

resistance. This worrisome trend prompted CDC to again update treatment recommendations and no longer recommend the use of cefixime as first-line treatment for gonococcal infections.

Under the GISP protocol, each of the 30 clinics submit an average of 20 isolates per clinic per month (i.e., 240 times per year) recorded on Form 1: Demographic/Clinical Data. The estimated time for clinical personnel to abstract data for Form 1: Demographic/Clinical Data is 11 minutes per response.

Each of the five Regional laboratories receives and processes approximately

20 isolates from each referring clinic per month (i.e., 121 isolates per regional laboratory per month [based on 2011 specimen volume]) using Form 2: Antimicrobial Susceptibility Testing. For Form 2: Antimicrobial Susceptibility Testing, the annual frequency of responses per respondent is 1,452 (121 isolates \times 12 months). Based on previous laboratory experience, the estimated burden of completing Form 2 for each participating laboratory is 1 hour per response, which includes the time required for laboratory processing of the patient's isolate, gathering and

maintaining the data needed, and completing and reviewing the collection of information. For Form 3: Control Strain Susceptibility Testing, a "response" is defined as the processing and recording of Regional laboratory data for a set of seven control strains. It takes approximately 12 minutes to process and record the Regional laboratory data on Form 3 for one set of seven control strains, of which there are 4 sets. The number of responses per respondent is 48 (4 sets \times 12 months). There are no additional costs to respondents. The total estimated annual burden hours are 8,628.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Clinic	Demographic Clinical Data Form 1	30	240	11/60
Laboratory	Antimicrobial Susceptibility Testing Form 2	5	1,452	1
	Control Strain Susceptibility Testing Form 3	5	48	12/60

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Office of Scientific Integrity, Office of the
Associate Director for Science, Office of the
Director, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10062, CMS-10146, CMS-10191, CMS-10308, CMS-R-43 and CMS-10453]

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 19, 2013:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, or Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
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: Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk

Adjusted Payments; *Use:* In the Balanced Budget Act of 1997 (BBA), Congress created the Medicare+Choice (M+C or Part C) program in order to expand the types of private entities eligible to contract with Medicare and to address some perceived flaws in the risk-contracting program. Congress subsequently refined the M+C program through the Balanced Budget Refinement Act of 1999 (BBRA) and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Most recently, under the Medicare Prescription Drug Benefit, Improvement and Modernization Act of 2003 (MMA), Congress restructured the M+C program into the Medicare Advantage (MA) program and added an outpatient prescription drug benefit, Part D.

The BBA of 1997 and later legislation required CMS to adjust per-beneficiary capitation payments with a risk adjustment methodology using diagnoses to measure relative risk due to health status instead of just demographic characteristics such as age, sex, and Medicaid eligibility. Risk adjustment using diagnoses provides more accurate payments for MA organizations, with higher payments for enrollees at risk for being sicker, and lower payments for enrollees predicted to be healthier.

The MMA also instituted a bidding system in Parts C and D with a significant role for risk adjustment. Thus, independent of enrollment and payment, risk adjustment now plays a significant role simply because it is central to the bidding process. Under the MMA, risk adjustment is used to standardize bids. Plans bid on the average beneficiary, referred to as a "standardized" bid for a beneficiary with a 1.0 risk score. This enables comparison of Part C and D bids against a baseline (average) standard, even though every plan will have different enrollee characteristics and benefit packages and will therefore have different costs.

Previously, we received PRA clearance to collect inpatient and outpatient data for Part C using the CMS-HCC model. Currently, we are seeking to renew that OMB approval and also clearance for changes in data collection in order to fulfill new mandates under the MMA. *Form Number:* CMS-10062 (OCN: 0938-0838); *Frequency:* Quarterly; *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions); *Number of Respondents:* 766; *Total Annual Responses:* 830,000; *Total Annual Hours:* 40,650; (For policy questions regarding this collection

contact Michael Massimini at 410-786-1566.)

2. Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Notice of Denial of Medicare Prescription Drug Coverage; *Use:* Section 1860D-4(g)(1) of the Social Security Act, requires that Part D plan sponsors who deny prescription drug coverage must provide a written notice of the denial to the enrollee. The written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process. The Part D denial notice has been revised for clarity and includes new optional language for Part D plan sponsors to use when explaining their denial rationale. Specifically, we added optional language in the denial rationale section of the notice to allow plans to populate text explaining that a drug denied under Part D may be (or is) covered under a different benefit, such as Part B. The instructions have also been changed to guide plans on when to use this optional text. We solicit feedback on this new addition as well as other situations where another benefit may cover a drug (i.e. employer group benefits) and what changes to the denial notice may be helpful in addressing those situations. We also seek comment regarding the potential viability and usefulness of developing a combined notice for Part C and Part D, which would allow MA-PD plans that deny a drug under Part D to simultaneously issue an approval letter under Part B. *Form Number:* CMS-10146 (OCN: 0938-0976); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 596; *Total Annual Responses:* 1,497,929; *Total Annual Hours:* 374,482; (For policy questions regarding this collection contact Caroline Baker at 410-786-0116.)

3. Type of Information Collection Request: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Parts C and D Universal Audit Guide; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations under 42 CFR parts 422 and 423, Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. In 2010 the explosive growth of these sponsoring organizations forced us to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, our audit strategy

reflected a move to a more targeted, data-driven and risk-based audit approach that focused on high-risk areas having the greatest potential for beneficiary harm.

To accomplish this we have combined all Part C and Part D audit elements into one universal guide which will also promote consistency, effectiveness and reduce financial and time burdens for both CMS and Medicare-contracting entities. The combined Medicare Part C & D Universal Audit Guide received OMB approval in 2010. The Health Plan Management System (HPMS) is the current conduit by which organizations submit many sources of audit materials such as bids and other ongoing updates to us. Please note the guide is very comprehensive in that it describes all areas that could be audited. Due to limited resources, we are unable to audit all areas for any particular sponsor. Some areas could be monitored by the account manager, etc. Other areas could be the audited in the program audits.

To maximize resources, we will focus on assisting the industry to improve their operations to ensure beneficiaries receive access to care. We will accomplish this by developing an annual audit strategy which describes how sponsors will be selected for audit and the areas that will be audited. The audit strategy will be shared with the industry via the CMS Web site, HPMS memo, the Part C & D user call, and other conferences. Once the audit areas are defined, we will design audit protocols describing in detail the focus of the audit, the data required for the audit, etc. The Engagement Letter and Protocols will be sent to all sponsors selected for audit 4 weeks prior to starting the audit. In addition, the protocols will be released to the industry at the beginning of each calendar year via the same manner as the audit strategy. To assist in improving the audit process, we send the plan sponsors a survey at the end of each audit to complete in order to obtain the sponsors feedback. The sponsor is not required to complete the survey. The supporting materials for this information collection request have been revised since the 60-day **Federal Register** notice published on February 28, 2013 (78 FR 4412). *Form Number:* CMS-10191 (OCN: 0938-1000); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions); *Number of Respondents:* 195; *Total Annual Responses:* 195; *Total Annual Hours:* 24,180. (For policy questions regarding this collection contact Tracey Roberts at 410-786-8643.)

4. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Parts C and D Complaints Resolution Performance Measures. *Use:* We seek to conduct a survey as part of the Part C and D Complaints Resolution Performance Measure project. The purpose of the project is to develop and support implementation of internal monitoring tools for the Medicare Advantage (Part C) and Prescription Drug (Part D) program that represents, from the beneficiary's perspective, the way in which plans handle complaints. The data collection is necessary because a survey is the only way to collect information about the resolution process from the beneficiary's perspective. Currently, there is no other data source that collects such information for Part C and Part D Medicare plans. *Form Number:* CMS-10308 (OCN: 0938-1107); *Frequency:* Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 18,210; *Total Annual Responses:* 18,210; *Total Annual Hours:* 3,035. (For policy questions regarding this collection contact Carolyn Scott at 410-786-1190.)

5. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. These conditions are based on a provision specified in law relating to diagnostic X-ray tests "furnished in a place of residence used as the patient's home," and are designed to ensure that each supplier has a properly trained staff to provide the appropriate type and level of care, as well as, a safe physical environment for patients. We use these conditions to certify suppliers of portable X-ray services wishing to participate in the Medicare program. This is standard medical practice and is necessary in order to help to ensure the well-being, safety and quality professional medical treatment accountability for each patient. *Form Number:* CMS-R-43 (OCN: 0938-0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 578; *Total Annual Responses:* 578; *Total Annual Hours:* 948. (For policy questions regarding this collection contact Alesia Hovatter at 410-786-6861.)

6. *Type of Information Collection Request:* New collection (Request for a

new OMB control number); *Title of Information Collection:* The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits CFR 422.111(b)(12); *Use:* We are requesting OMB approval for the information collection requirements referenced in the April 15, 2011 final rule revising the Medicare Advantage (MA) and Part D programs for calendar year 2012 (77 FR 21432-21577). The rule revised the MA disclosure requirements in 42 CFR 422.111(b) by adding the authority for CMS to require MA organizations to furnish a written explanation of benefits directly to enrollees, in a manner we specify and in a form easily understandable to enrollees, when benefits are provided under Part 422. The collection instrument that requires OMB approval concerns the disclosure requirements in paragraph 42 CFR 422.111(b)(12).

In order to provide all Medicare Advantage enrollees with consistent, clear, useful information about their medical claims, we established a requirement, in the April 2011 final rule, that MA organizations furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under Part 422. We finalized this policy based on the public comments and input we have received from beneficiaries, advocacy organizations, health plans and industry organizations. This EOB will help ensure that people in the Medicare Advantage program receive clear, timely information, as do people receiving the Medicare MSN and the Part D EOB, so that they may make confident, informed decisions about their healthcare options.

We stated that we would develop a model EOB for Part C benefits modeled after the EOB currently required for Part D enrollees at § 423.128(e). After publication of the final rule in April 2011, we engaged MA organizations, industry and advocacy groups and beneficiaries in listening sessions to gather ideas and feedback. We developed models based on that input, as well as the newly redesigned and consumer tested Medicare Summary Notice and the Part D EOB. We have tested models through a small pilot program with a volunteer MA organization in CY 2012. In designing our model EOB, we considered language and design from Medicare MSN, integration of Part C and Part D EOBs, level of detail, and frequency of EOB dissemination as part of this process.

We sought additional public comments on the model EOBs that we developed through a Health Plan

Management System (HPMS) memo release with a 30 day comment period. Our goal was to implement a model Part C EOB document in mid-year 2013 based on this process, and to require all MA organizations to periodically send an EOB to enrollees for Part C benefits in future years. This customized information would supplement general plan information in the annual notice of change (ANOC) and evidence of coverage (EOC) documents as well as enhance the currently available information through tools such as Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF), which provide general information about plan costs. Based on public comments we received on the HPMS memo and November 26, 2012 **Federal Register** notice (77 FR 70445) and the revisions we made to the initial templates and guidance, we are extending the timeline for implementation to April, 2014. We intend for the Part C EOB to provide personal information to beneficiaries that would help them understand their current utilization, keep track of their out-of-pocket expenses, and to consider using other tools and resources, including MOC and MPDPF, to determine whether to select a new plan.

As a result of comments received during the 60-day comment period associated with the November 26, 2012, **Federal Register** notice (77 FR 70445), we revised the collection request. Specifically, we shortened the templates by removing two sections. One section was deemed to include information that was not needed and information from the second section was incorporated into other sections. We clarified and streamlined the presentation of the information and modified some of the language to be more beneficiary-friendly. *Form Number:* CMS-10453 (OCN: 0938-New); *Frequency:* On occasion; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 564; *Number of Responses:* 2,256; *Total Annual Hours:* 101,520. (For policy questions regarding this collection contact Chris McClintick at 410-786-4682.)

Dated: July 15, 2013.

Martique Jones,

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

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