As required by OMB regulations, 5 CFR Part 1320, the FTC is providing this second opportunity for public comment.

Likely Respondents: Real estate agents and brokers, advertising agencies, home builders, lead generators, rate aggregators, and others that may provide commercial communications regarding mortgage credit product terms.[9]

Estimated Annual Hours Burden: 1,800,000 hours.

- Derived from 1.2 million likely respondents[10] × approximately 3 hours each respondent per year to do these tasks = 3.6 million hours.
- Since the FTC shares enforcement authority with the CFPB for Regulation N, the FTC's allotted PRA burden is 1,800,000 annual hours.[11]

Estimated Annual Cost Burden: $24,264,000, which is derived from 1.8 million hours × $13.48 per hour.[12]

[9] The Commission does not know what percentage of these persons are, in fact, engaged in covered conduct under the Rule, i.e., providing commercial communications about mortgage credit product terms. For purposes of these estimates, the Commission has assumed all of them are covered by the recordkeeping provisions and are not retaining these records in the ordinary course of business.

[10] No general source provides precise numbers of the various categories of covered persons. Commission staff, therefore, has used the following sources and inputs to arrive at this estimated total: (1) 1 million real estate brokers and agents—from the National Association of Realtors, *see http://www.realtor.org* (last visited June 24, 2013) ; (2) 140,000 home builders—from the National Association of Home Builders, *see http://www.NAHB.org* (last visited June 24, 2013); (3) 350 finance companies—from the American Financial Services Association, *see http://www.afsaonline.org* (last visited June 24, 2013); (4) 29,770 advertising agencies—from the North American Industry Classification System Association's database of U.S. businesses, see *http://www.naics.com* (last visited June 24, 2013); (5) 1,000 lead generators and rate aggregators—based on staff's administrative experience. These inputs add to 1,171,120; for rounding, and to account further for potentially unspecified other covered persons, however, staff has increased the resulting total to 1.2 million.

[11] This burden estimate includes recordkeeping requirements of the FTC's Mortgage Acts and Practices Rule for the period from December 1, 2013—December 29, 2013. The Commission retained its authority to enforce the Mortgage Acts and Practices—Advertising Rule from the Rule's issuance in July 2011 until the CFPB's republished rule, Regulation N, became effective on December 30, 2011. Thus, the Commission's Rule had a correlative two-year recordkeeping for the above period concluding on December 29, 2013. Burden imposed on covered entities after that time are covered by the same recordkeeping requirements under Regulation N, which commenced December 30, 2011.

[12] This estimate is based on mean hourly wages for office support file clerks provided by the Bureau of Labor Statistics. *See* U.S. Bureau of Labor Statistics, *Occupational Employment and Wages—May 2012,* table 1 (''National employment and wage data from the Occupational Employment Statistics survey by occupation,'' released Mar. 29, 2013), *available at http://www.bls.gov/news.release/pdf/ocwage.pdf.*

Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 9, 2013. Write ''Regulation N: FTC File No. P134811; K05'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is * * * privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you are required to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online, or to send it to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/regulationnpra2,* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov*, you also may file a comment through that Web site.

If you file your comment on paper, write ''Regulation N: FTC File No. P134811; K05'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 9, 2013. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.shtm.*

Comments on the information collection requirements subject to review under the PRA should also be submitted to OMB. If sent by U.S. mail, address comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395–5167.

David C. Shonka,

Principal Deputy General Counsel.

[FR Doc. 2013–26697 Filed 11–6–13; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Core Needle and Open Surgical Biopsy for Diagnosis of Breast Lesions

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from

the public on core needle and open surgical biopsy for diagnosis of breast lesions. Scientific information is being solicited to inform our review of *Core Needle and Open Surgical Biopsy for Diagnosis of Breast Lesions,* which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on core needle and open surgical biopsy will improve the quality of this review. AHRQ is conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before December 9, 2013.

ADDRESSES:

Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/. Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: SIPS@epc-src.org.

Print submissions: Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–220–8262 ext. 58652 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for *Core Needle and Open Surgical Biopsy for Diagnosis of Breast Lesions—An Update to the 2009 Report.*

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on core needle and open surgical biopsy, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayProduct&productID=1723.*

This notice is to notify the public that the EHC program would find the following information on core needle and open surgical biopsy helpful:

- A list of completed studies your company has sponsored for this indication. In the list, *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies your company has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayProduct&productID=1723.*

The Key Questions

The Key Questions (KQs) and study selection criteria (population, intervention, comparator, outcome, timing, and setting; PICOTS) for this update began with those specified in the original report. On the basis of input from clinical experts during the development of this protocol, we have made selected revisions to the KQs and study eligibility criteria to clarify the focus of the updated systematic review.

The following three KQs will be addressed in the review:

Question 1

In women with a palpable or nonpalpable breast abnormality, what is the test performance of different types of core-needle breast biopsy when compared with open biopsy for diagnosis?

I. What factors associated with the patient and her breast abnormality influence the test performance of different types of core-needle breast biopsy when compared with open biopsy for diagnosis of a breast abnormality?

II. What factors associated with the procedure itself influence the test performance of different types of core-needle breast biopsy when compared with open biopsy for diagnosis of a breast abnormality?

III. What clinician and facility factors influence the test performance of core-needle breast biopsy when compared with open biopsy for diagnosis of a breast abnormality?

Question 2

In women with a palpable or nonpalpable breast abnormality, what are the harms associated with different types of core-needle breast biopsy when compared with open biopsy for diagnosis?

I. What factors associated with the patient and her breast abnormality influence the harms of core-needle breast biopsy when compared with the open biopsy technique in the diagnosis of a breast abnormality?

II. What factors associated with the procedure itself influence the harms of core-needle breast biopsy when

compared with the open biopsy technique in the diagnosis of a breast abnormality?

III. What clinician and facility factors influence the harms of core-needle breast biopsy when compared with the open biopsy technique in the diagnosis of a breast abnormality?

Question 3

How do open biopsy and various core-needle techniques differ in terms of patient preference, availability, costs, availability of qualified pathologist interpretations, and other factors that may influence choice of a particular technique?

Study Eligibility Criteria (PICOTS: Population, Intervention, Comparators, Outcomes, Timing, and Setting)

Population

The population for all KQs is women who have been referred for biopsy for the diagnosis of primary breast cancer (including multifocal and bilateral disease) following self-examination, physical examination, or screening mammography. Studies carried out in women at high baseline risk of breast cancer (e.g., due to BRCA mutations) will therefore be included; however studies carried out in women who have been previously diagnosed with breast cancer and are being examined for recurrence will be excluded [a].

Interventions

For all KQs, the intervention is a core-needle biopsy done to evaluate whether a breast lesion is malignant. Other uses of biopsy techniques (e.g., use of biopsy to examine the sentinel lymph nodes in women with an established diagnosis of breast cancer) are excluded.

Comparators (Reference Standard and Comparator Index Tests)

For test performance outcomes (KQ 1) the reference standard is either open surgical biopsy or follow-up by clinical examination and/or mammography for at least 6 months. The diagnostic performance of each core biopsy technique (each index test) will be quantified versus the reference standard [b]. The comparative diagnostic performance of alternative core-needle biopsy techniques is also of interest [c].

For harms and patient-relevant outcomes (outcomes other than diagnostic performance; KQs 2 and 3) the comparators are:

I. Open surgical biopsy
II. Follow-up by clinical examination and/or mammography for at least 6 months
III. Alternative core-needle biopsy methods (e.g., stereotactic mammography vs. ultrasound to locate the breast lesion; use vs. nonuse of vacuum assistance to extract tissue samples)

Outcomes

I. For KQ 1, test performance outcomes, as assessed by the following measures:

A. Sensitivity (proportion of cancerous tumors detected by the reference standard that are also detected by core-needle biopsy)
B. False-negative rate (proportion of negative findings according to core-needle biopsy that are classified as positive by the reference standard)
C. The underestimation rate for atypical ductal hyperplasia (ADH; proportion of core needle biopsy findings of ADH that are found to be malignant according to the reference standard)
D. The underestimation rate for DCIS (proportion of core-needle biopsy findings of DCIS that are found to be invasive according to the reference standard)

II. For KQ 2:

A. Rate of inconclusive biopsy findings (e.g., inadequate sampling of the lesion)
B. Repeat biopsy rate
C. Subsequent false-positive and false-negative rates on mammography
D. Dissemination (seeding) of cancerous cells along the needle track
E. Patient-centered outcomes (including bruising, bleeding or hematomas, pain, use of pain medication, infections, fainting or near fainting, and time to recover)

III. For KQ 3:

A. Patient-relevant outcomes
  1. Patient preferences for specific procedures
  2. Cosmetic results
  3. Quality of life
  4. Anxiety and other psychological outcomes
  5. Time to complete tumor removal (for women with cancer)
  6. Recurrence rate (for women with cancer, including local, regional, and distant recurrence)
  7. Cancer-free survival and overall survival
B. Resource use and logistics
  1. Costs
  2. Resource utilization other than cost (number of additional surgical procedures [e.g., re-excisions, procedural time])
  3. Subsequent surgical procedures
  4. Wait time for test results
C. Availability of technology and relevant expertise
  1. Physician experience
  2. Availability of equipment
  3. Availability of (qualified) pathologists to evaluate biopsy samples

Timing

Duration of clinical and/or mammographic follow-up must be at least 6 months in studies where open surgical biopsy was not performed.

Setting

Studies in all geographic locations and care settings will be evaluated, including general hospitals, academic medical centers, and ambulatory surgical centers, among others.

Explanation to References in Population and Interventions Sections Above

[a] The original review excluded studies carried out in women at high risk of breast cancer; however, magnetic resonance imaging (MRI)-guided biopsy, which has been identified as a topic of interest for the updated review, is used mainly in this subset of patients. For this reason, following extensive discussions with the TEP (Technical Expert Panel), we decided to broaden the scope of the review to cover women at high risk for cancer. In effect, this will be a de novo review with respect to this population subset.

[b] Most assessments of diagnostic performance quantify the sensitivity and the specificity of each index test—here each core-needle biopsy technique. Sensitivity and specificity are probabilities conditional on true disease status and are noncomparative in nature. The reference standard is used in their definition and is not a ''comparator test.''

[c] That is, differences or ratios of sensitivities and of specificities between alternative core-needle biopsy techniques.

Dated: October 31, 2013.

Richard Kronick,

AHRQ Director.

[FR Doc. 2013–26617 Filed 11–6–13; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–14–0026]

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