

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.

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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]

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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.