Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost for this two year project. The annual cost to the Federal Government is estimated to be $10.3 million.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

[$ thousands]

Cost component	Total cost	Annualized cost
Project Development	$3,099	$1,550
Data Collection Activities	7,230	3,615
Data Processing and Analysis	7,230	3,615
Project Management	2,066	1,033
Overhead	1,033	517
Total	$20,658	$10,329

Note: Components may not sum to Total due to rounding.

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 health care research, quality improvement and 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: August 13, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–20021 Filed 8–19–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the AHRQ National Advisory Council for Healthcare Research and Quality Subcommittee on Quality Measures for Children's Healthcare in Medicaid and Children's Health Insurance Programs

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

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality Subcommittee on Quality Measures for Children's Healthcare in Medicaid and Children's Health Insurance Programs (CHIP).

DATES: The meeting will be held on Thursday, September 17, 2009, from 8 a.m. to 5 p.m. and Friday, September 18, 2009 from 8 a.m. to 12 p.m.

ADDRESSES: Holiday Inn Capitol, 550 C Street, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Padmini Jagadish, Public Health Analyst at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, (301) 427–1927. For press-related information, please contact Karen Migdail at (301) 427–1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Mr. Michael Chew, Director, Office of Equal Employment Opportunity Program, Program Support Center, on (301) 443–1144, no later than August 31, 2009.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality was established in accordance with Section 921 (now Section 931) of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of AHRQ to enhance the quality, and improve the outcomes, of health care services; improve access to such services through scientific research; and promote improvements in clinical practice and in the organization, financing, and delivery of health care services.

The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members.

AHRQ's National Advisory Council on Healthcare Research and Quality (NAC) has established a Subcommittee on Quality Measures for Children's Healthcare in Medicaid and Children's Health Insurance Programs (CHIP). The Subcommittee was created to provide advice to the NAC for consideration and transmission to AHRQ as AHRQ undertakes responsibilities in the identification of an initial core quality measure set for use by Medicaid and CHIP programs for children's healthcare. A roster of the Subcommittee members is available at *http://www.ahrq.gov/chip/chipraact.htm.* The first meeting of the subcommittee took place on July 22 and 23, 2009. The September meeting is the second working meeting that will be held as a part of this effort.

The identification of an initial core measure set for public comment is required under Public Law 111–3, the Child Health Insurance Program

Reauthorization Act (CHIPRA). The initial core measure set is required to be posted for public comment by January 1, 2010. CHIPRA reauthorized the Child Health Insurance Program (CHIP) originally established in 1997, and in Title IV of the law, added a number of new provisions designed to improve health care quality and outcomes for children. AHRQ is working closely with the Centers for Medicare and Medicaid Services (CMS) in implementing these provisions. For more information about AHRQ's role in carrying out the quality provisions of CHIPRA, see *http://www.ahrg.gov/chip/chipraact.htm.*

II. Agenda

On Thursday, September 17, 2009, the Subcommittee meeting will convene at 8 a.m., with the call to order by the Subcommittee Co-Chairs. The meeting will review results of the second stage of the Delphi Process of scoring measures for validity, feasibility, and importance, and proceed to select an initial core set of children's healthcare quality measures to recommend to the AHRQ National Advisory Committee (NAC). This process was started in the first subcommittee meeting, held July 22–23, 2009.

A more specific proposed agenda will be available before the meeting from Padmini Jagadish, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, (301) 427–1927, e-mail address *Padmini.Jagadish@ahrq.hhs.gov.* The final agenda, including the time for public comment during the meeting, will be available on the AHRQ Web site at *http://www.ahrg.gov/chip/chipraact.htm* no later than September 10, 2009. This AHRQ Web site links to an email address that can be used to submit comments on CHIPRA quality measure development as the process of identifying the initial core measure set proceeds. Subcommittee meeting minutes will be available within 21 business days after the meeting.

Dated: August 13, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–20020 Filed 8–19–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0374]

Educating the Public About Removal of Essential-Use Designation for Epinephrine; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Educating the Public About Removal of Essential-Use Designation for Epinephrine.'' The currently approved over-the-counter (OTC) epinephrine metered-dose inhalers (MDIs) contain chlorofluorocarbons (CFCs) and cannot be marketed after December 31, 2011. This 1-day public workshop is intended to seek input from key stakeholders in the asthma community, the pharmaceutical industry, experts in health care communication, and the public on strategies to educate consumers about the decision to remove epinephrine MDIs from the market and transition consumers to therapeutic alternatives that do not contain CFCs or other ozone-depleting substances (ODSs). The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

DATES: The public workshop will be held on September 25, 2009, from 8:30 a.m. to 3 p.m. However, depending on public participation, the meeting may be extended or may end early. See section III of this document for information on how to register for the workshop. Written or electronic comments must be submitted by November 24, 2009.

ADDRESSES: The public workshop will be held at FDA's, Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Submit written or electronic requests to make a presentation to Faith Dugan (see **FOR FURTHER INFORMATION CONTACT**). Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Faith Dugan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6182, Silver Spring, MD 20993–0002, 301–796–3446, FAX: 301–847–8752, e-mail: *Faith.Dugan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) and the Clean Air Act,[1] FDA, in consultation with the Environmental Protection Agency, is required to determine whether an FDA-regulated product that releases an ODS is an essential use of the ODS. Products containing an ODS, such as CFCs, that are not designated as essential uses cannot be sold or distributed in the United States. In the **Federal Register** of November 19, 2008 (73 FR 69532) (the final rule), we amended our regulation on the use of ODSs in self-pressurized containers to remove the essential-use designation for MDIs containing epinephrine. Epinephrine MDIs containing an ODS cannot be marketed after December 31, 2011. You may find copies of the final rule on the Internet at *http://www.regulations.gov.*

Epinephrine is a short-acting adrenergic bronchodilator used in the treatment of asthma. A new drug application (NDA) for OTC epinephrine MDIs was approved in 1956. Epinephrine was designated as an essential use in 1978 (43 FR 11301, March 17, 1978). Epinephrine MDIs are marketed OTC as PRIMATENE MIST and as generic brands for certain retail pharmacies. Epinephrine MDIs are the only MDIs for treatment of asthma (or any other disease) that are approved for OTC use. Consumers do not need a prescription from a health care provider to purchase OTC epinephrine MDIs.

In removing the essential-use designation for epinephrine, we applied the criteria for removing an essential-use designation in § 2.125(g)(2) (21 CFR 2.125(g)(2)). Under § 2.125(g)(2), an essential-use designation can be removed even though the active moiety is not available in a non-CFC product if it no longer meets the criteria specified in § 2.125(f) for adding a new essential use. The criteria in § 2.125(f)(1) are: ''(i) Substantial technical barriers exist to formulating the product without ODSs;

[1] Montreal Protocol on Substances that Deplete the Ozone Layer, September 16, 1987, 26 I.L.M. 1541 (1987); 1990 Amendments to the Clean Air Act, Public Law No. 101–549 (November 15, 1990).