

Estimated total average annual hours burden: 1,043,961 hours.

Based, in part, on industry data regarding the number of businesses under various industry codes, staff estimates that 1,101,780 non-GLBA entities under FTC jurisdiction have affiliates and would be affected by the Rule.⁵ Staff further estimates that there are an average of 5 businesses per family or affiliated relationship, and that the affiliated entities will choose to send a joint notice, as permitted by the Rule. Thus, an estimated 220,356 non-GLBA business families may send the affiliate marketing notice. Staff also estimates that non-GLBA entities under the jurisdiction of the FTC would each incur 14 hours of burden during the prospective requested three-year PRA clearance period, comprised of a projected 7 hours of managerial time, 2 hours of technical time, and 5 hours of clerical assistance.

Based on the above, total burden for non-GLBA entities during the prospective three-year clearance period would be approximately 3,084,984 hours. Associated labor cost would total \$101,874,986.⁶ These estimates include the start-up burden and attendant costs,

⁵ This estimate is derived from an analysis of a database of U.S. businesses based on SIC codes for businesses that market goods or services to consumers, which included the following industries: Transportation services; communication; electric, gas, and sanitary services; retail trade; finance, insurance, and real estate; and services (excluding business services and engineering, management services). See <http://www.naics.com/search.htm>. This estimate excludes businesses not subject to the FTC's jurisdiction and businesses that do not use data or information subject to the rule. To the resulting sub-total (6,677,796), staff applies a continuing assumed rate of affiliation of 16.75 percent, see 69 FR 33324, 33334 (June 15, 2004), reduced by a continuing estimate of 100,000 entities subject to the Commission's GLBA privacy notice regulations, see *id.*, applied to the same assumed rate of affiliation. The net total is 1,101,780.

⁶ The associated labor cost is based on the labor cost burden per notice by adding the hourly mean private sector wages for managerial, technical, and clerical work and multiplying that sum by the estimated number of hours. The classifications used are "Management Occupations" for managerial employees, "Computer and Mathematical Science Occupations" for technical staff, and "Office and Administrative Support" for clerical workers. See National Compensation Survey: Occupational Earnings in the United States 2009, U.S. Department of Labor, released August 2010, Bulletin 2738, Table 3 ("Summary: Full-time civilian workers: Mean and median hourly, weekly, and annual earnings and mean weekly and annual hours") <http://www.bls.gov/ncs/ocs/sp/ncb1346.pdf>. The respective private sector hourly wages for these classifications are \$43.99, \$36.07, and \$16.45. Estimated hours spent for each labor category are 7, 2, and 5, respectively. Multiplying each occupation's hourly wage by the associated time estimate, labor cost burden per notice equals \$462.32. This subtotal is then multiplied by the estimated number of non-GLB business families projected to send the affiliate marketing notice (220,356) to determine cumulative labor cost burden for non-GLBA entities (\$101,874,986).

such as determining compliance obligations. Non-GLBA entities, however, will give notice only once during the clearance period ahead. Thus, averaged over that three-year period, the estimated annual burden for non-GLBA entities is 1,028,328 hours and \$33,958,329 in labor costs.⁷

Entities that are subject to the Commission's GLBA privacy notice regulation already provide privacy notices to their customers.⁸ Because the FACT Act and the Rule contemplate that the affiliate marketing notice can be included in the GLBA notices, the burden on GLBA regulated entities would be greatly reduced. Accordingly, the GLBA entities would incur 6 hours of burden during the first year of the clearance period, comprised of a projected 5 hours of managerial time and 1 hour of technical time to execute the notice, given that the Rule provides a model.⁹ Staff further estimates that 3,350 GLBA entities under the FTC's jurisdiction would be affected,¹⁰ so that the total burden for GLBA entities during the first year of the clearance period would approximate 20,100 hours and \$857,667 in associated labor costs.¹¹ Allowing for increased familiarity with procedure, the PRA burden in ensuing years would decline, with GLBA entities each incurring an estimated 4 hours of annual burden (3 hours of managerial time and 1 hour of technical time) during the remaining two years of the clearance, amounting to 13,400 hours and \$562,934 in labor costs in each of the ensuing two years.¹² Thus, averaged over the three-year clearance period, the estimated annual burden for GLBA entities is 15,633 hours and \$661,178 in labor costs.

⁷ 3,084,984 hours ÷ 3 = 1,028,328; \$101,874,986 ÷ 3 = \$33,958,329.

⁸ Financial institutions must provide a privacy notice at the time the customer relationship is established and then annually so long as the relationship continues. Staff's estimates assume that the affiliate marketing opt-out will be incorporated in the institution's initial and annual notices.

⁹ As stated above, no clerical time is included in the estimate because the notice likely would be combined with existing GLBA notices.

¹⁰ Based on the previously stated estimates of 100,000 GLBA business entities (see *supra* note 5) at an assumed rate of affiliation of 16.75 percent (16,750), divided by the presumed ratio of 5 businesses per family, this yields a total of 3,350 GLBA business families subject to the Rule. For simplicity, staff assumes that all of these entities are new establishments and/or newly integrating the affiliated opt-out notice with the GLBA notice in the first year of the prospective three-year clearance period; thus, the higher estimate of hours assigned to the first year. This, too, then, would effectively overstate actual burden.

¹¹ 3,350 GLBA entities × [(\$43.99 × 5 hours) + (\$36.07 × 1 hour)] = \$857,667.

¹² 3,350 GLBA entities × [(\$43.99 × 3 hours) + (\$36.07 × 1 hour)] = \$562,934.

Cumulatively for both GLBA and non-GLBA entities, the average annual burden over the prospective three-year clearance period is 1,043,961 burden hours and \$34,619,507 in labor costs. GLBA entities are already providing notices to their customers so there are no new capital or non-labor costs, as this notice may be consolidated into their current notices. For non-GLBA entities, the Rule provides for simple and concise model forms that institutions may use to comply. Entities that already have on-line capabilities will offer consumers the choice to receive notices via electronic format (e.g., computer equipment and software), and covered entities are already equipped to provide disclosures (e.g., computers with word processing programs, copying machines, mailing capabilities). Thus, any capital or non-labor costs associated with compliance for these entities are negligible.

Willard K. Tom,
General Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Evaluation of the National Guideline Clearinghouse™." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on September 17th, 2010 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by December 20, 2010.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974

(attention: AHRQ's desk officer) or by e-mail at OIRA_submission@omb.eop.gov (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AURO Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluation of the National Guideline Clearinghouse™

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. 42 U.S.C. 299(b). AHRQ supports the dissemination of evidence-based guidelines through its National Guideline Clearinghouse™ (NGC).

The NGC serves as a publicly accessible Web-based database of evidence-based clinical practice guidelines meeting explicit criteria. The NGC also supports AHRQ's strategic goal on effectiveness: To improve health care outcomes by encouraging the use of evidence to make informed health care decisions. The NGC is a vehicle for such encouragement. The mission of the NGC is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to

further their dissemination, implementation and use.

AHRQ proposes to conduct a comprehensive evaluation of the NGC. This evaluation will build on the site trends AHRQ has already identified, including growth from 70,000 to 700,000 visits per month, 600 to approximately 40,000 e-mail subscribers, 250 to 2,370 guidelines represented, and 50 to nearly 300 participating guideline developer organizations from July 1999 to July 2009.

The objectives of the NGC evaluation are to gain a better understanding of how:

- The NGC is used.
- The NGC supports dissemination of evidence-based clinical practice guidelines and related documents.
- The NGC has influenced efforts in guideline development and guideline implementation and use.
- The NGC can be improved.

This study is being conducted by AHRQ through its contractor, AFYA, Inc. and The Lewin Group (AFYA/Lewin), pursuant to AHRQ's statutory authority to conduct and support research and disseminate information on healthcare and on systems for the delivery of such care, including activities with respect to clinical practice. 42 U.S.C. 299a(a)(4).

Method of Collection

To achieve the objectives of this project the following data collections will be implemented:

- (1) NGC evaluation survey—a Web-based survey administered to a convenience sample of both users and non-users of the NGC,
- (2) Focus groups—conducted with guideline developers, medical librarians, informatics specialists, clinicians, and students, and
- (3) Key informant interviews—in-person interviews conducted with influential individuals in medical

societies, health plans, and quality improvement organizations as well as medical librarians, researchers, and informatics specialists who produce, use, and disseminate guidelines.

Questions in the survey, focus group, and key informant discussion guides will focus on the effectiveness of NGC in areas of dissemination, implementation, and use of evidence-based clinical practice guidelines, and relative to other available guideline sources. For example, measures to be gathered through the instruments include the level of trust of the NGC, the use of the NGC relative to other guideline sources, and the influence of the NGC on various stakeholder groups. In addition, the instruments will be used to measure the use of other guideline resources which are used by non-NGC users.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this evaluation. The NGC evaluation questionnaire will be completed by approximately 40,220 persons and will require 10 minutes to complete for users of the NGC and about 2 minutes for non-users. For the purpose of calculating respondent burden an average of 8 minutes is used and reflects a mix of users and non-users with most respondents expected to be users.

Eleven different focus groups consisting of 9 persons each will be conducted and are expected to last 90 minutes each. Key informant interviews will be conducted with 30 individuals and will last about 60 minutes. The total annual burden hours are estimated to be 5,542 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in this project. The total annual cost burden is estimated to be \$185,712.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
NGC Evaluation Survey	40,220	1	8/60	5,363
Focus Groups	99	1	1.5	149
Key Informant Interviews	30	1	1	30
Total	40,349	NA	NA	5,542

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
NGC Evaluation Survey	40,220	5,363	\$33.51	\$179,714

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Data collection method	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Focus Groups	99	149	33.51	4,993
Key Informant Interviews	30	30	33.51	1,005
Total	40,349	5542	NA	185,712

* Based upon the mean of the average wages for healthcare practitioner and technical occupations (29-0000) presented in the National Compensation Survey: Occupational wages in the United States, May 2009, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the government for this one year project. The total cost is estimated to be \$350,000 to conduct the one-time survey, 11 focus groups,

and 30 key informant interviews and to analyze and present their results. This amount is the contract total for AFYA's contract with AHRQ to evaluate the NGC. This amount, includes the costs for project development and management (\$70,000 or 20% of the entire contract amount); data collection

activities (\$105,000 or 30% of the entire contract amount); data processing and analysis (\$70,000 or 20% of the entire contract amount); and administrative support activities and reporting (\$105,000 or 30% of the entire contract amount).

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development and Management	\$70,000	\$70,000
Data Collection Activities	105,000	105,000
Data Processing and Analysis	70,000	70,000
Administrative Support and Reporting	105,000	105,000
Total	350,000	350,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 10, 2010.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2009-N-0554]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Manufactured Food Regulatory Program Standards" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 3, 2010 (75 FR 9605), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An

agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0601. The approval expires on September 30, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: November 12, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2010-29055 Filed 11-17-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health**

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,