these forms to (1) grant public health professionals the continuing education (CE) they need to maintain professional licenses and certifications, (2) create a transcript or summary of training at the participant's request, (3) generate management reports, and (4) maintain training statistics; and a revision that will allow CDC to comply with new continuing education accreditation organization requirements for collection of additional profession-specific data.

CDC is accredited by six different continuing education (CE) organizations to award CE: (1) The International Association for Continuing Education and Training (IACET) to provide Continuing Education Units (CEUs), (2) the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education credits (CME), (3) the American Nurses Credentialing Center (ANNC) to provide Continuing Nurse Education credits (CNE), (4) the National Commission for Health Education Credentialing (NCHEC) to award CHES credit, (5) the Accreditation Council for Pharmacy Education (ACPE) to provide continuing pharmacy credit, and (6) the American Association of Veterinary State Boards to award Registry of Approved Continuing Education (RACE) credit. The accrediting organizations require a method of tracking participants who complete an educational activity and demographic data allows CDC to do so. Also, several of the organizations require a permanent record that includes the participant's name, address, and phone number, to facilitate retrieval of historical information about when a participant completed a course or several courses during a time period. This information provides the basis for a transcript or for determining whether a person is enrolled in more than one course. CDC uses the email address to verify the participant's electronic request for transcripts, verify course certificates, and send confirmation that a participant is registered for a course.

Tracking course attendance and meeting accrediting organizations' standards for reporting, require uniform standardized training application forms. The standardized data these forms request for laboratory training, classroom study, online training, and distance learning are not requested elsewhere. In other words, these forms do not duplicate requests for information from participants. Data are collected only once per course or once per new registration. The annual burden table has been updated to reflect an increase in distance learning to 6,792 burden hours; that is an average burden of 5 minutes per respondent. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
Health Professionals	Training and Continuing Education Online New Participant Registration Form (36.5).	75,000	1	5/60	6,250
Laboratorians	National Laboratory Training Network Registration Form (32.1).	6,500	1	5/60	542
Total					6,792

Dated: November 26, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–29174 Filed 12–3–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10418]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection:* Revision of a currently approved collection; *Title of Information Collection:* Annual MLR and Rebate Calculation Report and MLR Rebate Notices; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, federal and state taxes and licensing and regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding federal and states taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). An interim final rule (IFR) implementing the MLR was published on December 1, 2010 (75 FR 74865) and modified by technical corrections on December 30, 2010 (75 FR 82277), which added part 158 to Title 45 of the Code of Federal Regulations. The IFR was effective January 1, 2011. A final rule regarding selected provisions of the IFR was published on December 7, 2011 (76 FR 76574, CMS–9998–FC) and an interim final rule regarding an issue not included in issuers' reporting obligations (disbursement of rebates by non-federal governmental plans) was also published December 7, 2011 (76 FR 76596, CMS–9998–IFC2) Both rules published on December 7, 2011 and

were effective January 1, 2012. Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each state in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

Based upon HHS' experience in the MLR data collection and evaluation process, HHS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices. In addition, the notice requirement for issuers that do not owe rebates applied only to the 2011 reporting year, and does not apply to 2012 and subsequent MLR reporting years.

We have simplified the format of the reporting form and the method by which issuers submit their data. For the 2012 MLR reporting year, when submitting data to CMS, issuers will have the option to use either a Microsoft Excel (.xls) or a Comma Separated Value (.csv) file format. This will allow issuers flexibility and reduce the burden in submitting the MLR report. The new method will no longer include pre-calculated fields which will reduce the burden as well as the possibility of error.

The 2012 MLR Reporting Form and instructions also reflect changes for the 2012 reporting year and beyond that are set forth in the December 2011 Final Rule as to whether certain already reported expenditures such as ICD–10 conversion costs are taken into account in calculating an issuer's MLR.

HHS has created and published a host of electronic training tools to assist issuers with the preparation and submission of MLR data forms and Rebate calculations. Consequently the agency is reducing its current burden hours from 354,570 to 311,302. *Form Number:* CMS–10418 (OCN: 0938–1164); *Frequency:* Annual submission for each respondent; *Affected Public:* Private Sector, Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 502; *Number of Responses:* 3,085; *Total Annual Hours:* 311,302. (For policy questions regarding this collection, contact Carol Jimenez at (301) 492–4457. For all other issues, call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by February 4, 2013:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard,

Baltimore, Maryland 21244–1850.

Dated: November 29, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–29243 Filed 12–3–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0081]

Guidance on Investigational New Drug Applications for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs.'' The guidance is intended to assist manufacturers of PET drugs in submitting investigational new drug applications (INDs).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kyong (Kaye) Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2352, Silver Spring, MD 20993–0002, 301–796–2050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs.'' The guidance summarizes the IND process for PET drugs, makes recommendations for how to submit an IND, provides advice on expanded access options for investigational PET drugs, and describes the process for requesting permission to charge for an investigational PET drug.

A draft guidance of the same title was announced in the **Federal Register** on February 14, 2012 (77 FR 8262), and Docket No. FDA–2012–D–0081 was open for comments until May 14, 2012. We received comments from industry and professional societies. We have carefully considered, and where appropriate, we have made corrections, added information, or clarified the information in this guidance in response to the comments or on our own initiative.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the submission of INDs for PET drugs. 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.