

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.

**1. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** The Medicare and Medicaid Programs: Programs of All-inclusive Care for the Elderly (PACE); **Form Number:** CMS-R-244 (OMB#: 0938-0790); **Use:** PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their State's nursing home eligibility standards using capitated payments from Medicare and the State. PACE programs must provide all Medicare and Medicaid covered services including hospital, nursing home, home health, and other specialized services. This collection is necessary to ensure that only appropriate organizations are selected to become PACE organizations and that CMS has the information necessary to monitor the care they provide; **Frequency:** Reporting—Once and On occasion; **Affected Public:** Not-for-profit institutions and State, Local, or Tribal Governments; **Number of Respondents:** 54; **Total Annual Responses:** 108; **Total Annual Hours:** 44131.50.

**2. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** Application for Hospital Insurance Benefits; **Form Number:** CMS-18F5 (OMB#: 0938-0251); **Use:** The CMS-18F5 form is used to establish entitlement to and enrollment in Part A of Medicare for beneficiaries who are not automatically entitled to Medicare Part A under Title XVIII of the Social Security Act and must file an application. Sections 226(a), 227 and 1818A of the Social Security Act and sections 42 CFR 406.10, 406.11 and 406.20 outline the requirements for entitlement to Medicare hospital insurance (Part A). Section 42 CFR 406.6 provides information about who needs to file an application for Part A and who does not.

Section 42 CFR 406.7 lists the CMS-18F5 form as the application to be used by individuals applying for Part A of Medicare. The CMS-18F5 form was designed to capture all the information needed to make a determination of an individual's entitlement to hospital insurance (Part A); **Frequency:** Reporting—Once; **Affected Public:** Individuals or households; **Number of Respondents:** 50,000; **Total Annual Responses:** 50,000; **Total Annual Hours:** 12,495.

**3. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** Hospice Request for Certification in the Medicare Program; **Form Number:** CMS-417 (OMB#: 0938-0313); **Use:** The Hospice Request for Certification Form is the identification and screening form used to initiate the certification process and to determine if the provider has sufficient personnel to participate in the Medicare program; **Frequency:** Reporting—Yearly; **Affected Public:** Private Sector: Business or other for-profits; **Number of Respondents:** 2,286; **Total Annual Responses:** 2,286; **Total Annual Hours:** 572.

**4. Type of Information Collection Request:** Extension of a currently approved collection; **Title of Information Collection:** Psychiatric Hospital Survey Data and Supporting Regulations at 42 CFR 482.60, 482.61, and 482.62; **Form Number:** CMS-724 (OMB#: 0938-0378); **Use:** The Medicare/Medicaid Psychiatric Hospital Survey is used to collect data that is not collected elsewhere and assists CMS in program planning and evaluation of survey needs. In addition, the survey assists CMS in maintaining an accurate data base on providers participating in the Medicare psychiatric hospital program; **Frequency:** Reporting—Yearly; **Affected Public:** Private Sector: Business or other for-profits; **Number of Respondents:** 420; **Total Annual Responses:** 200; **Total Annual Hours:** 100.

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](mailto: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 at the address below, no later than 5 p.m. on July 3, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 27, 2007.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-245]

#### 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 the currently approved collection; **Title of Information Collection:** Medicare and Medicaid Programs OASIS Collection Requirements as Part of the Conditions of Participation for Home Health Agencies and Supporting Regulations in 42 CFR 484.55, 484.205, 484.245, 484.250; **Form No.:** CMS-R-245 (OMB# 0938-0760) **Use:** The Outcome and Assessment Information Set (OASIS) is a requirement for one of the Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet in

order to participate in the Medicare program. Specifically, the CoP at § 484.55 requires that each patient receive from an HHA a patient-specific, comprehensive assessment that identifies a patient's continuing need for home care and meets the patient's medical, nursing, rehabilitative, social and discharge planning needs. In addition, the regulation requires that as part of the comprehensive assessment, HHAs use a standard core assessment data set, the OASIS, to evaluate, non-maternity patients. The data collected using OASIS is used for three main purposes: assessing and improving the quality of care provided by an HHA, submitting and paying claims for Medicare home health services, and surveying the HHAs in accordance with Section 1891 of the Social Security Act (the Act).

We have made several modifications to this information collection without increasing the burden. The modifications include but are not limited to the following items. In order for the OASIS to have the information necessary to allow the grouper to price-out the claim, we propose to make the following changes to the OASIS to capture whether an episode is an early or later episode. In addition, for the purposes of payment, we propose to make changes to the OASIS in order to enable agencies to report secondary case mix diagnosis codes. The proposed changes clarify how to appropriately fill out OASIS items M0230 and M0240, using ICD-9-CM sequencing requirements if multiple coding is indicated for any diagnosis. The proposed OASIS revisions also include incorporating previously revised instructions regarding diagnosis coding in items M0190, M0210, and M0230/M0240/M0246 (previously M0245). The burden associated with these proposed changes includes possible training of staff, the time and effort associated with downloading a new form and replacing previously pre-printed versions of the OASIS, and utilizing updated vendor software. However, CMS will be removing or modifying existing questions in the OASIS data set to accommodate the requirements referenced above. Therefore, CMS believes the burden increase associated with these changes is negated by the removal or modification of several current data items. *Frequency:* Recordkeeping and Reporting—upon patient assessment; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 8,277; *Total Annual*

*Responses:* 10,105,827; *Total Annual Hours:* 11,977,601.

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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: April 27, 2007.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; *telephone:* 301/496-7057; *fax:* 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Method for Predicting and Detecting Tumor Metastasis

*Description of Technology:* Detecting cancer prior to metastasis greatly increases the efficacy of treatment and the chances of patient survival. Although numerous biomarkers have been reported to identify aggressive tumor types and predict prognosis, each biomarker is specific for a particular type of cancer, and no universal marker that can predict metastasis in a number of cancers have been identified. In addition, due to a lack of reliability, several markers are typically required to determine the prognosis and course of therapy.

Available for licensing are carboxypeptidase E (CPE) inhibitor compositions and methods to prognose and treat cancer as well as methods to determine the stage of cancer. The inventors discovered that CPE expression levels increase according to the presence of cancer and metastasis wherein CPE is upregulated in tumors and CPE levels are further increased in metastatic cancer. This data has been demonstrated both in vitro and in vivo experiments and in liver, breast, prostate, colon, and head and neck cancers. Metastatic liver cells treated with CPE siRNA reversed the cells from being metastatic and arrested cells from further metastasis. Thus, CPE as a biomarker for predicting metastasis and its inhibitors have an enormous potential to increase patient survival.

**Applications:**

1. Method to prognose multiple types of cancer and determine likelihood of metastasis.

2. Compositions that inhibit CPE such as siRNA.

3. Method to prevent and treat cancer with CPE inhibitors.

**Market:**

1. 600,000 cancer related deaths in 2006;

2. Global cancer market is worth more than eight percent of total global pharmaceutical sales;

3. Cancer industry is predicted to expand to \$85.3 billion by 2010.

**Development Status:** The technology is currently in the pre-clinical stage of development.

**Inventors:** Y. Peng Loh (NICHD) *et al.*

**Publication:** Manuscript in preparation.

**Patent Status:**

1. U.S. Provisional Application No. 60/885,809 filed 19 Jan 2007 (HHS Reference No. E-096-2007/0-US-01)

2. U.S. Provisional Application No. 60/887,061 filed 29 Jan 2007 (HHS Reference No. E-096-2007/1-US-01)