

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60 Day–14–14CL]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

An Investigation of Lung Health at an Indium-Tin Oxide Production Facility—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act, Public Law 91–596 (section 20[a] [1]), authorizes NIOSH to conduct research to advance the health and safety of workers. NIOSH is proposing to conduct a study regarding the lung health of workers at an indium-tin oxide production facility.

Indium-tin oxide (ITO) is a sintered material used in the manufacture of devices such as liquid crystal displays, touch panels, solar cells, and architectural glass. Indium lung disease is a novel, potentially fatal industrial disease that has occurred in workers making, using, or recycling ITO. This project aims to understand and prevent this occupational lung disease by investigating the relationship between exposure and lung health among current ITO manufacturing workers.

CDC requests Office of Management and Budget (OMB) approval to collect standardized information from current employees of the ITO production facility through an informed consent document, an interviewer-administered questionnaire, and a contact information form. As part of the same project, employees will be offered the opportunity to participate in medical testing and personal air sampling.

The questionnaire will collect contact information, demographic information, respiratory symptoms and diagnoses, work history, and cigarette smoking history. The questionnaire will allow NIOSH to report individual medical test results to each participant and to analyze aggregate data from the workforce to determine risk factors for abnormal lung health indices derived from the medical test results. The individual results will be used by employees and their personal physicians to make medical decisions, such as whether to pursue additional testing. The aggregate results will be used by NIOSH, facility management, and employees in ongoing efforts to reduce exposures and monitor key health indices.

For this study, we will recruit all current employees of the ITO production facility. Participation is voluntary. Employees who wish to participate in the questionnaire and medical testing will review and sign an informed consent document. Employees who wish to participate in the personal air sampling and would like to receive personal results will complete a contact information form. We anticipate approximately 100 study participants. The questionnaire will be administered privately at the workplace during normal working hours by trained NIOSH staff. Employees who are not available at the workplace during the study will be offered the opportunity to respond to the questionnaire at a later date by telephone. There are no costs to participants other than their time.

The total estimated burden for the one-time collection of data is 66 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Current ITO production facility employees.	Informed consent document .....	100	1	15/60	25
	Questionnaire .....	100	1	20/60	33
	Contact information form .....	100	1	5/60	8
<b>Total .....</b>	.....	.....	.....	.....	<b>66</b>

**LeRoy Richardson,**

Chief, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3288-NC]

#### Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS), Framework Measures and Methodology

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

**ACTION:** Notice with comment.

**SUMMARY:** This notice with comment describes the overall Quality Rating System (QRS) framework for rating Qualified Health Plans (QHPs) offered through an Exchange. The purpose of this notice is to solicit comments on the list of proposed QRS quality measures that QHP issuers would be required to collect and report, the hierarchical structure of the measure sets and the elements of the QRS rating methodology. In addition, this notice solicits comments on ways to ensure the integrity of QRS ratings, and on priority areas for future QRS measure enhancement and development.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 21, 2014.

**ADDRESSES:** In commenting, refer to file code CMS-3288-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3288-NC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3288-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written only to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Nidhi Singh Shah, (301) 492-5110, for general information. Elizabeth Flow-Delwiche, (410) 786-1718, for matters relating to the Quality Rating System.

**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

## I. Background

### A. Legislative Background

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-309) (collectively referred to as the Affordable Care Act) establish Affordable Insurance Exchange or Exchange (also known as a Health Insurance Marketplace or Marketplace) within each state. Qualified individuals and qualified employers in each state will be able to shop for affordable health insurance through Exchanges.

The Department of Health and Human Services (the Secretary) holds primary responsibility for establishing the standards and guidelines for the Exchanges. The Affordable Care Act provides States with the flexibility to establish and operate their own Exchange (State-based Exchange). However, if a state elects not to establish a State-based Exchange or if a state will not have an Exchange that is operational by January 1, 2014, pursuant to section 1321(c)(1) of the Affordable Care Act, the Secretary will establish and operate a Federally-facilitated Exchange in those states. The Affordable Care Act and applicable Exchange regulations establish that health plans offered through an Exchange must meet specific standards to be certified as QHPs and to offer coverage in an Exchange beginning in January 2014.

The Affordable Care Act also requires the Secretary to develop a number of reporting requirements to support the delivery of quality health care coverage offered in the Exchanges. Specifically, sections 1311(c)(3) and (c)(4) of the Affordable Care Act direct the Secretary to develop—(1) a system that rates qualified health plans (QHPs) based on the relative quality and price; and (2) an enrollee satisfaction survey system that assesses the level of enrollee experience (that is, consumer experience) with QHPs. Because we believe that QHP consumer experience is an important part of rating the overall quality of a QHP, we intend to use some of the information collected from the Enrollee