1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* For-Profit PACE Study; *Use:* The Program of All Inclusive Care of the Elderly (PACE) aims to provide integrated care and services to the frail elderly at risk of institutionalization to enable them to remain in the community. Under the Balanced Budget Act of 1997 (BBA), the not-for-profit PACE plans were established as permanent providers under the Medicare and Medicaid programs. The BBA also mandated a demonstration of for-profit PACE plans. This study will estimate the differences in quality and access to care between the for-profit and not-for-profit PACE plans. The data collected in the survey will be used to measure the outcomes of interest-differences in access to and quality of care delivered to PACE enrollees. To measure these key outcomes, the survey will collect data on access to and satisfaction with healthcare, personal care, and transportation assistance provided by the plans. *Form Number:* CMS–10427 (OCN: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals. *Number of Respondents:* 813. *Number of Responses:* 813. *Total Annual Hours:* 447. (For policy questions regarding this collection contact Julia Zucco at 410–786–6670. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Generic Social Marketing & Consumer Testing Research; *Use:* The purpose of this submission is to request an Information Collection Request (ICR) generic clearance for a program of consumer research aimed at a broad audience of those affected by CMS programs including Medicare, Medicaid, Children's Health Insurance Program (CHIP), and health insurance exchanges. This program extends strategic efforts to reach and tailor communications to beneficiaries, caregivers, providers, stakeholders, and any other audiences that would support the Agency in improving the functioning of the health care system, improve patient care and outcomes, and reduce costs without sacrificing quality of care. With the clearance, CMS will create a fast track, streamlined, proactive process for collection of data and utilizing the feedback on service delivery for continuous improvement of communication activities aimed at diverse CMS audiences.

The generic clearance will allow rapid response to inform CMS initiatives using a mixture of qualitative and quantitative consumer research strategies (including formative research studies and methodological tests) to improve communication with key CMS audiences. As new information resources and persuasive technologies are developed, they can be tested and evaluated for beneficiary response to the materials and delivery channels. Results will inform communication development and information architecture as well as allow for continuous quality improvement. The overall goal is to maximize the extent to which consumers have access to useful sources of CMS program information in a form that can help them make the most of their benefits and options.

The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic question that can be drawn upon to allow for the rapid turn-around consumer testing required for CMS to communicate more effectively with its audiences. The questions in the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. A Study Initiation Request Form detailing each specific study (description, methodology, estimated burden) conducted under this clearance will be submitted before any testing is initialed. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. *Form Number:* CMS–10427 (OCN: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals. *Number of Respondents:* 41,592. *Number of Responses:* 28,800. *Total Annual Hours:* 21,488. (For policy questions regarding this collection contact Neal Hickson at 410–786–6737. For all other issues call 410–786–1326.)

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 Email 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.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *August 6, 2012.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: June 29, 2012.

Martique Jones,

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

[FR Doc. 2012–16526 Filed 7–5–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–R–218, CMS–10428, CMS–10441, CMS–10261, CMS–10338, CMS–10137, CMS–10237 and CMS–10003]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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) 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.

1. Type of Information Collection Request: Extension without change of a currently approved collection. *Title of Information Collection:* HIPAA Standards for Electronic Transactions and Supporting Regulations in 45 CFR Part 162. *Use:* This information collection request has no substantive changes since the last OMB approval. The adopted transaction standards currently in use for electronic transactions (Version 4010/4010a) are compatible with the ICD–9–CM adopted code set that is used to report diagnoses and hospital inpatient services. However, the ICD–10 codes cannot be used with Version 4010/4010a, because this version does not have a specific qualifier or indicator for reporting ICD–10 codes.

Version 5010 supports the use of the ICD–10 code set by making available a qualifier to indicate that an ICD–10 code is being reported. Like ICD–9, ICD–10 codes are reported in claim and payment transactions, as well as eligibility inquiries and responses and requests for referrals and authorizations. In Version 5010, the number of codes required in any given transaction does not change. It is possible that a fewer number of codes in a given transaction may be necessary to report the same information reported with ICD–9 codes because ICD–10 codes are more specific. *Form Number:* CMS–R–218 (OCN: 0938–0866). *Frequency:* Occasionally. *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions). *Number of Respondents:* 696,026. *Total Annual Responses:* 696,026. *Total Annual Hours:* 6,960,260. (For policy questions regarding this collection contact Gladys Wheeler at 410–786–0273. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title:* PCIP Authorization to Share Personal Health Information; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148. Section 1101 of the law establishes a ''temporary high risk health insurance pool program'' (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with states or private, non-profit entities.

Reapproval of this package is being requested as a result of CMS, in its administration of the PCIP program, serving as a covered entity under the Health Insurance Portability and Accountability Act (HIPAA). Without a valid authorization, the PCIP program is unable to disclose information, with respect to an applicant or enrollee, about the status of an application, enrollment, premium billing or claim, to individuals of the applicant's or enrollee's choosing. The HIPAA Authorization Form has been modeled after CMS' Medicare HIPAA Authorization Form (OMB control number 0938–0930) and is used by applicants or enrollees to designate someone else to communicate with PCIP about their protected health information (PHI).

Unless permitted or required by law, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits CMS' PCIP program (a HIPAA covered entity) from disclosing an individual's protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements.

CMS will make available to PCIP applicants and enrollees a standard, valid authorization to enable beneficiaries to communicate with PCIP about their personal health information. This is a critical tool because the population the PCIP program serves is comprised of individuals with pre-existing conditions who may be incapacitated and need an advocate to help them apply for or receive benefits from the program. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for the PCIP program.

Each individual will be asked to complete the form which will include providing the individual's name, PCIP account number (if known), date of birth, what personal health information they agree to share, the length of time the individual agrees their personal health information can be shared, the names and addresses of the third party the individual wants PCIP to share their personal health information with, and an attestation that the individual is giving PCIP permission to share their personal health information with the third party listed in the form. This completed form will be submitted to the PCIP benefits administrator, GEHA, which contracts with CMS.

We estimate that it will take approximately 15 minutes per applicant to complete and submit a HIPAA Authorization Form to the PCIP program.

The federally-run PCIP program operates in 23 states plus the District of Columbia and receives an average of 35,000 enrollment applications per year. To estimate the number of PCIP applicants and enrollees who may complete an authorization, we looked at the percentage of individuals who request an authorization in Medicare as a baseline. Medicare estimates 3% of its population will submit an authorization per year. However, since the PCIP program caters to an exclusive population comprised of individuals who have one or more pre-existing conditions, we believe it is likely we could receive double the percentage estimated by Medicare. Accordingly, PCIP estimates 6% (or 2,100) of its applicants and enrollees may submit an authorization per year.

Based on the above, it is estimated that up to 2,100 applicants and enrollees may submit an authorization annually. There is no cost to PCIP beneficiaries to request, complete, submit, or have the authorization form processed by PCIP. It should take approximately 15 minutes for a beneficiary to complete the authorization form. 15 minutes multiplied by 2,100 beneficiaries equals 525 hours. *Form Number:* CMS–10428 (OCN#: 0938–1161); *Frequency:* Reporting—Once; *Affected Public:* Individuals or households; *Number of Respondents:* 2,100; *Total Annual Responses:* 2,100; *Total Annual Hours:* 525. (For policy questions regarding this collection contact Geoffrey Cabin at 410–786–1744. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* New collection; *Title:* Medicare Plan Finder Experiment; *Use:* The mission of the Centers for Medicare & Medicaid Services (CMS) is to ensure the provision of health care to its beneficiaries. Recent legislative mandates, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, require CMS to provide information to beneficiaries about the quality of the Medicare health and prescription drug plans. To provide that information, all Medicare health and prescription drug plans with an enrollment of 600 or more are required to collect and report data following protocols that CMS has established. CMS has also contracted with various organizations to develop valid and reliable quality measures and to consider how best to report those measures to beneficiaries.

A primary vehicle for reporting quality information to beneficiaries is the Medicare Plan Finder, a section of the Medicare Web site that is intended to help beneficiaries make informed choices among health and prescription drug plans. The Medicare Plan Finder

tool contains a great deal of potentially useful information, including extensive data on the fixed and variable costs associated with being enrolled in plans, the benefits and coverage that plans offer, and the quality of service that plans provide, as revealed by member experience data, disenrollment statistics, and a variety of measures of clinical processes and outcomes.

One of the key challenges that CMS has faced is how to engage beneficiaries with the quality information provided in the Medicare Plan Finder. Among the possible reasons that beneficiaries may fail to engage with this information are first, that several steps are required for a user of the Medicare Plan Finder to gain access to comparative plan information, and second that once the user does reach a data display, the amount of information presented is voluminous, and can seem overwhelming.

This study will use an experimental design to assess the effectiveness of two potential enhancements to the Medicare Plan Finder tool that may help address these barriers to engagement and use of quality information. The purpose of this experiment is to test the effects of two prospective enhancements to the Medicare Plan Finder (MPF) Web site. We refer to these prospective enhancements as the ''Quick Links'' home page and the ''enhanced data display.'' *Form Number:* CMS–10441 (OCN#: 0938–New); *Frequency:* Reporting—Once; *Affected Public:* Individuals or Households; *Number of Respondents:* 600; *Total Annual Responses:* 600; *Total Annual Hours:* 252. (For policy questions regarding this collection contact David Miranda at 410–786–7819. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR § 422.516(a); *Use:* The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Advantage Organizations (MAOs) under the authority described in 42 CFR § 422.516(a). It is noted that each MAO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the cost of its operations, patterns of service utilization, availability, accessibility, and acceptability of its services, developments in the health status of its enrollees, and other matters that CMS may require.

CMS also has oversight authority over cost plans which includes establishment of reporting requirements. The data requirements in this supporting statement are specifically relevant to the cost plan requirements in section 1876(c)(1)(C) of the Social Security Act which establishes beneficiary enrollment and appeal rights.

CMS initiated new Part C reporting requirements with the Office of Management and Budget (OMB) approval of the ''Information Collection Request'' (ICR) under the Paperwork Reduction Act of 1995 (PRA) in December, 2008 (OMB# 0938–New; CMS–10261). National PACE plans and 1833 cost plans are excluded from reporting all the new Part C Reporting Requirements measures. The initial ICR involved thirteen measures. Two of these thirteen measures have been suspended from reporting because the information is available elsewhere: Measurement #10 Agent Compensation Structure and; Measurement #11 Agent Training and Testing. One new measure was added beginning 2012: Enrollment and Disenrollment. The ICR Reference number is 201105–0938–008. The OMB control number is 0938–1054.

CMS suspended the ''Benefit Utilization'' measure in late 2011. Thus, calendar year 2011 benefit utilization data were not reported. This suspension remains in effect and will lead to a reduction in burden. CMS is requesting the suspension of two additional measures: ''Procedure Frequency'' and Provider Network Adequacy.'' The suspensions are all due to the fact that equivalent data are already being collected or are available through other sources in CMS. These suspensions will lead to a decrease in burden. CMS is adding one additional data element to its ''grievances'' measure. The grievance measure currently has 10 reporting categories. The additional category will be ''CMS Issues.'' This will add a slight increase to burden for this measure only. Overall, the approval of this ICR will lead to an estimated burden reduction of 88,730 hours and $5,420,095 in costs on an annual basis. *Form Number:* CMS–10261 (OCN#: 0938–1054); *Frequency:* Yearly, Quarterly; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 1,375; *Total Annual Responses:* 6,715; *Total Annual Hours:* 120,190. (For policy questions regarding this collection contact Terry Lied at 410–786–8973. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use:* The Patient Protection and Affordable Care Act, Public Law 111–148, (the Affordable Care Act) was enacted by President Obama on March 23, 2010. As part of the Act, Congress added PHS Act section 2719, which provides rules relating to internal claims and appeals and external review processes. On July 23, 2010, interim final regulations (IFR) set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations. The DOL claims procedure regulation requires an employee benefit plan to provide third-party notices and disclosures to participants and beneficiaries of the plan. In addition, paragraphs (b)(3)(ii)(C) and (b)(2)(ii)(C) of the IFR add an additional requirement that non-grandfathered group health plans and issuers of non-grandfathered health policies provide to the claimant, free of charge, any new or additional evidence considered, or generated by the plan or issuer in connection with the claim. Paragraph (b)(3)(i) of the IFR requires issuers offering coverage in the individual health insurance market to also generally comply with the DOL claims procedure regulation as updated by the Secretary of HHS in paragraph (b)(3)(ii) of the IFR for their internal claims and appeals processes.

Furthermore, PHS Act section 2719 and the IFR provide that non-grandfathered group health plans, issuers offering group health insurance coverage, and self-insured non-federal governmental plans (through the IFR amendment dated June 24, 2011) must comply either with a State external review process or a Federal external review process. The IFR provides a basis for determining when such plans and issuers must comply with an applicable

State external review process and when they must comply with the Federal external review process. Plans and issuers that are required to participate in the Federal external review process must have electronically elected either the HHS-administered process or the private accredited IRO process as of January 1, 2012, or, in the future, at such time as the plans and issuers use the Federal external review process. Plans and issuers must notify HHS as soon as possible if any of the above information changes at any time after it is first submitted. The election requirements associated with this ICR are articulated through guidance published June 22, 2011 at *http://cciio.cms.gov/resources/files/hhs_srg_elections_06222011.pdf.* The election requirements are necessary for the Federal external review process to provide an independent external review as requested by claimants. Form Number: CMS–10338 (OCN: 0938–1099); Frequency: Occasionally; Affected Public: State, Local, Tribal Governments; Business or other for-profit; Not-for-profit institutions; Number of Respondents: 46,773; Number of Responses: 218,657,161; Total Annual Hours: 930,267. For policy questions regarding this collection, contact Colin McVeigh at (301) 492–4263. For all other issues call (410) 786–1326.

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Application for New and Expanding Medicare Prescription Drug Plans and Medicare Advantage Prescription Drug (MA–PD), including Cost Plans and Employer Group Waiver Plans; *Use:* The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the voluntary Prescription Drug Benefit Program (''Part D''). The MMA was amended on July 15, 2008 by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), on March 23, 2010 by the enactment of the Patient Protection and Affordable Care Act and on March 30, 2010 by the enactment the Health Care and Education Reconciliation Act of 2010 (collectively the Affordable Care Act).

Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled ''*Application Procedures and Contracts with PDP Sponsors.*''

Effective January 1, 2006, the Part D program established an optional prescription drug benefit for individuals who are entitled to Medicare Part A or enrolled in Part B. In general, coverage for the prescription drug benefit is provided through PDPs that offer drug-only coverage, or through MA organizations that offer integrated prescription drug and health care coverage (MA–PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA–CCPs) must offer either a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA–PFFS) may choose to offer a Part D benefit. Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Plans may also provide a Part D benefit. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Applicants may offer either a PDP or MA–PD plan with a service area covering the Nation (i.e., offering a plan in every region) or covering a limited number of regions. MA–PD and Cost Plan applicants may offer local plans.

There are 34 PDP regions and 26 MA regions in which PDPs or regional MA–PDs may be offered respectively. The MMA requires that each region have at least two Medicare prescription drug plans from which to choose, and at least one of those must be a PDP. Requirements for contracting with Part D Sponsors are defined in Part 423 of 42 CFR.

This clearance request is for the information collected to ensure applicant compliance with CMS requirements and to gather data used to support determination of contract awards. *Form Number:* CMS–10137 (OCN: 0938–0936); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 241; *Total Annual Responses:* 241; *Total Annual Hours:* 2,132. (For policy questions regarding this collection contact Linda Anders at 410–786–0459. For all other issues call 410–786–1326.)

7. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Part C Medicare Advantage and 1876 Cost Plan Expansion Application; *Use:* Collection of this information is mandated in Part C of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) in Subpart K of 42 CFR 422 entitled ''*Contracts with Medicare Advantage Organizations.*'' In addition, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended titles XVII and XIX of the Social Security Act to improve the Medicare program.

In general, coverage for the prescription drug benefit is provided through prescription drug plans (PDPs) that offer drug-only coverage or through Medicare Advantage (MA) organizations that offer integrated prescription drug and health care products (MA–PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA–CCPs) either must offer a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA–PFFS) may choose to offer enrollees a Part D benefit. Employer Group Plans may also provide Part D benefits. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Organizations wishing to provide healthcare services under MA and/or MA–PD plans must complete an application, file a bid, and receive final approval from CMS. Existing MA plans may request to expand their contracted service area by completing the Service Area Expansion (SAE) application. Applicants may offer a local MA plan in a county, a portion of a county (i.e., a partial county) or multiple counties. Applicants may offer a MA regional plan in one or more of the 26 MA regions.

This clearance request is for the information collected to ensure

applicant compliance with CMS requirements and to gather data used to support determination of contract awards. *Form Number:* CMS–10237 (OCN 0938–0935). *Frequency:* Yearly. *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions). *Number of Respondents:* 566. *Total Annual Responses:* 566. *Total Annual Hours:* 22,955. (For policy questions regarding this collection contact Barbara Gullick at 410–786–0563. For all other issues call 410–786–1326.)

8. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Notice of Denial of Medical Coverage (or Payment); *Use:* Section 1852(g)(1)(B) of the Social Security Act (SSA) requires Medicare health plans to provide enrollees with a written notice in understandable language that explains the plan's reasons for denying a request for a service or payment for a service the enrollee has already received. The written notice must also include a description of the applicable appeals processes. Regulatory authority for this notice is set forth in Subpart M of Part 422 at 42 CFR 422.568, 422.572, 417.600(b), and 417.840.

Section 1932 of the Social Security Act (SSA) sets forth requirements for Medicaid managed care plans, including beneficiary protections related to appealing a denial of coverage or payment. The Medicaid managed care appeals regulations are set forth in Subpart F of Part 438 of Title 42 of the CFR. Rules on the content of the written denial notice can be found at 42 CFR § 438.404.

This notice combines the existing Notice of Denial of Medicare Coverage with the Notice of Denial of Payment and includes *optional* language to be used in cases where a Medicare health plan enrollee also receives full Medicaid benefits that are being managed by the Medicare health plan. *Form Number:* CMS–10003 (OCN: 0938–0829). *Frequency:* Occasionally. *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions). *Number of Respondents:* 665. *Total Annual Responses:* 6,960,410. *Total Annual Hours:* 1,159,604. (For policy questions regarding this collection contact Gladys Wheeler at 410–786–0273. For all other issues call 410–786–1326.)

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 Email 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by September 4, 2012:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 29, 2012.

Martique Jones,

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

[FR Doc. 2012–16514 Filed 7–5–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0187 Formerly Docket No. 2000D–1267]

Draft Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry, and Product Management To Reduce the Risk of Transfusion-Transmitted Malaria; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria'' dated June 2012. The draft guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, allowing their reentry, and product management to reduce the risk of transfusion-transmitted malaria. This guidance replaces the draft guidance entitled ''Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria'' dated June 2000. The draft guidance, when finalized, will supersede the FDA memorandum to all registered blood establishments entitled ''Recommendations for Deferral of Donors for Malaria Risk'' dated July 26, 1994. The recommendations contained in the draft guidance are not applicable to donors of Source Plasma.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 4, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria'' dated June 2012. The draft guidance document provides blood establishments that collect blood and