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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10302, CMS-R-297/CMS-L564, CMS-4040, CMS-379 and CMS-10316]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and 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 [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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:

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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 Web Site address at

<https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

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:* Extension of a currently approved collection; *Title of Information Collection:* Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen; *Use:* Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: ‘On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.’ We believe that the implementation of this statutory provision that compendia have a “publicly transparent process for evaluating therapies

and for identifying potential conflicts of interests” is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB control number: 0938-1078); *Frequency:* Annually; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

2. *Type of Information Collection Request:* Reinstatement without change of a currently approved collection; *Title of Information Collection:* Request for Employment Information; *Use:* The form CMS-L564, also referred to as CMS-R-297, is used, in conjunction with form CMS-40-B, Application for Supplementary Medical Insurance, during an individual’s special enrollment period (SEP). Completed by an employer, the CMS-L564 provides proof of an applicant’s employer group health coverage. The Social Security Administration (SSA) uses it to obtain information from employers regarding whether a Medicare beneficiary’s coverage under a group health plan is based on current employment status. This form is available in both English and Spanish.

Section 1837(i) of the Social Security Act (the Act) provides a SEP for individuals who delay enrolling in Medicare Part B because they are covered by a group health plan based on their own or a spouse's current employment status. Disabled individuals with Medicare may also delay enrollment because they have large group health plan coverage based on their own or a family member's current employment status. When these individuals apply for Medicare Part B, they must provide proof that the group health plan coverage is (or was) based on current employment status. Form CMS L564 provides this proof so that SSA can determine eligibility for the SEP. Individuals eligible for the SEP can enroll in Part B without incurring a late enrollment penalty. Individuals may also use this form to prove that their group health plan coverage is based on current employment status and to have the assessed Medicare late enrollment penalty reduced. The form is available online via Medicare.gov and CMS.gov for individuals who are requesting the SEP to obtain and submit to their employer for completion. The employer must complete and sign the form, and submit it to the individual to accompany their enrollment or late enrollment penalty reduction request. The information on the completed form is reviewed manually by SSA. Thus, the collection of this information does not involve the use of information technology. *Form Number:* CMS-R-297/CMS-L564 (OMB control number: 0938-0787); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 15,000; *Total Annual Responses:* 15,000; *Total Annual Hours:* 1,250. (For policy questions regarding this collection contact Carla D. Patterson, at 410-786-1000.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Enrollment in Supplementary

Medical Insurance (SMI) and Supporting Regulations in 42 CFR 407.10, 407.11 and 408.40(a)(2); *Use:* Section 1836 of the Social Security Act, and CMS regulations at 42 CFR 407.10, provide the eligibility requirements for enrollment in Part B for individuals age 65 and older who are not entitled to premium-free Part A. The individual must be a resident of the United States, and either a U.S. Citizen or an alien lawfully admitted for permanent residence that has lived in the US continually for 5 years. CMS regulations 42 CFR 407.11 lists the CMS-4040 as the application to be used by individuals who are not eligible for monthly Social Security/Railroad Retirement Board benefits or free Part A.

The CMS-4040 solicits the information that is used to determine entitlement for individuals who meet the requirements in section 1836 as well as the entitlement of the applicant or their spouses to an annuity paid by OPM for premium deduction purposes. The application follows the application questions and requirements used by SSA. This is done not only for consistency purposes but to comply with other Title II and Title XVIII requirements because eligibility to Title II benefits and free Part A under Title XVIII must be ruled out in order to qualify for enrollment in Part B only. *Form Number:* CMS- 4040 (OMB control number: 0938-0245); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 29,663; *Total Annual Responses:* 29,663; *Total Annual Hours:* 7,416 hours. (For policy questions regarding this collection contact Carla D. Patterson, at 410-786-1000.)

4. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Financial Statement of Debtor *Use:* When a Medicare Administrative Contractor (MAC) overpays a physician or supplier, the overpayment

is associated with a single claim, and the amount of the overpayment is moderate. In these cases, the physician/supplier usually refunds the overpaid amount in a lump sum. Alternatively, the MAC may recoup the overpaid amount against future payments. A recoupment is the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. The recoupment can be made only if the physician/supplier accepts assignment since the MAC makes payment to the physician/supplier only on assigned claims.

The physician/supplier may be unable to refund a large overpaid amount in a single payment. The MAC cannot recover the overpayment by recoupment if the physician/supplier does not accept assignment of future claims, or is not expected to file future claims because of going out of business, illness or death. In these unusual circumstances, the MAC has authority to approve or deny extended repayment schedules up to 12 months, or may recommend to the Centers for Medicare and Medicaid Services (CMS) to approve up to 60 months. Before the MAC takes these actions, the MAC will require full documentation of the physician's/supplier's financial situation. Thus, the physician/supplier must complete the CMS-379, Financial Statement of Debtor.

Section 1893(f)(1)) of the Social Security Act and 42 CFR 401.607 provides the authority for collection of this information. Section 42 CFR 405.607 requires that, CMS recover amounts of claims due from debtors including interest where appropriate by direct collections in lump sums or in installments. *Form Number:* CMS- 379 (OMB control number: 0938-0270); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500;

Total Annual Responses: 500; *Total Annual Hours:* 1,000 hours. (For policy questions regarding this collection contact Anita Crosier, at 410-786-0217.)

5. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan (PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides a requirement to collect and report performance data for Part D prescription drug plans. Specifically, the MMA under Sec. 1860D-4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding the PDP and MA contracts pursuant to section 1860D-4(d).

The Centers for Medicare & Medicaid Services (CMS) developed the Disenrollment Survey to capture the reasons for disenrollment at a time that is as close as possible to the actual date of disenrollment. Through this survey, CMS seeks to: (1) obtain information about beneficiaries' expectations relative to provided benefits and services (for both MA and PDPs) and (2) determine the reasons that prompt beneficiaries to voluntarily disenroll. It is important to include such information from disenrollees as CMS assesses plan performance, because plan disenrollment can be a broad indicator of beneficiary dissatisfaction with some aspect of plan services, such as access to care, customer service, cost, benefits provided, or quality of care. Information obtained from the Disenrollment Survey also supports the quality improvement efforts of individual plans and provides data to assist consumer choice through use of the Medicare Plan Finder website.

The survey results are an important plan monitoring tool for CMS to ensure that Medicare beneficiaries are receiving high quality services from contracted providers. CMS uses information from the survey to track changes in the reasons Medicare beneficiaries cite for disenrolling to monitor improvements/declines over time nationally and at the plan level. CMS also uses the disenrollment survey results to support the quality improvement efforts of individual plans, by providing plans with a detailed, annual report showing the reasons disenrollees cited for voluntarily leaving the plan and comparing the plan's scores to regional and national benchmarks. Additionally, CMS uses the plan-specific results of the survey to provide Medicare beneficiaries with information (i.e., reasons cited for disenrolling from a plan and the frequency with which disenrollees cite each of the reasons) to assist beneficiaries with their annual consumer choice of plans. *Form Number:* CMS-10316 (OMB control number: 0938-1113); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 43,872; *Total Annual Responses:* 43,872; *Total Annual Hours:* 9,354. (For policy questions regarding this collection contact Beth Simon at 415-744-3780.)

Dated: March 18, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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