[sic] [should be *Calcified Tissue Research*] 17:327–335, 1975.

(I) Aronow, W.S., Goldsmith, J.R., Kern, J.C., Cassidy, J, [Palmer, P.J.], Johnson, L.L., Adams, W., & Nelson, W.H. ''Effect of smoking cigarettes on cardiovascular hemodynamics.'' *Archives of Environmental Health* 28, 330–332, 1974.

(j) Seltzer, C.C., Friedman, G.D., Siegelaub, A.B., & [Palmer, P.J., replaced Collen, M.F.]. ''Smoking habits and pain tolerance.'' *Archives of Environmental Health* 29,170–172, 1974.

Ms. Palmer has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed for a period of three (3) years, beginning on January 26, 2004:

(1) To exclude herself from any contracting or subcontracting with any agency of the United States government and from eligibility or involvement in nonprocurement programs of the United States government referred to as ''covered transactions'' as defined in the debarment regulations at 45 CFR part 76; and

(2) To exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852; (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. 04–3336 Filed 2–13–04; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Testing of Integration of the Hospital CAHPS (HCAHPS®) Instrument Prior to the National Implementation

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

ACTION: Notice of request.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is inviting hospitals, vendors, and other interested parties to voluntarily test a revised 32-item Hospital CAHPS (HCAHPS®) instrument prior to the national implementation. The purpose of this project is to provide another opportunity to the hospital industry to use the revised draft of the HCAHPS® instrument and a chance to add items to the instrument, if desired, prior to the national implementation. It should be noted that, as a result of the additional testing (*see* FR, Vol. 68, No. 147 published on July 31, 2003 which can be accessed at *http://www.access.gpo.gov/su_docs/fedreg/a030731c.html*) the HCAHPS® instrument may undergo some further refinement prior to finalization for the national implementation effort. In effect, this project provides an occasion to test items that vendors, hospitals, and others wish to add to the HCAHPS® instrument and to evaluate the impact of integrating HCAHPS into the hospital's current instrument as well as to further evaluate the methods of data collection prior to national implementation of HCAHPS®.

For the purposes of this project, up to forty (40) items may be added to the revised draft of HCAHPS® and be tested, however, please be aware that the maximum number of items that may be added to the HCAHPS® instrument for national implementation is currently thirty (30).

After permission to use the instrument is granted by AHRQ, a site or sites may field the instrument until June 2004, with subsequent submission of requested analyses to AHRQ by August 2004 or earlier, if possible.

For more information about this project or to download an application for authorization, please visit the CAHPS Survey User Network Web site at *http://www.cahps-sun.org.* The HCAHPS® pre-national implementation testing Web site will be active until April 15, 2004.

DATES: Please submit requests on or before April 19, 2004.

ADDRESSES: Applications for permission to use the revised 32-item HCAHPS® instrument, to add items, and field test the instrument may be submitted either in electronic format or via facsimile communication. Applications can be sent in letter form, preferably with an electronic file on a 3½ inch floppy disk as a standard word processing format or as an e-mail with an attachment. Responses should be submitted to:

Marybeth Farquhar, RN, MSN, Agency for Healthcare Research and Quality, Center for Quality Improvement and Patient Safety, 540 Gaither Road, Rockville, MD 20850, E-mail: *hospital-cahps@ahrq.gov.*

In order to facilitate handling of submissions, please include full information about the person requesting permission for testing: (a) Name, (b) title, (c) organization, (d) mailing address, (e) telephone and fax numbers, and (f) e-mail address.

Other requested information includes: (a) List of the hospital in which HCAHPS® will be used (including city and State); (b) sample size for each hospital; (c) intended mode of administration; (d) length of time after discharge the initial contact with the patient will be made; (e) name of vendor that will be administering the HCAHPS® survey; (f) proposed dates for fielding; (g) whether items will be added to the HCAHPS® survey and how many; and (h) a copy of the proposed questionnaire. (Again, please note: Items added to the HCAHPS® survey will be limited to forty (40) for this testing project and can only be placed near the end of the HCAHPS® items and just before the ''About You'' section of the questionnaire.) Electronic requests are encouraged. To help in the evaluation of the revised 32-item version of HCAHPS®, AHRQ and the Centers for Medicare & Medicaid Services (CMS) are asking participants to submit a brief summary of their experience with administering the HCAHPS® survey, including sampling and survey data collection procedures. An analysis of the psychometrics of the instrument should also be provided. Analytic results should include:

- Participation (response) rates to the survey;
- Item missing data rates;
- Distribution of responses to each item;
- Intercorrelations among items;
- Correlations of items with composites (corrected for overlap where appropriate);
- Internal consistency reliability (Cronbach's alpha);
- Hospital-level reliability (if the survey is fielded with multiple hospitals); and,
- Correlations of items and composites with the global rating items and whether the respondent would recommend the hospital to family and friends (question #24).

FOR FURTHER INFORMATION CONTACT: Marybeth Farquhar, Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850; Phone: (301) 427–1317; Fax: (301) 427–1341; e-mail: *mfarquha@ahrq.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Agency for Healthcare Research and Quality (AHRQ) has been a leading proponent and supporter of the development of instruments for

measuring patient experiences within the health care system of the United States. As the research partner of the Centers for Medicare & Medicaid Services (CMS), AHRQ is charged with the development of a hospital patient experience of care instrument as well as the development of reporting strategies to maximize the utility of the survey results.

The mutual goal of AHRQ and CMS is to develop a standardized instrument for use in the public reporting of patients' hospital experiences that is reliable and valid, freely accessible, and that will make comparative non-identifiable information on hospital patients' perspectives on care widely available. While there are many good survey tools available to hospitals, there is currently no nationally used or universally accepted survey instrument that allows comparisons across all hospitals. In response, and at the request of CMS, AHRQ and the CAHPS® II Grantees developed an initial instrument with input from the various stakeholders in the industry. The initial draft of the HCAHPS® instrument was tested as part of a CMS three-State pilot by hospitals in Arizona, Maryland, and New York. Based on an analysis of these data, the instrument was revised and shortened. The revised 32-item HCAHPS® instrument is currently undergoing additional testing as specified in a **Federal Register** Notice published on July 31, 2003 (FR Vol. 68, No. 147, 44951–44953) which can be accessed at *http://www.access.gpo.gov/su_docs/fedreg/a030731c.html.* Based on the results of this additional testing by selected sites and public comments on the current instrument, further revisions to the HCAHPS® instrument may be made.

Once the HCAHPS® instrument is finalized, it will be on the AHRQ and CMS websites for use by interested individuals and organizations. Plans have been made to make the HCAHPS instrument available to ''The Quality Initiative: A Public Resource on Hospital Performance,'' which is a public/private partnership that includes the major hospital associations, governments, consumer groups, measurement and accrediting bodies, and other stakeholders interested in reporting on hospital quality. In the first phase of the partnership (which has already begun), hospitals are voluntarily reporting the results of their performance on ten clinical quality measures for three medical conditions: acute myocardial infarction, heart failure, and pneumonia. HCAHPS® reporting will comprise an additional and differently focused phase of quality of care measurement. For more information or to participate in the Quality Initiative, please visit *http://www.aha.org* under ''Quality and Patient Safety, Quality Initiative,'' or at *http://www.fah.org,* under ''Issue/Advisories,'' or at *http://www.aamc.org* by going to ''Government Affairs,'' ''Teaching Hospitals'' and then ''Quality.''

Dated: February 9, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–3332 Filed 2–13–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 5, 2004, from 9 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, ext. 127, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss general issues surrounding the use of intraocular lenses for correction of presbyopia after clear lens extraction. The committee will address clinical study design elements including the risk/benefit ratio for patients with various refractive errors, study sample size, the need for control groups, inclusion/exclusion criteria, and the incidence of retinal detachment and other complications. Background information, including the attendee list, agenda, and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 24, 2004. On March 5, 2004, formal oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. Near the end of the committee discussion a second 30-minute open public session will be conducted for interested persons to comment further on the discussion topic. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 24, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at 301–594–1283, ext. 113 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 9, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–3334 Filed 2–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0016]

Medical Devices; Revised MedWatch Forms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.