

<http://ManagingMeds.Challenge.gov> and register (Registration is free) or log in with an existing ChallengePost account. After a Contestant signs up, a confirmation email will be sent to the email address provided. The Contestant must use the confirmation email to verify his or her email address. The registered Contestant will then be able to enter a Submission.

2. On <http://ManagingMeds.Challenge.gov>, click "Accept this challenge" to register your interest in participating. This step ensures that you will receive important challenge updates.

3. Create a video and ensure the following (please read the Official Rules on <http://ManagingMeds.Challenge.gov> for complete requirements):

- a. Your video must demonstrate how technology can be used to help you take your meds as prescribed.
- b. Your video encourages viewers to visit www.HealthIT.gov to learn more about using technology to improve your health.
- c. Your video is no longer than 2 minutes.
- 4. Confirm that you have read and agreed to the Official Rules.
 - The title of the Video;
 - A link to the Video on YouTube.com or Vimeo.com (the Video should be no longer than 2 minutes);
 - A text description of your use of health IT to improve medication management, and a transcript of the words spoken in the video;
 - A transcript of the words spoken or sung in the video;
 - Uploaded consent forms for everyone who appears in the video regardless of age.

All individuals that appear in a Video must complete and sign the Video Consent Form. If a minor appears in the Video, the minor's parent/legal guardian must also sign the Video Consent Form. A Submission will not be considered complete and eligible to win prizes without a completed Video Consent Form being uploaded from all individuals that appear in the Video. All completed Video Consent Forms must include a handwritten signature, and be scanned, combined in to a single file (ZIP, PDF, or doc), and uploaded on the submission form on BloodPressure.Challenge.gov.

AMOUNT OF THE PRIZE

Winner	Prize	Quantity
First Prize	\$3,000	1
Second Prize	2,000	1
Third Prize	1,000	1
Honorable Prize	500	2

AMOUNT OF THE PRIZE—Continued

Winner	Prize	Quantity
Popular Choice	500	1

Basis Upon Which Winner Will Be Selected

Videos will be judged based on the following criteria (to be equally weighted):

1. Quality of the Idea (Includes elements such as the relevance and originality of your use of health IT).
 2. Potential Impact on health IT adoption (Includes whether the video is compelling, instructive, and easy to follow so that others can perform similar activities using health technology).
- The five (5) Contestants whose Submissions earn the highest overall score will win, respectively, the prizes identified below in Section 8. In the event of a tie, winners will be selected based on their score on the criteria described in (3), then (2), and then (1). If there is still a tie then the winner will be selected based on a vote by the judging panel.

Dated: August 3, 2012.

Erin Poetter,
Consumer e-Health Policy Analyst, Office of Consumer e-Health, Office of the National Coordinator for Health Information Technology (ONC), Office of the Secretary (OS).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10390]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper

performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Hospice Quality Reporting Program;
Use: Section 1814(i)(5) of the Social Security Act (the Act) added by section 3004 of the Patient Protection and Affordable Care Act, Public Law 111–148, enacted on March 23, 2010 (Affordable Care Act) authorizes the Secretary to establish a quality reporting for hospices. Section 1814(i)(5)(A)(i) of the Act requires the Secretary, beginning with FY 2014, reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that fiscal year.

The Hospice Quality Data Submission Form was created for hospice providers to collect specified quality data and submit that data to CMS, for the data collection period starting October 1, 2012, through December 31, 2012, and continuing on a calendar year thereafter. Webinar training on data collection and data submission has been and will continue to be provided by CMS. Use of the Hospice Quality Data Submission Form is necessary in order for hospices to submit the quality data specified for the Hospice Quality Reporting Program. *Form Number:* CMS–10390 (OCN: 0938–1153); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 3632; *Total Annual Responses:* 7264; *Total Annual Hours:* 657,392. (For policy questions regarding this collection contact Robin Dowell at 410–786–0060. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at

the address below, no later than 5 p.m. on *September 12, 2012*.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: OIRA_submission@omb.eop.gov.

Dated: August 7, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012-19689 Filed 8-10-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meeting

AGENCY: Office of Head Start (OHS), Administration for Children and Families, HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, notice is hereby given of a one-day Tribal Consultation Session to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of this Consultation Session is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations.

DATES: October 15, 2012 and October 17, 2012.

ADDRESSES: 2012 Office of Head Start Tribal Consultation Session will be held at the following locations: Monday, October 15, 2012—Portland, Oregon—Westin Portland, 750 SW Alder Street, Portland, OR 97205; and Wednesday, October 17, 2012—Anchorage, Alaska—Hilton Anchorage Hotel, 500 West Third Avenue, Anchorage, AK 99501.

FOR FURTHER INFORMATION CONTACT: Ann Linehan, Deputy Director, Office of Head Start, email Ann.Linehan@acf.hhs.gov or phone (202) 205-8579. Additional information and online meeting registration is available at <http://www.headstartresourcecenter.org>.

SUPPLEMENTARY INFORMATION: The Department of Health and Human

Services (HHS) announces Office of Head Start (OHS) Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs in Region X and in Alaska. The Consultation Session for Region X will take place Monday, October 15, 2012, in Portland, Oregon. The Consultation Session for the State of Alaska will take place Wednesday, October 17, 2012, in Anchorage, Alaska, immediately preceding the annual Alaska Federation of Natives convention. As much as possible, OHS Tribal Consultations are scheduled in conjunction with other Tribal Leader events. This is done in an effort to minimize the financial and travel burden for participants.

The agenda for the scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of AI/AN children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2011 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for the Oklahoma City Consultation Session should contact Ann Linehan at Ann.Linehan@acf.hhs.gov. Proposals must be submitted at least three days in advance of the session and should include a brief description of the topic area, along with the name and contact information of the suggested presenter.

The Consultation Session will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives (42 U.S.C. 9835, Section 640(l)(4)(A)). Designees must have a letter from the Tribal Government authorizing them to represent the tribe. The letter should be submitted at least three days in advance of the Consultation Session to Ann Linehan at (202) 205-9721 (fax). Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Session will be prepared and made available within 90 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Ann Linehan at Ann.Linehan@acf.hhs.gov either prior to

the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for the Consultation Session has been sent to tribal leaders via email and posted on the Head Start Resource Center Web site at <http://www.headstartresourcecenter.org>.

Dated: July 23, 2012.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0523]

Draft Guidance for Industry and Food and Drug Administration Staff; Refuse To Accept Policy for 510(k)s; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Refuse to Accept Policy for 510(k)s." The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a premarket notification (510(k)) submission is administratively complete, which determines whether it should be accepted for substantive review. This guidance is applicable to 510(k)s reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 27, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Refuse to Accept Policy for 510(k)s" to the Division of Small Manufacturers, International and Consumer Assistance, Center for