

that can be used to create a mix of relevant questions for each proposed message testing data collection method. However, programs may request to use additional questions if needed. Message testing questions will focus on issues such as comprehension, impressions, personal relevance, content and wording, efficacy of response, channels, and spokesperson/sponsor. Such information will enable message developers to enhance the effectiveness of messages for intended audiences. Data collection methods proposed for HMTS include intercept interviews, telephone interviews, focus groups, online surveys, and cognitive interviews. In almost all instances, data will be collected by outside organizations under contract with CDC.

For many years, CDC programs have used HMTS to test and refine message concepts and test draft materials for clarity, salience, appeal, and persuasiveness to target audiences. Having this Generic Clearance available has enabled them to test their information and get critical health information out to the public quickly. Over the last three years, more than 22 messages have been tested using this clearance. CDC’s Division of Tuberculosis Elimination was approved to conduct message testing for their Latent Tuberculosis Infection (LTBI)

Awareness Campaign within target audiences—non-US-born Vietnamese and Filipino persons and the healthcare professionals (primary care physicians, nurse practitioners, and physician assistants) that serve them. Assessing the immediate effects of campaign materials provides helpful insights that can be used to inform adjustments of campaign materials for intended audiences.

CDC’s Division of Nutrition, Physical Activity, and Obesity (DNPAO) is tasked with leading our nation’s efforts to prevent chronic diseases by promoting good nutrition, regular physical activity, and a healthy weight. One of the key ways DNPAO does this is by providing State and community partners with practical tools to promote healthy lifestyles such as the SCHMC communication resources. It is imperative that this ad testing be conducted so that CDC/DNPAO can best support grantees and local partners by providing timely information about how specific ads resonate with key audiences. The insights gained from the ad testing also provided DNPAO with timely information to inform development of additional ads and communication materials that they will resonate with audiences and lead to intended actions/behavior changes related to increasing physical activity,

reducing sugary drink consumption, and improving infant and toddler nutrition.

The National Center for Injury Prevention and Control (NCIPC) collected data to assess older adults’ perceptions of products developed as part of the expansion phase of CDC’s Still Going Strong Campaign. Digital products were developed as part of this effort to expand the campaign to address social connectedness and isolation. The messages conveyed the importance of social connectedness to health to maintaining a high quality of life as we age. Participants learned about how social connectedness as well as physical and mental health are interconnected and critical to the well-being of older adults.

Over 17,307 respondents were queried and over 5,400 burden hours used during this time period. Because the availability of this data collection has been so critical to programs in disseminating their materials and information to the public in a timely manner, The Office of Communications is requesting a three-year Extension of this information collection. CDC requests OMB approval for an estimated 2,470 annual burden hours. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Public Health Professionals, Health Care Providers, State and Local Public Health Officials, Emergency Responders, General Public.	Moderator’s Guides, Eligibility Screeners, Interview Guides, Opinion Surveys, Consent Forms.	18,525	1	8/60	2,470
Total	2,470

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–142 and CMS–10379]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to

comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and

clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by August 5, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____ Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

ADDRESSES).
CMS–R–142 Examination and Treatment for Emergency Medical Conditions and Women in Labor (EMTALA)

CMS–10379 Rate Increase Disclosure and Review Requirements (45 CFR part 154)

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Examination and Treatment for Emergency Medical Conditions and Women in Labor (EMTALA); *Use:* Pursuant to section 1866(a)(1)(I) of the Act, Congress has mandated that the Secretary enforce section 1867 of the Act. Under section 1867, effective August 1, 1986, hospitals may continue to participate in the Medicare program only if they are not out of compliance with its provisions. Continued Paperwork Reduction Act (PRA) approval of the regulation sections cited below will promote uniform and thorough application of the section 1866 and 1867 requirements. They will also provide information when requested by Congress and other interested parties regarding the implementation of the statute. During 2004 through 2018, approximately 8,146 complaints were received, approximately 7,770 of those complaints were investigated, and approximately 3,567 EMTALA deficiencies were found. During Federal fiscal years 2001 through 2005 the Inspector General’s Office imposed civil monetary penalties on hospitals in 105 cases, for a total of \$2,645,750 in penalties. An audit completed by the Office of Inspector General (OIG) (entitled, Office of Inspector General: Implementation and Enforcement of the Examination and Treatment for Emergency Medical Conditions and Women in Labor by the Health Care Financing Administration, April 1995, A–06–93–00087) determined that CMS’s implementation of the Act was generally effective, but Regional Offices (RO) were not consistent with conducting timely investigations, sending acknowledgments to complaints, ensuring that investigations were thorough, or ensuring that violations were referred to the OIG in accordance with CMS policy for possible civil monetary penalty action. OIG further concluded that without proper

compliance, there is an increased risk that individuals with emergency medical conditions will not receive the treatment needed to stabilize their condition, which may place them in greater risk of death. *Form Number:* CMS–R–142 (OMB control number: 0938–0667); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 5,166; *Total Annual Responses:* 5,166; *Total Annual Hours:* 5,166. (For policy questions regarding this collection contact Renate Dombrowski at (410) 786–4645.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Rate Increase Disclosure and Review Requirements (45 CFR part 154); *Use:* 45 CFR part 154 implements the annual review of proposed increases in premiums for health insurance coverage called for by section 2794 of the Public Health Service Act (PHS Act). The regulation established a rate review program to ensure that all rate increases that meet or exceed an established threshold are reviewed by a state or the Centers for Medicare & Medicaid Services (CMS) to determine whether the proposed rate increases are unreasonable. Each state or CMS also reviews all proposed rate changes from issuers offering non-grandfathered health insurance coverage in the individual and/or small group markets for compliance with the Federal rating rules at sections 2701, 2705, 2717(c)(4), and 2753 of the PHS Act, section 1312(c) of the Affordable Care Act, and 45 CFR 147.102, 147.110, 148.180, and 156.80. Accordingly, issuers offering non-grandfathered health insurance coverage in the individual and/or small group markets are required to submit Rate Filing Justifications to CMS. 45 CFR 154.103 exempts grandfathered health plan coverage as defined in 45 CFR 147.140, excepted benefits as described in section 2791(c) of the PHS Act and student health insurance coverage, as defined in § 147.145, from Federal rate review requirements.

The Rate Filing Justification consists of three parts. All issuers must continue to submit a Uniform Rate Review Template (URRT) (Part I of the Rate Filing Justification) for all single risk pool plans. 45 CFR 154.200(a)(1) establishes a 15 percent Federal default threshold for reasonableness review. Issuers that submit a rate filing that includes a plan with a proposed rate increase that meets or exceeds the threshold must include a written description justifying the rate increase,

also known as the consumer justification narrative (Part II of the Rate Filing Justification). We note that the threshold set by CMS constitutes a minimum standard, and most states currently employ stricter rate review standards and may continue to do so. Issuers offering a QHP or any single risk pool submission containing a rate increase of any size must continue to submit an actuarial memorandum (Part III of the Rate Filing Justification). The actuarial memorandum is required whenever a state with an Effective Rate Review Program, as determined in accordance with 45 CFR 154.301, requires it to be submitted, and for all plans in states that do not have an Effective Rate Review Program. *Form Number*: CMS-10379 (OMB control number: 0938-1141); *Frequency*: Annually; *Affected Public*: Private Sector; Businesses or other for-profits, Not-for-profit institutions, State, Local, or Tribal Governments; *Number of Respondents*: 620; *Number of Responses*: 2,551; *Total Annual Hours*: 46,102. (For policy questions regarding this collection, contact Keith McNamara at 410-786-7010.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Shaker Mousa, Ph.D., M.B.A., FACC, FACB (Respondent), who was a Professor, Chairman, and Executive Vice President of the Pharmaceutical Research Institute, Albany College of Pharmacy and Health Sciences (ACPHS). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grant R21 CA135245 and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK052798. The administrative actions, including supervision for a period of four (4) years, were implemented

beginning on May 15, 2024, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Shaker Mousa, Ph.D., M.B.A., FACC, FACB, Albany College of Pharmacy and Health Sciences (ACPHS): Based on the report of an investigation conducted by ACPHS and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Shaker Mousa (Respondent), former Professor, Chairman, and Executive Vice President of the Pharmaceutical Research Institute, ACPHS, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grant R21 CA135245 and NIDDK, NIH, grant R01 DK052798. ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating chick chorioallantoic membrane (CAM) assays used to determine angiogenesis activities of small molecules in:

- Tetraiodothyroacetic acid-conjugated PLGA nanoparticles: a nanomedicine approach to treat drug-resistant breast cancer. *Nanomedicine (Lond)* 2013 Dec;8(12):1943-54. doi: 10.2217/nnm.12.200 (hereafter referred to as "*Nanomedicine (Lond)* 2013").
- The proangiogenic action of thyroid hormone analogue GC-1 is initiated at an integrin. *J. Cardiovasc. Pharmacol.* 2005 Sep;46(3):356-60. doi: 10.1097/01.fjc.0000175438.94906.a0 (hereafter referred to as "*J. Cardiovasc. Pharmacol.* 2005"). Retraction in: *J. Cardiovasc. Pharmacol.* 2023 Sep 8. doi: 10.1097/FJC.0000000000001471.

Specifically, ORI found that Respondent intentionally, knowingly, or recklessly falsified and/or fabricated:

- seven (7) micrograph panels in *Nanomedicine (Lond)* 2013 and *J. Cardiovasc. Pharmacol.* 2005 by reusing CAM images from the same source and falsely relabeling them to report pro-angiogenic factors as alternate pro-angiogenic factors, anti-angiogenic drug treatments as alternate anti-angiogenic drug treatments, and control treatments as anti-angiogenic treatments as the same treatment in:

—FGF2 images in Figure 3A of *Nanomedicine (Lond)* 2013 and in Figure 2A of *J. Cardiovasc. Pharmacol.* 2005 and GC-1 image in

Figure 4A of *J. Cardiovasc. Pharmacol.* 2005

—FGF2 + T-PLGA-NPs image in Figure 3A in *Nanomedicine (Lond)* 2013 and GC-1 + XT199 image in Figure 4A of *J. Cardiovasc. Pharmacol.* 2005

—FGF2 + tetrac in Figure 3A of *Nanomedicine (Lond)* 2013 and PBS Control image in Figure 4A of *J. Cardiovasc. Pharmacol.* 2005

Respondent entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have his research supervised for a period of four (4) years beginning on May 15, 2024 (the "Supervision Period"). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2-3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of four (4) years from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing him submits, in conjunction with each application for