individual patients in Table 1 of the *IJC* paper and their inappropriate impact on the antibody values reported in Table II of the *IJC* paper were reported in detail by Respondent to the Managing Editor in *IJC* in email communications dated September 24 and 29, 2008.

Dr. Ravindranath has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on July 2, 2012:

(1) To have any PHS-supported research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) That any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS- supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions is his own or properly cites the source of copied language and ideas; and

(3) To exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2012–18990 Filed 8–2–12; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Baker Brothers Site in Toledo, Ohio, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the Bakers Brothers site in Toledo, Ohio, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Baker Brothers.

Location: Toledo, Ohio.

Job Titles and/or Job Duties: All employees who worked in any area.

Period of Employment: June 1, 1943 to December 31, 1996.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–19047 Filed 8–2–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6042–N]

Medicare Program; Prior Authorization for Power Mobility Device (PMD) Demonstration

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a 3-year Medicare Prior Authorization for Power Mobility Device (PMD) Demonstration for certain PMD codes in seven states where there have been high incidences of fraudulent claims and improper payments

DATES: This demonstration begins on September 1, 2012.

FOR FURTHER INFORMATION CONTACT: Daniel Schwartz, 410–786–4197.

Questions regarding the Medicare Prior Authorization for PMD Demonstration should be sent to *pademo@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Power Mobility Devices have had historically high incidents of fraud and improper payments. PMD suppliers also continue to be subject to significant law enforcement investigation.

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) Task Force was launched in May 2009 and is co-chaired by the Deputy Secretary of HHS and the Deputy Attorney General of DOJ. Medicare Fraud Strike Force teams are a key component of HEAT, since their inception and based on data driven investigations, prosecutors have filed more than 600 cases charging more than 1,150 defendants who collectively billed the Medicare program more than $2.9 billion in fraudulent claims. DME is a primary focus of investigation for these strike forces.

The Comprehensive Error Rate Testing (CERT) Program noted in a 2010 Report [1] that 92.6 percent of claims for motorized wheelchairs did not meet Medicare coverage requirements. Although we recognize that many improper payments are not the result of willful fraud, this error rate represents over $822 million dollars in estimated improper payments.

II. Legislative Authority

Section 402(a)(1)(J) of the Social Security Amendments of 1967, 42 U.S.C. 1395b–1(a)(1)(J), authorizes the Secretary to conduct demonstrations designed to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services provided under the Medicare program. We plan to conduct a demonstration that implements a prior authorization process for power mobility devices (PMDs), an area with historically high levels of fraud and improper payments, to develop improved methods for the investigation and prosecution of fraud

[1] *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/Downloads/CERT_Nov_2010_Appendix_-final.pdf* Supplemental Appendix, Table B2.

in order to protect the Medicare Trust Fund from fraudulent actions and the resulting improper payments. We are conducting this 3-year demonstration in California, Florida, Illinois, Michigan, New York, North Carolina, and Texas. The beneficiary's address as reported to the Social Security Administration (SSA) will determine participation in the demonstration.

We believe this demonstration will provide the agency with valuable data through which the agency, working with its partners, can develop new avenues for combating the submission of fraudulent claims to the Medicare program for PMDs. We will share data developed from this demonstration within the agency, with our contractors, and with our law enforcement partners for further analysis and investigation. We believe that data evidencing changes in physician ordering and supplier billing practices that coincide with this demonstration could provide investigators and law enforcement with important information for determining how and where to focus their investigations concerning fraud in the provision of PMDs. For instance, results from this demonstration could potentially indicate collaboration between ordering physicians and suppliers in submitting fraudulent claims for PMDs. This data could assist investigators and law enforcement in targeting their investigations in this area. Additionally, changes in billing practices that result from this demonstration could provide specific leads for investigators and law enforcement personnel. For instance, where a supplier that frequently submitted claims prior to the demonstration stops submitting claims during the demonstration, law enforcement may determine it prudent to investigate that supplier.

Data we will analyze will include the following:

- Suppliers who no longer bill or have a significant decrease in billing.
- Physicians/treating practitioners with a high volume of submissions.
- Codes that show a dramatic increase in use.
- Codes that show a dramatic decrease in use.

The demonstration will likely have a secondary benefit to help identify and reduce improper payments. We recognize that many improper payments are not the result of willful fraud. Information shared with law enforcement will be limited to data on those providers and suppliers who are potentially submitting fraudulent claims and other information that we believe will assist with the investigation and prosecution of fraud.

Section 402(b) of the Social Security Amendments of 1967 authorizes the Secretary to waive requirements in Title XVIII that relate to reimbursement and payment in order to carry out the demonstrations authorized under section 402(a). In accordance with section 402(b), the Secretary waives certain requirements of sections 1834(a), 1834(j)(4) and 1879 of the Social Security Act to the extent necessary to implement this demonstration, including, but not limited to, certain payment and reimbursement regulations set forth at 42 CFR part 414, Subpart D and 42 CFR Part 411, Subpart K.

III. Provisions of the Notice

This demonstration will implement a prior authorization process for PMDs in seven states where historically there has been extensive evidence of fraud and improper payments (CA, FL, IL, MI, NY, NC, and TX).

The prior authorization process under this demonstration is available for the following codes for Medicare payment:

- Group 1 Power Operated Vehicles (K0800 through K0802 and K0812).
- All standard power wheelchairs (K0813 through K0829).
- All Group 2 complex rehabilitative power wheelchairs (K0835 through K0843).
- All Group 3 complex rehabilitative power wheelchairs without power options (K0848 through K0855).
- Pediatric power wheelchairs (K0890 and K0891).
- Miscellaneous power wheelchairs (K0898).

Prior to the start of the demonstration, we have conducted and will continue to conduct outreach and education including webinars, in-state meetings and other education sessions. Additional information about the implementation of the prior authorization demonstration is available on the CMS Web site (go.cms.gov/PAdemo). In addition, suppliers who have recently furnished and practitioners who have recently ordered a PMD for a beneficiary residing in a demonstration state will be notified via certified letters about the demonstration prior to the start date of the demonstration.

Under this demonstration, a physician, treating practitioner, or supplier will be encouraged to submit to their Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item along with the written order for the covered item. The physician, treating practitioner or supplier who submits the request on behalf of the physician or treating practitioner, is referred to as the ''submitter.'' In order to be affirmed, the request for prior authorization must meet all applicable rules, policies, and National Coverage Determination (NCD)/Local Coverage Determination (LCD) requirements for PMD claims.

LCD requirements mandating physician/treating practitioner origination, such as the seven-element order, face-to-face encounter documentation and whatever other clinical documentation is necessary, must be completed by the physician/treating practitioner regardless of which entity is functioning as the submitter. The supplier will still complete the detailed product description regardless of which entity is functioning as the submitter.

After receipt of all relevant documentation, CMS or its agents will make every effort to conduct a review and postmark the notification of their decision with the prior authorization number within 10 business days. Notification is provided to the physician/treating practitioner, supplier, and the Medicare beneficiary for the initial submission. If a subsequent prior authorization request is submitted after a nonaffirmative decision on a prior authorization request, then CMS or its agents will make every effort to conduct a review and postmark the notification of decision with the prior authorization number within 20 business days. These timeframes will become part of the contractors' performance metrics.

There will also be a mechanism in place to request an expedited review in emergency situations where a practitioner indicates clearly, with supporting rationale that the standard (routine) timeframe for a Prior Authorization Decision (10 days) could seriously jeopardize the beneficiary's life or health. In these cases, the contractor will conduct an expedited review. The expedited request must be accompanied by the required supporting documentation for this request to be considered complete thus commencing the 48 hours for review. Inappropriate expedited requests may be downgraded to standard requests. After conducting an expedited review, CMS or its agents will communicate a decision for the prior authorization request to the submitter within 48 hours of the complete submission.

The following explains the various prior authorization scenarios:

- Scenario 1: When a submitter sends a prior authorization request to the DME

MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the PMD, then the DME MAC sends an affirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary. When the claim is submitted to the DME MAC by the supplier, it is linked to the Prior Authorization via the claims processing system and so long as all applicable requirements in the applicable NCD/LCD are met, the claim is paid.

• Scenario 2: When a submitter sends a prior authorization request but all relevant Medicare coverage requirements are not met for the PMD, then the DME MAC sends a nonaffirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary advising them that Medicare will not pay for the item. A supplier can deliver the PMD, and submit a claim with a non-affirmative prior authorization decision, at which point the DME MAC would deny the claim. The supplier and/or the beneficiary would then have the Medicare denial for secondary insurance purposes and would have full appeal rights.

If an applicable PMD claim is submitted without a prior authorization decision it will be stopped and documentation will be requested to conduct medical review. After the first 3 months of the demonstration, we will assess a payment reduction for claims that, after review, are deemed payable, but did not first receive a prior authorization decision. As evidence of compliance, the supplier must submit the prior authorization number on the claim in order to avoid a 25 percent payment reduction. The 25 percent payment reduction is non-transferrable to the beneficiary and not subject to appeal. In the case of capped rental items, the payment reduction will be applied to all claims in the series.

The 25-percent reduction in the Medicare payment is for each payable base claim not preceded by a prior authorization request except in competitive bidding areas. If a competitive bid contract supplier submits a payable claim for a beneficiary with a permanent residence in a competitive bidding area, that is included in the supplier's contract, without first receiving a prior authorization decision, that competitive bid supplier would receive the applicable single payment amount under the competitive bid program, and would not be subject to the 25-percent reduction. These suppliers must still adhere to all other requirements of the demonstration.

• Scenario 3: When a submitter sends a prior authorization request where documentation is incomplete, the prior authorization request is sent back to the submitter with an explanation about what information is missing. The submitter can rectify the situation and resubmit the prior authorization request. The physician or treating practitioner, supplier, and Medicare beneficiary are also notified.

• Scenario 4: When the DME supplier fails to receive a prior authorization decision, but nonetheless delivers the item to the beneficiary and submits the claim to the DME MAC for payment, the PMD claim will be reviewed under normal medical review processing timeframes.

++ If the claim is determined to be not medically necessary or insufficiently documented, the claim will be denied. The supplier and/or beneficiary can appeal the claim denial. If the claim, after review, is deemed not payable then all current beneficiary/supplier liability policies and procedures as well as appeal rights remain in effect.

++ If the claim is determined to be payable, it will be paid. However, 3 months after the start of the demonstration, a 25-percent reduction in the Medicare Payment will be applied for failure to receive a prior authorization decision before the submission of a claim. This payment reduction will not be applied for competitive bidding program contract suppliers submitting claims for beneficiaries who maintain a permanent residence in a Competitive Bidding Area in their contracts according to the Common Working File (CWF)); these contract suppliers will continue to receive the applicable single payment amount under their contracts. The 25-percent payment reduction is non-transferrable to the beneficiary for the claims that are deemed payable. This payment reduction will begin 3 months after the start of the demonstration and is not subject to appeal. In the case of capped rental items the payment reduction will be applied to all claims in the series. After a claim is submitted and processed, appeal rights are available as they normally are.

Under the demonstration, we will work to limit the impact on beneficiaries. We will educate beneficiaries as part of this protection. If the prior authorization request is not affirmed, and the claim is still submitted by the supplier, the claim will be denied in full, but beneficiaries will continue to have all normal appeal rights as well as the option of signing an Advance Beneficiary Notice in order to receive and be liable for payment for a denied PMD.

Additional information is available on the CMS Web site at go.cms.gov/PAdemo.

IV. Collection of Information Requirements

We announced and solicited comments for the information collection requirements associated with the Medicare Prior Authorization for Power Mobility Device (PMD) Demonstration for certain PMD codes in 60-day and 30-day **Federal Register** notices that published on February 7, 2012 (77 FR 6124) and May 29, 2012 (77 FR 31616), respectively. The information collection requirements are approved under OMB control number 0938–1169.

Authority: Section 402(a)(1)(J) of the Social Security Amendments of 1967.

Dated: July 30, 2012

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–19014 Filed 8–1–12; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 4, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All