DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-359/CMS-360, CMS-10706, CMS-10725 and CMS 10728]

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

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: 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
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 information collection; *Title of Information Collection:* Comprehensive Outpatient Rehabilitation Facility (CORF) Certification and Survey Forms; *Use:* The form CMS-359 is an application for

health care providers that seek to participate in the Medicare program as a Comprehensive Outpatient Rehabilitation Facility (CORF). The form initiates the process for facilities to become certified as a CORF and it provides the CMS Location and State Survey Agency (SA) staff identifying information regarding the applicant that is stored in the Automated Survey Processing Environment (ASPEN) system.

The form CMS-360 is a survey tool used by the SAs to record information in order to determine a provider's compliance with the CORF Conditions of Participation (COPs) and to report this information to the Federal government. The form includes basic information on the COP requirements, check boxes to indicate the level of compliance, and a section for recording notes. CMS has the responsibility and authority for certification decisions which are based on provider compliance with the COPs and this form supports this process. *Form Number:* CMS-359/360 (OMB control number: 0938-0267); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 49 *Number of Responses:* 8; *Total Annual Hours*: 74. (For questions regarding this collection contact Caroline Gallaher (410)786-8705.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Generic Clearance for the Center for Clinical Standards and Quality IT Product and Support Teams; Use: The Health Information Technology for Economic and Clinical Health (HITECH) Act is part of the American Reinvestment and Recovery Act (ARRA) of 2009. As noted in the HITECH Act, CMS is responsible for defining "meaningful use" of certified electronic health record (EHR) technology and developing incentive payment programs for Medicare and Medicaid providers. CMS is continually implementing and updating information systems as legislation and requirements

change. To support this initiative, CCSQ IT Product and Support Teams (CIPST) must have the capacity for engagement with users in an ongoing variety of research, discovery, and validation activities to create and refine systems that do not place an undue burden on users and instead are efficient, usable, and desirable.

The Center for Clinical Standards and Quality (CCSQ) is responsible for administering appropriate information systems so that the public can submit healthcare-related information. While beneficiaries ultimately benefit, the primary users of (CIPST) are healthcare facility employees and contractors. They are responsible for the collection and submission of appropriate beneficiary data to CMS to receive merit-based compensation.

The generic clearance will allow a 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 information systems that serve CMS audiences. CMS implements human-centered methods and activities for the improvement of policies, services, and products. As information systems and technologies are developed or improved upon, they can be tested and evaluated for end-user feedback regarding utility, usability, and desirability. The overall goal is to apply a human-centered engagement model to maximize the extent to which CMS CIPST product teams can gather ongoing feedback from consumers. Feedback helps engineers and designers arrive at better solutions, therefore minimizing the burden on consumers and meeting their needs and goals.

The activities under this clearance involve voluntary engagement with target CIPST users to receive design and research feedback. Voluntary end-users from samples of self-selected customers, as well as convenience 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 is for use in both quantitative and qualitative groups collecting data related to human-computer interactions with information system development. We will use the findings to create the highest possible public benefit. *Form Number:* CMS–10706 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 11,476; *Total Annual Responses:* 11,476; *Total Annual Hours:* 4,957. (For policy questions regarding this collection contact Stephanie Ray at 410-786-0971)

3. *Type of Information Collection Request*: New information collection; *Title of Information Collection*: Pharmacy Benefit Manager Transparency; *Use*: The Patient Protection and Affordable Care Act (P.L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (P.L.111-152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs) — private health and dental insurance plans that are certified as meeting certain standards. The PPACA added section 1150A of the Social Security Act, which requires pharmacy benefit managers (PBMs) to report prescription benefit information to the Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. The Centers for Medicare and Medicaid Services (CMS) files this information collection request (ICR) in connection with the prescription benefit information that PBMs must provide to HHS under section 1150A. The burden estimate for this ICR reflects the time and effort for PBMs to submit the information

regarding PBMs and prescription drugs. *Form Number*: CMS-10725 (OMB control number: 0938-NEW); *Frequency*: Annually; *Affected Public*: Private Sector (business or other for-profits), *Number of Respondents:* 40; *Number of Responses*: 275. *Total Annual Hours*: 1,400. For questions regarding this collection contact Ken Buerger at 410-786-1190.

4. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Value in Opioid Use Disorder Treatment Demonstration; *Use:* Value in Opioid Use Disorder Treatment (Value in Treatment) is a 4-year demonstration program authorized under section 1866F of the Social Security Act (Act), which was added by section 6042 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The purpose of Value in Treatment, as stated in the statute, is to "increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce Medicare program expenditures." As required by statute, Value in Treatment will be implemented no later than January 1, 2021.

Section 1866F(c)(1)(A)(ii) specifies that individuals and entities must apply for and be selected to participate in the Value in Treatment demonstration pursuant to an application and selection process established by the Secretary. Section 1866F(c)(2)(B)(iii) specifies that in order to receive CMF and performance-based incentive payments under the Value in Treatment program, each participant shall report data necessary to: monitor and evaluate the Value in Treatment program; determine if criteria are met; and determine the performance-based incentive payment. *Form Number*: CMS-10728 (OMB control number: 0938-New); *Frequency*: Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 12,096; *Total Annual Responses:* 12,096; *Total Annual Hours:* 1,285. (For policy questions regarding this collection

contact Rebecca VanAmburg at 410-786-0524.)

Dated: September 8, 2020. _____

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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