

Community as a Learning Health System. Committee members will consider ways to implement components of the graphic on the Influences on the Population's Health, in the Shaping a Health Statistics Vision for the 21st Century report. The Co-chairs for the Privacy, Confidentiality and Security Subcommittee will brief the Committee about an upcoming hearing to obtain input about implementing health data stewardship, and the Standards and Quality Subcommittees will also provide updates on plans and activities.

On the morning of the second day, the Committee will continue to discuss ways to promote alignment throughout the Committee to enhance its effectiveness, focus on its themes, and utilize expertise of the NCVHS Working Group on HHS Data Access and Use. Once the full Committee adjourns, the NCVHS's Working Group on HHS Data Access and Use will convene to discuss best practices and suggestions to further the dissemination and use of open HHS data, and summarize future plans of the Working Group. Further information will be provided on the NCVHS Web site at <http://www.ncvhs.hhs.gov/>.

The times shown above are for the full Committee meeting. Subcommittee breakout sessions are scheduled for late in the afternoon on the first day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available.

*Contact Person for More Information:* Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: January 31, 2013.

**James Scanlon,**

*Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10419]

#### 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 Request:* New collection (request for a new OMB control number). *Title of Information Collection:* Transparency Reports and Reporting of Physician Ownership or Investment Interests. *Use:* Reports of Payments or Other Transfers of Value to Covered Recipients.

Section 403.904 requires direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient, and that direct and indirect payments or other transfers of value provided to a third party at the request of (or designated by) the applicable manufacturer on behalf of a covered recipient, be reported by the applicable manufacturer to CMS on an annual basis.

#### Reports of Physician Ownership and Investment Interests

Under § 403.906, each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

## Data Collection

The data templates will provide detailed information about the data to be collected including the data element name, format, allowable values, required versus optional fields, and other associated rules intended to aid the applicable manufacturers and applicable group purchasing organizations as they prepare for and participate in data collection. Applicable manufacturers and applicable GPOs will engage in data collection external to CMS within their own systems or tracking tools. If we intend to make changes to the data templates, we will provide them at least 90 days prior to first day of data collection for the next reporting year. In providing revised templates, we will also comply with the requirements of the Paperwork Reduction Act to seek public comments on the proposed changes to the information collections, as required by law. This will allow applicable manufacturers and applicable GPOs to make any necessary changes to prepare for the next reporting year. This is the same time as the date by which we will publish the list of teaching hospitals.

#### Data Submission Procedures for Electronic Submission of Reports

Section 403.908 requires that reports must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year. *Form Number:* CMS-10461 (OCN 0938—New). *Frequency:* Annual. *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 396,514. *Total Annual Responses:* 396,514. *Total Annual Hours:* 13,327,065. (For policy questions regarding this collection contact Erica Breese at 202-260-6079. 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](mailto: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 April 9, 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: February 5, 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-2012-N-0560]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable**

**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 March 11, 2013.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0582. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—(OMB Control Number 0910-0582)—Extension**

FDA’s investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket

submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812, Investigational Device Exemptions, under 21 CFR 812.2(c)(3), but FDA’s regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1, 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level 1 guidance document, entitled “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable,” issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours (700 × 4 = 2,800).

In the **Federal Register** of June 12, 2012 (77 FR 34954), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Federal Food, Drug, and Cosmetic Act Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
520(g) (21 U.S.C. 360j(g))	700	1	700	4	2,800

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.