present regulatory challenges similar to those posed by products using other emerging technologies and that these challenges may be magnified because nanotechnology can be used in, or used to make, any FDA-regulated product. In addition, the properties of a material with features in the nanoscale range might change, impacting the safety and effectiveness of the FDA-regulated products.

The objective of this public workshop is to obtain information on manufacturing, characterization, and evaluation of biocompatibility of medical devices containing or utilizing nanomaterials and nanostructures.

II. Public Participation

There are two types of opportunities for participation planned for the public workshop: Time limited oral presentations and round-table discussions.

If you wish to make an oral presentation during the public workshop, you must indicate this at the time of registration. The number of presentations may be limited based on the number of requests received during the public comment period. When registering, you will be required to identify the title of the topic you wish to address in your presentation and answer all the related questions on the registration form at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. FDA will do its best to accommodate requests to present and will focus discussion to the topics described in this document (see section III of this document). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for joint presentations. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin.

To close each of the two sessions, FDA will hold a round-table discussion between FDA staff and selected participants representing a range of constituencies. If you wish to be a participant in round-table discussions, you must indicate this interest at the time of registration, and also submit a brief statement that describes your experience or expertise with nanotechnology. FDA will attempt to have a range of constituencies represented in this discussion group. Others in attendance at the workshop will have an opportunity to listen during each round-table discussion and provide public comments, time permitting. FDA will determine the participants based on the requests received. The participants in each round-table discussion will remark on the presentations given during the session, engage in a dialogue with each other and FDA staff, and provide closing thoughts on the session. Round-table participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives.

III. Issues for Discussion

The workshop will focus on two topics: (1) Manufacturing and characterization of medical devices containing or utilizing nanomaterials or nanostructures; (2) biocompatibility evaluation of medical devices containing or utilizing nanomaterials or nanostructures. The discussion on manufacturing and characterization will include the evaluation of physico-chemical properties of nanomaterials or nanostructures, characterization methods required, device manufacturing processes and evaluation of the final processed device after sterilization, and stability and aging studies. The discussion on biocompatibility evaluation will include testing for potential release of nanomaterials and additional testing considerations other than standard testing methods to determine the biocompatibility and toxicity of devices containing or utilizing nanomaterials or structures. For further information, please refer to the meeting registration Web page at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*.

IV. Transcripts

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information Act request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

Dated: August 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20837 Filed 8–20–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute's Best Practices for Biospecimen Resources

AGENCY: National Institutes of Health (NIH), National Cancer Institute (NCI).

ACTION: Notice with request for comment.

SUMMARY: As part of the commitment to maintaining current and scientifically accurate best practices, the National Cancer Institute (NCI) is seeking public comment on a revised version of the *NCI Best Practices for Biospecimen Resources.* This revised version of the *NCI Best Practices* is intended to both respond to comments received from the biospecimen resource community and provide more current and detailed recommendations related to biospecimen and data quality. Major revisions include the addition of new sections on Biospecimen Resource Management and Operations and Conflict of Interest, expansion of recommendations related to Custodianship and Informed Consent based on NCI workshops, addition of current references throughout the document and harmonization with current federal guidance documents and recommendations from international biospecimen organizations.

DATES: *Effective Date:* The updated *NCI Best Practices for Biospecimen Resources* are open for public comment for a period of 30 days. Comments must be received by September 22, 2010 in order to ensure consideration. After the public comment period has closed, the comments received by NCI will be considered in a timely manner by the NCI Office of Biorepositories and Biospecimen Research. Subsequently, appropriate changes will be made on the Best Practices Web site *http://biospecimens.cancer.gov/bestpractices/.*

ADDRESSES: Comments submitted via e-mail should use *nciobbr@mail.nih.gov* and enter "NCI Best Practices" in the subject line. While NCI prefers that comments be sent by email, NCI will accept written comments. Written comments may be sent to: NCI/OBRR, NIH, 11400 Rockville Pike, Rockwall I Building, Bethesda, MD 20892, Attn: Dr. Nicole Lockhart.

FOR FURTHER INFORMATION CONTACT: Implementation assistance and inquiries should be directed to senior staff of the relevant NCI Extramural and Intramural Program offices.

SUPPLEMENTARY INFORMATION: The *NCI Best Practices for Biospecimen Research*

may be found online at *http://biospecimens.cancer.gov/bestpractices/*.

Dated: August 12, 2010.

Douglas R. Lowy,

Deputy Director, National Cancer Institute, National Institutes of Health.

[FR Doc. 2010–20872 Filed 8–20–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Request for Measures of Health Plan Efforts To Address Health Plan Members' Health Literacy Needs

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

ACTION: Notice of request for measures.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is soliciting the submission of instruments or items that measure how well health plans and health providers address health plan enrollees' health literacy needs and how well they communicate with health plan enrollees. This initiative is in response to the need identified by AHRQ to develop a new supplemental item set (the "new instrument") for addressing health literacy for the CAHPS® Health Plan Survey. The intent of the planned survey is to gain patients' perspective on how well health and health plan information is communicated to them by healthcare professionals and health plans. The results of the planned survey may become an important source of information for health plans, clinicians, group practices, and other interested parties assessing quality of health information or planning changes in how health plan information is delivered to health plan enrollees.

Based on prior work, there are several functional areas that the new instrument could address. Depending on the communication mode, the new instrument could assess, for example, clarity and simplicity of provided health information related to: (a) Preventive services (*e.g.,* risks and benefits of the service, explanation of screening results); (b) health problems/concerns (*e.g.,* information on how to stay healthy or prevent illness); (c) treatment choices, instructions, or goals (*e.g.,* pros and cons of each option); (d) medications (*e.g.,* reason for taking medications, instructions on how to take medications, possible side effects); and, (e) care management/disease management. A survey using the new instrument may also assess the quality of services supporting health information delivery such as language access (*e.g.,* availability and timeliness of customer service and interpreter services in other languages, availability of forms and patient education materials in other languages), the quality and accessibility of member services and nurse advice lines, the quality and accessibility of health plan information on coverage, benefits, and billing information (including availability in other languages), health plan system navigation and health plan environment (language access and assistance in completing medical paperwork or forms, signage).

DATES: Please submit instruments and supporting information on or before October 22, 2010. AHRQ will not respond individually to submitters, but will consider all submitted instruments and publicly report the results of the review of the submissions in aggregate.

ADDRESSES: Submissions should include a brief cover letter, a copy of the instrument or items for consideration and supporting information as specified under the Submission Criteria below. Submissions may be in the form of a letter or e-mail, preferably with an electronic file as an E-mail attachment. Responses to this request should be submitted to:

Cindy Brach, Center for Delivery, Organization, and Markets, Agency for Healthcare Research and Quality, 540 Gaither Road, Room 5129, Rockville, MD 20850, *Phone:* (301) 427–1444, *Fax:* (301) 427–1430, *E-mail: Cindy.Brach@AHRQ.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Cindy Brach, at the address above.

Submission Criteria

Instruments and items submitted should focus on patients' perspective on quality of health and health plan information provided by health plans, clinicians, and/or group practices.

Measures submitted must meet these criteria to be considered: (a) Assess patients' or their caregivers' experiences receiving health and health plan information and (b) demonstrate substantial reliability and validity. Submitters must agree to grant to the Government a nonexclusive, irrevocable, royalty-free right to use, distribute to the public, reproduce and create derivative works from the proffered instruments, items or their arrangement. AHRQ must have the right to freely use and authorize others to use the new instrument, which will be distributed under the CAHPS® trademark. The new instrument will combine the best features of all the submissions as well as any ideas that may develop from reviewing them. AHRQ, in collaboration with CAHPS grantees, will evaluate all submitted instruments or items. As they construct the CAHPS instrument, they may select one or more proffered instruments and their items either in whole or in part or modify the items prior to testing them. AHRQ will own and assume responsibility for new instrument as well as any future modifications to it. The new instrument will bear the CAHPS® trademark and it will be made freely available for use by all interested parties.

Each submission should include the following information: The name of the instrument, domains included, language(s) the instrument is available in, evidence of cultural/cross group comparability, if any, instrument reliability (internal consistency, test-retest, *etc.*), validity (content, construct, criterion-related), response rates, methods and results of cognitive interviews/testing and field-testing and description of sampling strategies (including payer type) and data collection protocols, including such elements as mode of administration, use of advance letters, timing and frequencies of contacts. In addition, a list of where the instrument has been fielded should also be included in the submission. Submission of copies of existing report formats developed to disclose findings to consumers and providers is desirable, but not required. Additionally, information about existing database(s) for the instrument(s) submitted is helpful, but not required for submission. Evidence of the criteria should be demonstrated through publication and submission of peer-reviewed journal article(s) or through the best evidence available at the time of submission. Please include citations of peer-reviewed journal articles.

To facilitate handling of submissions, please include full information about the instrument developer or contact: (a) Name; (b) title; (c) organization; (d) mailing address; (e) telephone number; (f) fax number; and (g) e-mail address.

SUPPLEMENTARY INFORMATION:

Background

The CAHPS program was initiated in 1995 to develop a survey and report on the consumers' perspective on the quality of their health plans. Since that time, the CAHPS program in partnership with CMS and others has expanded its scope and developed surveys and reports regarding individual clinicians, group practices, in-center hemodialysis services, nursing