

Dated: October 2, 2001.

Barbara M. Williams,

*Deputy Standard and Optional Forms
Management Officer, General Services
Administration.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Steven F. Arnold, Ph.D., Tulane University: Based on the report of an investigation conducted by Tulane University, dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Arnold, former Research Assistant Professor at the Center for Bioenvironmental Research at Tulane University Medical Center, engaged in scientific misconduct. Dr. Arnold committed scientific misconduct by intentionally falsifying the research results reported in Table 3 of a paper published in the journal *Science*¹ and by providing falsified and fabricated materials to investigating officials at Tulane University in response to a request for original data to support the research results and conclusions reported in the *Science* paper. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the *Science* paper as a whole.

Specifically, PHS finds that Dr. Arnold's research reported in the *Science* paper involved a finding that environmental chemicals, such as certain insecticides and hydroxylated polychlorinated biphenyls (PCBs), which have a weak estrogenic activity when acting alone, were up to 1000 times more potent in mimicking estrogen when tested in combination. These research results and conclusions were important to the public health

¹ Steven F. Arnold, Diane M. Klotz, Bridgette M. Collins, Peter M. Vonier, Louis J. Guillette, Jr., John A. McLachlan. "Synergistic Activation of Estrogen Receptor with Combinations of Environmental Chemicals." *Science* 272:1489-1492 (June 7, 1996) (hereafter referred to as the "*Science* paper").

because they suggested that the Environmental Protection Agency (EPA) may need to adjust its guidelines on exposure limits to such chemicals. The *Science* paper was withdrawn on July 25, 1997. See *Science* 277:462 (July 25, 1997).

This research formed the basis of National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grant application 1 R29 DK52420-01, "Two Estrogen Binding Sites on the Estrogen Receptor."

Dr. Arnold has entered into a Voluntary Exclusion Agreement (Agreement) with PHS in which he has voluntarily agreed for a period of five (5) years, beginning on September 20, 2001:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 C.F.R. Part 76 (Debarment Regulations);

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

During discussions about the proposed Agreement, Dr. Arnold was cooperative with ORI and accepted responsibility for his actions, admitted to scientific misconduct, and conceded that there were no original data or other corroborating evidence to support the conclusions reported in the *Science* paper.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443-5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-238]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and 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 and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), 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 functions; (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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Inpatient Psychiatric Services for Individuals Under Age 21 and Supporting Regulations in 42 CFR 441.152; *Form No.:* CMS—(OMB# 0938-0754); *Use:* Certification requirements in section 441.152 are modified to require that the certification of need for inpatient psychiatric services include documented clinical evidence that serves as the basis for the certification of need for inpatient psychiatric care. Section 1905(h)(1)(B) requires physicians and other personnel qualified to make determinations with respect to mental health conditions and the treatment thereof certify the need for care which they have determined to be necessary on an inpatient basis; *Affected Public:* State, local, or tribal govt, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 80,000; *Total Annual Responses:* 80,000; *Total Annual Hours:* 1.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services,

Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown CMS-R-238, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 4, 2001.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01-25683 Filed 10-11-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-50]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and 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 and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), 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 functions; (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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medical Records Review Under PPS and Supporting Regulations in 42 CFR 412.40-412.52; *Form No.:* CMS-R-0050 (OMB # 0938-0359); *Use:* Peer Review Organizations (PRO) are authorized to conduct medical review activities under the Prospective Payment System. In order to conduct the medical review activities we depend upon hospitals to make available medical records. PROs ensure that admissions are medically necessary, provided in the appropriate setting, and that they meet acceptable

standards of quality; *Frequency:* When records are reviewed; *Affected Public:* Business or other for profit; *Number of Respondents:* 7,087; *Total Annual Responses:* 899,340; *Total Annual Hours:* 26,865.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown, CMS-R-50, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 4, 2001.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-211]

Agency Information Collection Activities: Proposed Collection; 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 and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), 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 functions; (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.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Model Application Template for State Child Health Plan Under Title XXI of the Social Security Act, State Children's Health Insurance Program, and Model Application Template and Instructions; *Form No.:* CMS-(OMB# 0938-0707); *Use:* States are required to submit Title XXI plans and amendments for approval by the Secretary pursuant to section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. The model application Template is used to assist States in submitting a State Child Health Plan and amendments to that plan; *Frequency:* Once; *Affected Public:* State, local, or tribal gov't; *Number of Respondents:* 42; *Total Annual Responses:* 42; *Total Annual Hours:* 3,360.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown, CMS R 211, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 4, 2001.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

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