

randomly sampled as part of the CERT process; *Frequency*: On occasion; *Affected Public*: Business or other for-profit; *Number of Respondents*: 1600; *Total Annual Responses*: 1600; *Total Annual Hours*: 454.

2. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Medicare Participating Physician or Supplier Agreement; *Form No.*: CMS-460 (OMB# 0938-0373); *Use*: Form number CMS-460 is completed by nonparticipating physicians and suppliers if they choose to participate in Medicare Part B. By signing the agreement, the physician or supplier agrees to take assignment on all Medicare claims. To take assignment means to accept the Medicare allowed amount as payment in full for the services they furnish and to charge the beneficiary no more than the deductible and coinsurance for the covered service. In exchange for signing the agreement, the physician or supplier receives a significant number of program benefits not available to nonparticipating suppliers. The information associated with this collection is needed to identify the recipients of the program benefits; *Frequency*: Other—when starting a new business; *Affected Public*: Business or other for-profit; *Number of Respondents*: 6000; *Total Annual Responses*: 6000; *Total Annual Hours*: 1500.

3. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Information Collection Requirements in Final Peer Review Organization Regulations, 42 CFR Sections 1004.40, 1004.50, 1004.60, 1004.70; *Form No.*: CMS-R-65 (OMB# 0938-0444); *Use*: This final rule updates the procedures governing the imposition and adjudication of program sanctions predicated on the recommendations of Peer Review Organizations (PROs). These changes are being made as a result of statutory revisions designed to address health care fraud and abuse issues in the OIG sanction process. The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act, creating the Utilization and Quality Control Peer Review Organization program. Section 1156 of the Social Security Act imposes obligations on health care practitioners and other persons who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. QIOs may allow

practitioners or other persons, opportunities to submit relevant information before determining that a violation has occurred. These requirements are used by the QIOs to collect the information necessary to make their determinations; *Frequency*: On occasion; *Affected Public*: Not-for-profit institutions; *Number of Respondents*: 53; *Total Annual Responses*: 1060; *Total Annual Hours*: 22,684.

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/regulations/pra/>, 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.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Reduction Act Reports Clearance Officer designated at the address below:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: William N. Parham, III, Room C5-13-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 24, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05-6533 Filed 4-1-05; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10008]

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*: Revision of a currently approved collection; *Title of Information Collection*: Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radio-pharmaceutical Agents for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS) and Supporting Regulations in 42 CFR, Section 419.43; *Use*: Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. Interested parties such as hospitals, pharmaceutical companies, and physicians can apply for transitional pass-through payment for drugs and biologicals used with services covered under the OPPS. CMS uses this information to determine if the criteria for making a transitional pass-through payment are met and if an interim HCPCS code for a new drug or biological is necessary. The revisions made to this collection include the addition of Section 303 of the MMA. This new section establishes the use of the average sales price (ASP) methodology for payment; *Form Number*: CMS-10008 (OMB# 0938-0802); *Frequency*: On occasion; *Affected Public*: Business or other for-profit and Not-for-profit institutions; *Number of Respondents*: 58; *Total Annual Responses*: 58; *Total Annual Hours*: 203.

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/regulations/pra/>, 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.

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: Christopher Martin, New
Executive Office Building, Room 10235,
Washington, DC 20503.

Dated: March 24, 2005.

John P. Burke, III,

*CMS Paperwork Reduction Act Reports
Clearance Officer, Office of Strategic
Operations and Regulatory Affairs,
Regulations Development Group.*

[FR Doc. 05-6534 Filed 4-1-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0112]

Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; Availability

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing the
availability of a draft guidance for
industry entitled "Clinical Trial
Endpoints for the Approval of Cancer
Drugs and Biologics."

This is the first of a series of
guidances that will provide
recommendations to sponsors on
endpoints for cancer clinical trials
submitted to FDA to support
effectiveness claims in new drug
applications (NDAs), biologics license
applications (BLAs), or supplemental
applications. Sponsors are encouraged
to use this draft guidance to design
cancer clinical trials and to discuss
protocols with the agency. This draft
guidance provides background
information and discusses general
regulatory principles. Each subsequent
guidance will focus on endpoints for
specific cancer types (e.g., lung cancer,
colon cancer) to support drug approval
or labeling claims. These guidances are
expected to speed the development and
improve the quality of protocols
submitted to the agency to support
anticancer effectiveness claims.

DATES: Submit written or electronic
comments on the draft guidance by June
3, 2005. General comments on agency
guidance documents are welcome at any
time.

ADDRESSES: Submit written requests for
single copies of the draft guidance to the
Division of Drug Information (HFD-
240), Center for Drug Evaluation and
Research, Food and Drug

Administration, 5600 Fishers Lane,
Rockville, MD 20857, or the Office of
Communication, Training, and
Manufacturers Assistance (HFM-40),
Center for Biologics Evaluation and
Research, Food and Drug
Administration, 1401 Rockville Pike,
Rockville, MD 20852-1448. Send one
self-addressed adhesive label to assist
that office in processing your requests.
The draft guidance may also be obtained
by mail by calling the Center for
Biologics Evaluation and Research
Voice Information System at 1-800-
835-4709 or 301-827-1800. Submit
written comments on the draft guidance
to the Division of Dockets Management
(HFA-305), Food and Drug
Administration, 5630 Fishers Lane, rm.
1061, Rockville, MD 20852. Submit
electronic comments to [http://
www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). See
the **SUPPLEMENTARY INFORMATION** section
for electronic access to the draft
guidance document.

FOR FURTHER INFORMATION CONTACT:

Grant Williams, Center for Drug
Evaluation and Research (HFD-
150), Food and Drug
Administration, 1451 Rockville
Pike, Rockville, MD 20852, 301-
594-5758;

Patricia Keegan, Center for Drug
Evaluation and Research (HFD-
107), Food and Drug
Administration, 1451 Rockville
Pike, Rockville, MD 20852, 301-
827-5097; or

Steven Hirschfeld, Center for
Biologics Evaluation and Research
(HFM-755), Food and Drug
Administration, 1401 Rockville
Pike, Rockville, MD 20852, 301-
827-6536.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of
a draft guidance for industry entitled
"Clinical Trial Endpoints for the
Approval of Cancer Drugs and
Biologics." FDA is developing guidance
on oncology endpoints through a
process that includes public workshops
of oncology experts and discussions
before FDA's Oncologic Drugs Advisory
Committee. This draft guidance is the
first in a planned series of cancer
endpoint guidances. It provides
background information and general
principles. The endpoints discussed in
this draft guidance are for drugs to treat
patients with an existing cancer. This
draft guidance does not address
endpoints for drugs to prevent or
decrease the incidence of cancer.

This draft guidance is being issued
consistent with FDA's good guidance

practices regulation (21 CFR 10.115).
The draft guidance, when finalized, will
represent the agency's current thinking
on clinical trial endpoints for the
approval of cancer drugs and biologics.
It does not create or confer any rights for
or on any person and does not operate
to bind FDA or the public. An
alternative approach may be used if
such approach satisfies the
requirements of the applicable statutes
and regulations.

II. Comments

Interested persons may submit to the
Division of Dockets Management (see
ADDRESSES) written or electronic
comments on the draft guidance. Submit
one copy of electronic comments or two
paper copies of any mailed comments,
except that individuals may submit one
paper copy. Comments are to be
identified with the docket number
found in brackets in the heading of this
document. The draft guidance and
received comments are available for
public examination in the Division of
Dockets Management between 9 a.m.
and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet
may obtain the document at [http://
www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm),
[http://www.fda.gov/cber/
guidelines.htm](http://www.fda.gov/cber/guidelines.htm), or [http://www.fda.gov/
ohrms/dockets/default.htm](http://www.fda.gov/ohrms/dockets/default.htm).

Dated: March 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-6647 Filed 4-1-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans

SUMMARY: In compliance with the
provisions of section 3507(1)(D) of the
Paperwork Reduction Act of 1995, for
opportunity for public comments on
proposed data collection projects, the
National Institutes of Health (NIH),
National Cancer Institute (NCI) has
submitted to the Office of Management
and Budget (OMB) a request to review
and approve the information collection
listed below. This proposed information
collection was previously published in
the **Federal Register** on October 29,
2004 (Volume 69, No. 209, pages 63159-
63160) and allowed 60 days for public