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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10302, CMS-R-290 and CMS-10437]

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

AGENCY: Centers for Medicare & Medicaid Services.

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: Extension of a currently approved collection; Title of Information Collection: Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen Use: Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: 'On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying

potential conflicts of interest.’ We believe that the implementation of this statutory provision that compendia have a “publicly transparent process for evaluating therapies and for identifying potential conflicts of interests” is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. Form Number: CMS–10302 (OCN: 0938–1078); Frequency: Annually; Affected Public: Business and other for-profits and Not-for-profit institutions; Number of Respondents: 845; Total Annual Responses: 900; Total Annual Hours: 5,135. (For policy questions regarding this collection contact Brijet Coachman at 410-786-7364. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Reinstatement of a currently approved collection; Title: Medicare Program: Procedures for Making National Coverage Decisions; Use: We revised our April 27, 1999 (64 FR 22619) notice and published a new notice on September 26, 2003 (68 FR 55634) that described the process we use to make Medicare coverage decisions including decisions regarding whether new technology and services can be covered. We have made changes to our internal procedures in response to the comments we received following publication of the 1999 notice and experience under our new process. Over the past several

years, we received numerous suggestions to further revise our process to continue to make it more open, responsive, and understandable to the public. We share the goal of increasing public participation in the development of Medicare coverage issues. This will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. Form Number: CMS-R-290 (OCN: 0938-0776); Frequency: Annual; Affected Public: Private Sector: Business or other for-profits; Number of Respondents: 200; Total Annual Responses: 200; Total Annual Hours: 8,000. (For policy questions regarding this collection contact Katherine Tillman at 410-786-9252. For all other issues call 410-786-1326.)

1. Type of Information Collection Request: New collection (Request for a new control number; Title of Information Collection: Generic Social Marketing & Consumer Testing Research; Use: The purpose of this submission is to request an Information Collection Request (ICR) generic clearance for a program of consumer research aimed at a broad audience of those affected by CMS programs including Medicare, Medicaid, Children's Health Insurance Program (CHIP), and health insurance exchanges. This program extends strategic efforts to reach and tailor communications to beneficiaries, caregivers, providers, stakeholders, and any other audiences that would support the Agency in improving the functioning of the health care system, improve patient care and outcomes, and reduce costs without sacrificing quality of care. With the clearance, we will create a streamlined and proactive process for collection of data and utilizing the feedback on service delivery for continuous improvement of communication activities aimed at diverse CMS audiences.

The generic clearance will allow rapid response to inform CMS initiatives using a mixture of

qualitative and quantitative consumer research strategies (including formative research studies and methodological tests) to improve communication with key CMS audiences. As new information resources and persuasive technologies are developed, they can be tested and evaluated for beneficiary response to the materials and delivery channels. Results will inform communication development and information architecture as well as allow for continuous quality improvement. The overall goal is to maximize the extent to which consumers have access to useful sources of CMS program information in a form that can help them make the most of their benefits and options

The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic questions that can be drawn upon to allow for the rapid turn-around consumer testing required for us to communicate more effectively with our audiences. The questions in the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. A Study Initiation Request Form detailing each specific study (description, methodology, estimated burden) conducted under this clearance

will be submitted before any testing is initialed. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. Form Number: CMS-10437 (OCN: 0938-New); Frequency: Yearly; Affected Public: Individuals. Number of Respondents: 41,592. Number of Responses: 28,800. Total Annual Hours: 21,488. (For policy questions regarding this collection contact Julie Franklin at 410-786-8126. 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 E-mail 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 **[insert date 30 days after date of publication in the Federal Register.]**

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-6974

E-mail: OIRA_submission@omb.eop.gov

Dated: May 28, 2013

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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