Background and Brief Description

Each year in the United States, more than 30,000 children are born with congenital CMV infection. Approximately 80% develop normally, while the remaining 20% are born with or subsequently develop disabilities such as hearing loss or mental retardation. A similar number of children are affected by serious CMV-related disabilities than by several better-known childhood conditions, including Down Syndrome and Spina Bifida.

The birth prevalence of congenital CMV infection is several times higher than the combined birth prevalence of all metabolic or endocrine disorders in the core U.S. newborn screening panel. Because newborn CMV screening is rarely performed, and because a definitive diagnosis of congenital CMV requires access to urine, saliva, or blood collected soon after birth, most infected children are never diagnosed. Newborn CMV screening offers some clear potential benefits, but few studies have assessed the potential for harm (e.g., increased parental anxiety, ''fragile child syndrome'').

CDC is requesting OMB approval for one year to collect information about newborn CMV screening. The purpose of this information collection is to understand the psychosocial impact of newborn screening on parents whose infants underwent CMV screening as part of a routine infant CMV screening program in Houston, Texas. The potential study population includes approximately 70 CMV-infected children who were symptomatic at birth, 100 CMV-infected children who were asymptomatic at birth (20 of whom developed sequelae), and 50 controls that were CMV-uninfected. The goals of this information collection are to: (1) Document the positive and negative psychosocial impacts of newborn CMV screening on parents and their children; (2) identify modifiable factors that might increase positive psychosocial impacts and decrease negative psychosocial impacts of newborn CMV screening; (3) use what is learned about psychosocial impacts to identify key messages that parents need relative to newborn CMV screening and follow-up; and (4) to learn what challenges are associated with obtaining a congenital CMV diagnosis in the absence of CMV newborn screening.

Much of the potential study population is unique in that their children experienced newborn CMV screening as part of a previous research study. Universal CMV screening has not been recommended by medical associations or state or federal governments and as a result newborn CMV screening is not typically performed. The parents' experience with CMV screening and follow-up will help inform decisions about whether newborn CMV screening would be good public health policy. This study represents the first assessment of the experiences of parents whose children were screened for CMV at birth.

Respondents fall into four categories depending on the past experiences of their child who was screened for CMV:

- Parent Group 1 (PG1)—Child screened positive for congenital CMV at birth, asymptomatic at birth, but *did not* develop sequelae
- Parent Group 2 (PG2)—Child screened positive for congenital CMV at birth, asymptomatic at birth, but *did* subsequently develop sequelae (e.g., hearing loss)
- Parent Group 3 (PG3)—Child was diagnosed with congenital CMV and had symptoms at birth
- Parent Group 4 (PG4)—Child screened negative for congenital CMV at birth

Information will be collected from PG1 via focus groups, from PG2 and PG3 via interviews, and from all four parent groups via a mail survey. The focus group, interview and survey respondents will be asked to participate only once. It is estimated that 71 parents will participate in either individual interviews or focus groups and that 230 will participate in the mail survey. The interviews are planned to take 60 minutes while the focus groups will be held for 90 minutes. The survey is estimated to take 10 minutes per respondent to complete and mail based on previous administrations reported in the literature. Reading and responding to the focus group and interview recruitment letters is estimated to take 5 minutes each. There is no cost to respondents other than their time. The annualized estimated burden hours are 135.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Responses per respondent	Average burden per response (in hours)
Parent Group 1	Focus Group Guide	36	1	1.5
	Focus group recruitment letter	50	1	5/60
Parent Groups 2 and 3	Interviewer guide	35	1	1
	Interview recruitment letter	50	1	5/60
Parent Groups 1,2,3, and 4	Survey	230	1	10/60

Dated: January 14, 2013.

Ron A. Otten,

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

[FR Doc. 2013–01163 Filed 1–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10191]

Agency Information Collection Activities: Proposed Collection; 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) 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:* Revision of a currently 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 CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' 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 CMS. Please note the guide is very comprehensive in that it describes all areas that could be audited. Due to limited resources, CMS is unable to audit all areas for any particular sponsor. Some areas could be monitored by the account manager, etc. Other areas could be audited in the program audits.

To maximize resources, CMS will focus on assisting the industry to improve their operations to ensure beneficiaries receive access to care. One way to accomplish this is CMS will develop 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, CMS 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, CMS sends the plan sponsors a survey at the end of each audit to complete in order to obtain the sponsor's feedback. The sponsor is not required to complete the survey.

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. 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 March 25, 2013:

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: January 16, 2013.

Martique Jones,

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

[FR Doc. 2013–01167 Filed 1–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10453]

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB); Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Agency information collection activities: Proposed collection; comment request; extension of comment period.

SUMMARY: This notice extends the comment period for a 60-day notice request for proposed information collection request associated with the notice [Document Identifier: CMS–10453] entitled ''The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits CFR 422.111(b)(12)'' that was published in the November 26, 2012 (77 FR 70445) **Federal Register**. The comment period for the information collection request, which would have ended on January 25, 2013, is extended to February 1, 2013.

DATES: The comment period for the information collection request published in the January 25, 2013, **Federal Register** (77 FR 70445) is extended to February 1, 2013.

FOR FURTHER INFORMATION CONTACT: William Parham, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the FR Doc. 2012–28570 of November 26, 2012 (77 FR 70445), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the document entitled ''The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits CFR 422.111(b)(12).''

There were technical delays with making the information collection request publicly available; therefore, in this notice we are extending the comment period from the date originally listed in the November 26, 2012, notice.

II. Extension of Comment Period

We are extending the comment period for the notice [Document Identifier: CMS–10453] in FR Doc. 2012–28570 published on November 26, 2012 (77 FR 70445).

The date listed on page 70445, third column, second full paragraph, on the fifth line in the paragraph beginning with ''To be assured consideration,