertinent agencies refer such cases to the Unit, consistent with patient confidentiality and consent. Pertinent agencies vary by State but may include licensing and certification agencies, the State Long Term Care Ombudsman, and adult protective services offices.

E. The Unit provides timely information, when requested, to those agencies identified in (D) above regarding the status of referrals.

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. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

A. Each stage of an investigation and prosecution is completed in an appropriate timeframe.

B. Supervisors approve the opening and closing of all investigations and review the progress of cases 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 limited to situations imposed by 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 balance of fraud and, where appropriate, patient abuse and neglect cases. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

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 maintains a balance of fraud and patient abuse and neglect cases for those States in which the Unit has original jurisdiction to investigate or prosecute patient abuse and neglect cases.

E. As part of its case mix, the Unit seeks to maintain, consistent with its legal authorities, a balance of criminal and civil fraud 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. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

A. Reviews by supervisors 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 promptly, as defined by the Unit's 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 monitoring and reporting of case information, including 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 by the Unit to other agencies.

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 restitution ordered in a criminal case and the dollar amount of recoveries and the types of relief obtained through civil judgments or prefiling settlements.

Performance Standard 8—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. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

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

B. The Unit cooperates and, as appropriate, coordinates with OIG's Office of Investigations 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 OIG or another Federal agency.

C. The Unit makes available, to the extent authorized by law and 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 OIG or other relevant agencies under procedures as set by those agencies.

E. For cases that have 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 Social Security 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, the National Practitioner Data Bank, or successor data bases.

Performance Standard 9—Program Recommendations

A Unit makes statutory or programmatic recommendations, when warranted, to the State government. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

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

Performance Standard 10—Agreement With Medicaid Agency

A Unit periodically reviews its Memorandum of Understanding (MOU) with the State Medicaid agency to ensure that it reflects current practice, policy, and legal requirements. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

A. The MFCU documents that it has reviewed the MOU at least every 5 years, and has renegotiated the MOU as necessary, to ensure that it reflects current practice, policy, and legal requirements.

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 State Agency to a Medicaid Fraud Control Unit.*

Performance Standard 11—Fiscal Control

A Unit exercises proper fiscal control over Unit resources. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

A. The Unit promptly submits to OIG its preliminary budget estimates, proposed budget, and Federal financial expenditure reports.

B. The Unit maintains an equipment inventory that is updated regularly to reflect all property under the Unit's control.

C. The Unit maintains an effective time and attendance system and personnel activity records.

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

E. The Unit employs a financial system in compliance with the standards for financial management systems contained in 45 CFR 92.20.

Performance Standard 12—Training

A Unit conducts training that aids in the mission of the Unit. To determine whether a Unit meets this standard, OIG will consider the following performance indicators:

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 comply with their training plans and maintain records of their staff's compliance.

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

D. The Unit participates in MFCU-related training, including training offered by OIG and other MFCUs, as such training is available and as funding permits.

E. The Unit participates in cross-training with the fraud detection staff of the State Medicaid agency. As part of such training, Unit staff provide training on the elements of successful fraud referrals and receive training on the role and responsibilities of the State Medicaid agency.

Dated: May 29, 2012.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2012–13332 Filed 5–31–12; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; CareerTrac

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Fogarty International Center (FIC), National Institute of Environmental Health Sciences (NIEHS), including the Intramural Research and Training Award (IRTA) and Superfund Research Program (SRP) within NIEHS, National Institute of General Medical Science (NIGMS), and National Cancer Institute (NCI), has submitted to the Office of Management and Budget (OMB) for review and approval. This is a renewal request. This proposed information collection was previously published in the **Federal Register** on May 12, 2009 (74 FR 22172). No comments were received from that notification regarding the cost and hour burden estimates.

Proposed Collection

Title: CareerTrac. *Type of Information Collection Request:* Revision (OMB NO.: 0925–0568 Expiration: September 30, 2012). *Need and Use of Information Collection:* This data collection system is being developed to track, evaluate and report short- and long-term outputs, outcomes and impacts of trainees involved in health research training programs—specifically tracking this for at least ten years following training by having Principal Investigators enter data after trainees have completed the program. The data collection system provides a streamlined, web-based application permitting principal investigators to record career achievement progress by trainee on a voluntary basis. FIC, NIEHS, NCI and NIGMS management will use this data to monitor, evaluate and adjust grants to ensure desired outcomes are achieved, comply with OMB Part requirements, respond to congressional inquiries, and as a guide to inform future strategic and management decisions regarding the grant program.