

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10000]

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

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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 Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Consumer Assessment Survey of Health Plan Survey (CAHPS)—Fee for Service; *HCFA Form Number:* HCFA-10000 (OMB approval #: 0938-0796); *Use:* Under the Balanced Budget Act of 1997, HCFA is required to provide general and plan comparative information to beneficiaries that will help them make more informed health plan choices. A CAHPS fee for service survey is needed to provide information comparable to those data collected from the CAHPS managed care survey; *Frequency:* Annually; *Affected Public:* Individuals or households; *Number of Respondents:* 168,000; *Total Annual Responses:* 134,400; *Total Annual Burden Hours:* 44,800.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA'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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 5, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00-32334 Filed 12-19-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-10026]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits

under OMB's regulations at 5 CFR Part 1320. This is necessary to ensure that Medicare beneficiaries are able to continue to receive care in the event that their managed care provider leaves the Medicare program. We cannot reasonably comply with the normal clearance procedures because of public harm due to an unanticipated event. An unexpectedly significant number of managed care plans withdrew from Medicare or reduced their service areas at the end of 1998 and 1999 and more will withdraw at the end of 2000. We are concerned about the impact of the withdrawals on beneficiaries, particularly those living in areas with no remaining managed care options. We are also concerned about beneficiary confusion related to the withdrawals and beneficiary understanding of the options for replacing managed care coverage. As a result we need to conduct a survey that will give us the information we need to assist the beneficiaries.

HCFA is requesting OMB review and approval of this collection by January 15, 2001 with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by January 8, 2001. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval. *Type of Information Request:* New collection; *Title of Information Collection:* Survey of Beneficiaries Who Involuntarily Disenroll from Their Managed Care Plan; *HCFA Form Number:* HCFA-10026 (OMB approval #: 0938-NEW); *Use:* In December 2000, over 100 managed care plans will withdraw from Medicare or reduce their service area, affecting nearly 1,000,000 Medicare beneficiaries. HCFA wishes to survey approximately 3,400 affected beneficiaries in early 2001 to determine how they were affected by the withdrawals and whether they received sufficient information about options for replacing their managed care coverage; *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 3,385; *Total Annual Responses:* 3,385; *Total Annual Burden Hours:* 587.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA'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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements.

However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by January 8, 2001:

Health Care Financing Administration,
Office of Information Services,
Security and Standards Group,
Division of HCFA Enterprise
Standards, Room N2-14-26, 7500
Security Boulevard, Baltimore, MD
21244-1850. Fax Number: (410) 786-
0207 Attn: Julie Brown HCFA-10026
and,

Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Fax Number: (202) 395-6974
or (202) 395-5167 Attn: Wendy
Taylor HCFA Desk Officer.

Dated: December 5, 2000.

John P. Burke III,

*HCFA Reports Clearance Officer, HCFA,
Office of Information Services, Security and
Standards Group, Division of HCFA
Enterprise Standards.*

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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, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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 contacting Vasant Gandhi, J.D., Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext. 224; fax: 301/402-0220; e-mail: gandhiv@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Human Erythropoietin Receptor Transgenic Mice

Constance T. Noguchi (NIDDK)
DHHS Reference No. E-272-00/0

The inventors have developed a transgenic mouse which expresses the human erythropoietin receptor. Erythropoietin is a cytokine or hormone required for the production of red blood cells and acts by binding on early, undifferentiated blood progenitor cells to stimulate red blood cell formation. The model is particularly useful as human infectious agents or gene therapy vectors that selectively target human cells expressing the erythropoietin receptor can be studied.

Background scientific detail may be found in Liu, C., Liu, Z.Y., Shen, K. and Noguchi, C. T. (1997), "Regulated human erythropoietin receptor expression in mouse brain", *J. Biol. Chem.* 272:32395-32400.

Antitumor Immunity Elicited by Defensin-Tumor Antigen Fusions

Arya Biragyn, Larry W. Kwak (NCI)
DHHS Reference No. E-196-00/0 filed
15 Sep 2000

Tumor antigens are known to be poorly immunogenic and attempts to elicit immune responses against the epitopes of antigens specific to tumor cells have been largely unsuccessful. The inventors have developed a cancer vaccine comprising a defensin fused to a tumor antigen or viral antigen to enhance the immunogenicity of the tumor antigen or viral antigen. The inventors have demonstrated, with animal data, that chimeric proteins, comprising a defensin fused to a model tumor antigen (lymphoma-derived single-chain Fv), when administered to a subject, generate a measurable humoral and anti-tumor cellular immune response.

Methods and Compositions of Viral Chemokine-Antigen Fusion Proteins as Vaccines for Tumors and AIDS

Arya Biragyn, Larry W. Kwak (NCI)

DHHS Reference No. E-194-00/0 filed
15 Sep 2000

Tumor antigens are known to be poorly immunogenic and attempts to elicit immune responses against the epitopes of antigens specific to tumor cells have been largely unsuccessful. The inventors have developed a cancer vaccine comprising a tumor antigen fused with a human chemokine or viral antigen to enhance the immunogenicity of the tumor antigen or viral antigen. The inventors have demonstrated, with animal data, that chimeric proteins, comprising a viral chemokine fused to a model tumor antigen (lymphoma-derived single-chain Fv), when administered to a subject, generate a measurable humoral and anti-tumor cellular immune response.

HCDS1 Kinase Activates Breast Tumor Suppressor BRCA1 and Promotes DNA Damage Repair

Jay H. Chung (NHLBI)
DHHS Reference No. E-192-00/0 filed
06 Jul 2000

BRCA1 plays an important role in the cellular response to DNA damage. The technology relates to the development of BRCA1 serine 988 mutants and a method to modulate BRCA1 activity. For example, one mutant interferes with normal BRCA1 function and may thereby increase sensitivity of tumor cells to chemotherapeutic agents. Another mutant shows constitutive activity in the absence of cell cycle checkpoint enzyme hCds1 activation and may thereby increase the resistance of normal tissue to genotoxic agents such as ionizing radiation.

Specific Binding Agents for KSHV vIL- 6 that Neutralize a Biological Activity

Yoshiyasu Aoki, Giovanna Tosato (NCI)
DHHS Reference No. E-180-00/0 filed
31 Jul 2000

This invention relates to the field of herpesviruses, more specifically to human herpesvirus 8 (HHV-8), also known as Kaposi's sarcoma associated herpesvirus (KSHV), and to agents that bind the viral IL-6 encoded by this virus. KSHV encodes various proteins that have features suggesting their role in promoting cellular growth and transformation, including viral homologues of cyclin D, G-protein coupled receptor, interferon regulatory factor, macrophage inflammatory proteins and IL-6. All these viral proteins display structural similarities to their cellular counterparts. The inventors have developed a specific binding agent for KSHV interleukin-6 (vIL-6), which neutralizes vIL-6 activity.