

## EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

| Cost component | Total cost | Annualized cost |
|----------------|------------|-----------------|
| Total .....    | 3,184,333  | 1,061,444       |

**Request for Comments**

In accordance with the Paperwork Reduction Act, 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: April 19, 2012.

**Carolyn M. Clancy,**  
Director.

[FR Doc. 2012-10009 Filed 4-25-12; 8:45 am]

**BILLING CODE 4160-90-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Agency for Healthcare Research and Quality****Scientific Information Request on Local Therapies for Unresectable Primary Hepatocellular Carcinoma**

**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 manufacturers of local, minimally invasive, medical devices for unresectable primary hepatocellular carcinoma (e.g., ablation, radiotherapy, or embolization devices). Scientific information is being solicited to inform our Comparative Effectiveness Review

of Local Therapies for Unresectable Primary Hepatocellular Carcinoma, 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 Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

**DATES:** Submission Deadline on or before May 29, 2012.

**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 of current studies and complete the form to upload your documents.

*Email submissions:* [ehcsrc@ohsu.edu](mailto:ehcsrc@ohsu.edu) (please do not send zipped files—they are automatically deleted for security reasons).

*Print submissions:* Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239-3098.

**FOR FURTHER INFORMATION CONTACT:**

Robin Paynter, Research Librarian, Telephone: 503-494-0147 or Email: [ehcsrc@ohsu.edu](mailto:ehcsrc@ohsu.edu).

**SUPPLEMENTARY INFORMATION:**

In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for local therapies for unresectable primary hepatocellular carcinoma.

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 systematically requesting information (e.g., details of studies conducted) from medical device

industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on local therapies for unresectable primary hepatocellular carcinoma, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: <http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=1012&pageaction=displayproduct#5056>.

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes 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 withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.

- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

**Please Note:** The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

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 Key Questions

### Question 1

What is the comparative effectiveness of the various liver-directed therapies in patients with hepatocellular carcinoma (HCC) who are not otherwise candidates for surgical resection or transplantation with no evidence of extrahepatic disease regarding survival and quality of life?

### Question 2

What are the comparative harms of the various liver-directed therapies in patients with HCC who are not otherwise candidates for surgical resection or transplantation with no evidence of extrahepatic disease regarding adverse events?

### Question 3

Are there differences in comparative effectiveness of various liver-directed therapies in patients with HCC who are not otherwise candidates for surgical resection or transplantation for specific patient and tumor characteristics, such as age, gender, disease etiology, and Child-Pugh score?

Dated: April 19, 2012.

**Carolyn M. Clancy,**  
AHRQ, Director.

[FR Doc. 2012-10011 Filed 4-25-12; 8:45 am]

**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-12-0010]

### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

### Proposed Project

The National Birth Defects Prevention Study (NBDPS)—(0920-0010, Expiration 06/30/2012)—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serves as an early warning system for new teratogens. In 1997, the Birth Defects Risk Factor Surveillance (BDRFS) study, a case-control study of risk factors for selected birth defects, became the National Birth Defects Prevention Study

(NBDPS). The major components of the study did not change.

The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth defect surveillance registries in nine states, including metropolitan Atlanta. Control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. The interview takes approximately one hour. A maximum of thirty-six hundred interviews are planned, 2,700 cases and 900 controls, resulting in a maximum interview burden of approximately 3,600 hours for all Centers.

Parents are also asked to collect cheek cells from themselves and their infants for DNA testing. The collection of cheek cells by the mother, father, and infant is estimated to take about 10 minutes per person. Each person will be asked to rub 1 brush inside the left cheek and 1 brush inside the right cheek for a total of 2 brushes per person. Collection of the cheek cells takes approximately 1-2 minutes, but the estimate of burden is 10 minutes to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the cheek cells is 1,800 hours for all Centers.

Information gathered from both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years.

There are no costs to the respondents other than their time. The total estimated annualized burden is 5,400 hours.

### ESTIMATED ANNUALIZED BURDEN TABLE

| Type of respondents             | Form name                            | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---------------------------------|--------------------------------------|-----------------------|------------------------------------|--|
| Mothers .....                   | NBDPS mother questionnaire .....     | 3,600                 | 1                                  | 1                                      |
| Mothers, fathers, infants ..... | Cheek Cell Specimen Collection ..... | 10,800                | 1                                  | 10/60                                  |