

(3) What are the key functions of the B Reader certification and recertification examinations grading system, and how should the examinations be graded to accomplish those functions? Should the general approach currently used for grading<sup>1 2</sup> be changed and if yes, how and why?

(4) Should NIOSH consider alternative approaches to maintenance of B Reader certification besides recertification examinations every 4 years? If so, what alternative approaches would be both effective and desirable?

(5) NIOSH seeks to obtain materials, including published and unpublished reports and research findings that will help to answer these questions. NIOSH encourages respondents to provide these materials.

#### References

1. Morgan RH [1979]. Proficiency Examination of Physicians for Classifying Pneumoconiosis Chest Films. *AJR* 132: 803–808.
2. Wagner GR, Attfield MD, Kennedy RD, Parker JE [1992]. The NIOSH B Reader Certification Program—An Update Report. *J Occup Med* 34(9):879–84.

Dated June 7, 2013.

#### John Howard,

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 78 FR 30307–30312, dated May 22, 2013) is amended to reorganize the Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention, and to revise the functional statement for the Office of Scientific Integrity, Office of the Director, National Center for Immunization and Respiratory Diseases.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the functional statement for the Office of the Director (CAS1), Office of the Associate Director for Science (CAS), and insert the following:

Office of the Director (CAS1). (1) Directs, manages, and coordinates the activities of the OADS; (2) develops goals and objectives, provides leadership, policy formation, scientific oversight, and guidance in program planning and development; and (3) oversees functions of Office of Science Quality, Office of Scientific Integrity, Office of Technology and Innovation, and Special Projects Activity.

After the title and function statement for the Office of Scientific Integrity (CAS), Office of the Associate Director for Science (CAS), insert the following:

Office of Technology and Innovation (CASK). (1) Promotes and facilitates the development of technology and innovation throughout the spectrum of scientific discovery; (2) provides leadership and expertise to promote and effect the timely transfer of knowledge and technology for development of products and processes that improve public health; (3) manages CDC's intellectual property (e.g., patents, trademarks, copyrights) and promotes the transfer of new technology from CDC research to the private sector; (4) leads, develops, coordinates, and manages policies and/or activities that assure CDC intellectual property transfer, scientific training and technical assistance; (5) champions and facilitates innovation, collaborations and technology transfers among federal scientists, laboratories, academia and industry; (6) provides leadership and oversight for innovation activities that have the potential to transform the way that CDC and the private sector improve the public's health; (7) provides consultation and advice to the CDC Office of the Director, Centers/Institute/Offices, and programs related to technology transfer and innovation; and (8) maintains regular, open, and responsive communication with the CDC science community and other key partners including CDC Office of General Council, National Institute of Health, Department of Health and Human Services and United States Patent and Trademark Office.

Delete in its entirety the functional statement for the Office of Laboratory Science (CVG14), Office of the Director (CVG1), National Center for Immunization and Respiratory Diseases (CVG), and insert the following:

Office of Laboratory Science (CVG14). (1) Provides leadership, expertise and service in laboratory science; (2) represents NCIRD's interests in cross-

cutting laboratory services in OID which include, but are not limited to, laboratory information systems, quality management systems and bioinformatics; (3) ensures a safe working environment in NCIRD laboratories; and (4) collaborates effectively with other centers and offices in carrying out its functions.

Dated: June 6, 2013.

#### Sherri A. Berger,

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2013–14165 Filed 6–13–13; 8:45 am]

**BILLING CODE 4163–18–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10482]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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.

**DATES:** Comments must be received by August 13, 2013:

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and

recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send 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) that are 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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Call the Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

**CMS-10482 Evaluation of the Physician Quality Reporting System (PQRS) and Electronic Prescribing (eRx) Incentive Program**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before

submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Physician Quality Reporting System (PQRS) and Electronic Prescribing (eRx) Incentive Program; *Use:* The Physician Quality Reporting System (PQRS) was first implemented in 2007 as an incentive for voluntary reporting of quality measures in accordance with a section of the Tax Relief and Health Care Act of 2006. The PQRS was further extended and enhanced by legislation such as the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (MMSEA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). A number of changes have been made to the PQRS, including group measures, the group reporting option, and additional measures. The PQRS was extended further with the enactment of MMSEA. The MMSEA provided professionals greater flexibility for participating in the PQRS for 2008 and 2009 by authorizing us to establish alternative reporting criteria and alternative reporting periods for the reporting measures groups and for the submission of data on the PQRS quality measures through clinical data registries. The MIPPA, enacted in July 2008, made the PQRS program permanent, further enhanced the PQRS, and established a new standalone incentive program for successful electronic prescribers.

The eRx Incentive Program, the other program being evaluated in this project, was first implemented in 2009. The eRx is another incentive reporting program that uses a combination of incentive payments and payment adjustments to encourage eRx by eligible professionals. The program provides an incentive payment to practices with eligible professionals who successfully e-prescribe for covered Physician Fee Schedule services furnished to Medicare Part B Fee-For-Service (FFS) beneficiaries. Eligible professionals do not need to participate in PQRS to participate in the eRx Incentive Program.

In support of an evaluation the PQRS and the eRx Incentive Program, we will conduct three surveys. The surveys will include: Medicare beneficiaries, eligible professionals, and administrators. This evaluation is designed to determine how

well the PQRS and the eRx Incentive Program are contributing to better and affordable health care for Medicare beneficiaries. The PQRS is a voluntary reporting program that provides an incentive payment to eligible professionals who satisfactorily report data on quality measures. We use quality measures to promote improvements in care delivery and payment and to increase transparency. The PQRS program rewards eligible professionals based on a percentage of the estimated Medicare Physician Fee Schedule of their allowed Part B charges if they meet the defined reporting requirements. The PQRS was initially referred to as the Physician Quality Reporting Initiative (PQRI). *Form Number:* CMS-10482 (OCN: 0938-NEW); *Frequency:* Yearly; *Affected Public:* Individuals and households, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 6,350; *Total Annual Responses:* 6,350; *Total Annual Hours:* 2,545. (For policy questions regarding this collection contact Lauren Fuentes at 410-786-2290. For all other issues call 410-786-1326.)

Dated: June 11, 2013.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-D-0790]

**Food and Drug Administration Decisions for Investigational Device Exemption Clinical Investigations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.” This guidance document was initially issued in draft on November 10, 2011, and was developed to promote the initiation of clinical investigations to evaluate medical devices under FDA's IDE regulations. The guidance was also intended to provide clarification