proposed collection(s) summarized in this notice, you may make your request using one of following:


2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

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).

CMS–1045 Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5

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: Extension without change of a currently approved collection; Title of Information Collection: Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; Use: Section 42 CFR 424.5(a)(5) requires providers of services to submit a claim for payment prior to any Medicare reimbursement. Charges billed are coded by revenue codes. The bill specifies diagnoses according to the International Classification of Diseases, Tenth Edition (ICD–10) code. Inpatient procedures are identified by ICD–10 codes, and outpatient procedures are described using the CMS Common Procedure Coding System (HCPCS).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tropical Disease Priority Review Vouchers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 16, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0822. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tropical Disease Priority Review Vouchers

OMB Control Number 0910–0822—Revision

Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360n) is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. By enacting section
524 of the FD&C Act. Congress intended to
stimulate new drug development for
to treat certain tropical diseases for
which there are no or few available
treatments by offering additional
incentives for obtaining FDA approval
for pharmaceutical treatments for these
diseases. Under section 524 of the FD&C
Act, a sponsor of a human drug
application for a qualified tropical
disease may be eligible for a voucher
that can be used to obtain a priority
review for any application submitted
under section 505(b)(1) of the FD&C Act
(21 U.S.C. 355(b)(1)) or section 351 of
the Public Health Service Act (the PHS
Act).
Accordingly, we have developed the
guidance document entitled, “Guidance
for Industry (GFI): Tropical Disease
Priority Review Vouchers.” The
guidance explains how FDA will
implement the provisions of section 524
of the FD&C Act, how sponsors may use
priority review vouchers, and how
priority review vouchers may be
transferred to other sponsors. The
guidance also explains eligibility
criteria for tropical disease drug product
applications submitted under section
505(b)(1) of the FD&C Act and section
351 of the PHS Act, and provides
instructions to sponsors on how they may:
• Request a priority review voucher;
and
• Notify FDA of their intent to use a
priority review voucher, including
the date on which the sponsor intends
to submit the application.
The guidance also explains that
transfer of a priority review voucher
from one sponsor to another is
permitted and that each transfer should
document with a letter of transfer.
Finally, the guidance will be revised to
include new information collection
established by section 611 of the FDA
Reauthorization Act of 2017 (FDARA).
As amended, section 524 of the FD&C
Act requires the sponsor of a tropical
disease product application to include
an attestation regarding its eligibility for
a priority review voucher. The guidance
is available at https://www.fda.gov/
downloads/Drugs/Guidances/
UCM080599.pdf.
Description of Respondents: Sponsors
submitting applications under section
505(b)(1) of the FD&C Act or section 351
of the PHS Act.
In the Federal Register of November
7, 2018 (83 FR 55720), we published a
60-day notice requesting public
comment on the proposed collection of
information. No comments were
received.
We estimate the burden of the
information collection as follows:

<table>
<thead>
<tr>
<th>Information collection activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
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</thead>
<tbody>
<tr>
<td>Priority Review Voucher Request</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>8</td>
<td>40</td>
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<tr>
<td>Notifications of Intent to Use a Voucher</td>
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<td>1</td>
<td>2</td>
<td>8</td>
<td>16</td>
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<tr>
<td>Letters Indicating the Transfer of a Voucher Letter</td>
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<td>1</td>
<td>2</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Acknowledging the Receipt of a Transferred Voucher</td>
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<td>1</td>
<td>2</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Attestation of Eligibility</td>
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<td>1</td>
<td>5</td>
<td>2</td>
<td>10</td>
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<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>122</td>
</tr>
</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.

We have increased our burden
estimate since last approval to account
for attestations added by FDARA; however, all other information
collection elements remain unchanged.

Lowell J. Schiller,
Acting Associate Commissioner for Policy.

[FR Doc. 2019–07464 Filed 4–15–19; 8:45 am]

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0597]

Agency Information Collection
Activities; Submission for Office of
Management and Budget Review;
Comment Request; Oversight of
Clinical Investigations: A Risk-Based
Approach to Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA, Agency, or we) is
announcing that a proposed collection
of information has been submitted to the
Office of Management and Budget
(OMB) for review and clearance under

DATES: Fax written comments on the
collection of information by May 16,
2019.

ADDRESSES: To ensure that comments on
the information collection are received,
OMB recommends that written
comments be faxed to the Office of
Information and Regulatory Affairs,
OMB, Attn: FDA Desk Officer, Fax: 202–
395–7285, or emailed to
oirareview@omb.eop.gov. All
comments should be identified with the
OMB control number 0910–0733. Also
include the FDA docket number found in
brackets in the heading of this
document.

FOR FURTHER INFORMATION CONTACT:
Jonna Lynn Capezzuto, Office of
Operations, Food and Drug
Administration, Three White Flint
North, 10A–12M, 11601 Landsdown St.,
North Bethesda, MD 20852, 301–796–
3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In
compliance with 44 U.S.C. 3507, FDA
has submitted the following proposed
collection of information to OMB for
review and clearance.

Oversight of Clinical Investigations: A
Risk-Based Approach to Monitoring—
21 CFR Parts 312 and 812

OMB Control Number 0910–0733—
Extension

This information collection supports
reporting and recordkeeping found in
Agency guidance. Under parts 312 and
812 (21 CFR parts 312 and 812),
sponsors are required to provide
appropriate oversight of their clinical
investigations to ensure adequate
protection of the rights, welfare, and
safety of human subjects and to ensure
the quality and integrity of the resulting
data submitted to FDA. As part of this
oversight, sponsors of clinical
investigations are required to monitor
the conduct and progress of their
clinical investigations. The regulations
do not specify how sponsors are to