DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0085, Docket Number NIOSH–319]

Partnership Opportunity To Identify Products for Fentanyl Exposure in Personal Protective Equipment Information Database; Reopening of the Comment Period

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and reopening of comment period.

SUMMARY: On October 18, 2018 the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), published a notice in the **Federal Register** [83 FR 52834] announcing the availability of a *Partnership Opportunity to Identify Products for Fentanyl Exposure in Personal Protective Equipment Information Database.* Written comments were to be received by November 19, 2018. In response to requests from interested parties, NIOSH is announcing the reopening of the comment period.

DATES: Electronic or written comments must be received by April 1, 2019.

FOR FURTHER INFORMATION CONTACT: *ppeconcerns@cdc.gov,* NIOSH, National Personal Protective Technology Laboratory, Office of the Director, 626 Cochrans Mill Road, Pittsburgh PA 15236, 1–888–654–2294 (a toll free number).

ADDRESSES: You may submit comments, identified by CDC–2018–0085 and Docket Number NIOSH–319, by either of the following two methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Dated: January 23, 2019.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10330, CMS–10673, CMS–906, CMS–10433, CMS–276 and CMS–10694 and CMS–P–0015A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by April 1, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send 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) that are 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.

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' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10330 Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection under the Affordable Care Act

CMS–10379 Rate Increase Disclosure and Review Requirements (45 CFR part 154)

CMS–10673 Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

CMS–906 The Fiscal Soundness Reporting Requirements

CMS–276 Prepaid Health Plan Cost Report

CMS–10694 Testing of Web Survey Design and Administration for CMS Experience of Care Surveys

CMS–P–0015A Medicare Current Beneficiary Survey

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Extension; *Title of Information Collection:* Enrollment Opportunity Notice Relating to Lifetime Limits; Required Notice of Rescission of Coverage; and Disclosure Requirements for Patient Protection under the Affordable Care Act; *Use:* Sections 2712 and 2719A of the Public Health Service Act, as added by the Affordable Care Act, and the interim final regulations titled ''Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections'' (75 FR 37188, June 28, 2010) contain rescission notice, and patient protection disclosure requirements that are subject to the Paperwork Reduction Act of 1995. The rescission notice will be used by health plans to provide advance notice to certain individuals that their coverage may be rescinded as a result of fraud or intentional misrepresentation of material fact. The patient protection notification will be used by health plans to inform certain individuals of their right to choose a primary care provider or pediatrician and to use obstetrical/gynecological services without prior authorization.

The related provisions are finalized in the final regulations titled ''Final Rules under the Affordable Care Act for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections''. The final regulations also require that, if State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, a plan or issuer must provide a participant, beneficiary or enrollee adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by the individual. *Form Number:* CMS–10330 (OMB control number: 0938–1094); *Frequency:* Occasionally; *Affected Public:* Private Sector, State, Local, or Tribal Governments; *Number of Respondents:* 920; *Total Annual Responses:* 71,268; *Total Annual Hours:* 524. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration; *Use:* The Centers for Medicare & Medicaid Services (CMS) is testing a demonstration, under Section 402 of the Social Security Amendments of 1967 (as amended), entitled the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration (''the Demonstration''). The MAQI demonstration tests whether providing exclusions from the Merit-based Incentive Payment System (MIPS) reporting requirements, payment adjustments, and performance feedback (collectively, the ''MIPS exclusions'') for eligible clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) (combined with participation, if any, in Advanced Alternative Payment Models (APMs) with Medicare Fee-for-Service (FFS)) will increase or maintain participation in payment arrangements with MAOs similar to Advanced APMs and change the manner in which clinicians deliver care.

Clinicians may currently participate in one of two paths of the Quality Payment Program (QPP): (1) MIPS, which adjusts Medicare payments based on combined performance on measures of quality, cost, improvement activities, and advancing care information, or (2) Advanced Alternative Payment Models with Medicare (Advanced APMs), under which eligible clinicians may earn an incentive payment for sufficient participation in certain payment arrangements with Medicare fee-for-service (FFS) and other payers, and starting in the 2019 performance period, with other payers such as Medicare Advantage, commercial payers, and Medicaid managed care. To participate in the Advanced APM path of QPP for a given year and earn an incentive payment, eligible clinicians must meet the criteria of Qualifying APM Participants (QPs); in addition to earning an APM incentive payment, QPs are excluded from the MIPS reporting requirements and payment adjustment.

An eligible clinician that does not meet the criteria to be a QP for a given year will be subject to MIPS for that year unless the clinician meets certain other MIPS exclusion criteria, such as being newly enrolled in Medicare or meeting the low volume threshold for Medicare FFS patients, payments and services. The MAQI Demonstration allows participating eligible clinicians to have the opportunity to receive the MIPS exclusions for a given year if they participate to a sufficient degree in certain Qualifying Payment Arrangements with MAOs (and Advanced APMs with Medicare FFS) during the performance period for that year, without requiring them to be QPs or otherwise meet the MIPS exclusion criteria of QPP. Under this Demonstration, clinicians are not required to have a minimum amount of participation in an Advanced APM with Medicare FFS in order to receive the MIPS exclusions for a year, but if they did have participation in Advanced APMs with Medicare FFS, that participation will also be counted towards the thresholds that trigger the provision of MIPS exclusions under the demonstration.

The first performance period for the Demonstration was 2018 and the Demonstration will last up to five years. Clinicians who meet the definition of an eligible clinician under QPP, as defined under 42 CFR 414.1305, are eligible to participate in the MAQI Demonstration. Participation will last the duration of the Demonstration, unless participation is voluntarily or involuntarily terminated under the terms and conditions of the Demonstration. Demonstration participants will have the opportunity to submit the required documentation and be evaluated for the MIPS exclusions each year. If Demonstration participants submit information, but do not meet the conditions of the Demonstration, their participation in the Demonstration will not be terminated, but they will not receive the MIPS exclusions. Therefore, unless they become QPs or are excluded from MIPS for other reasons, the participating clinicians will be subject to MIPS and will face the MIPS payment adjustments for the applicable year.

In order to conduct an evaluation and effectively implement the MAQI Demonstration, CMS must collect information from Demonstration participants on (a) payment arrangements with MAOs and (b) Medicare Advantage (MA) payments and patient counts. CMS requires a new collection of this information as this information is not already available through other sources. The information collected in these forms will allow CMS to evaluate whether the payment arrangement(s) that clinicians have with MAOs meet the Qualifying Payment Arrangement criteria, and determine whether a clinician's MAO and FFS APM patient population or payments meet demonstration thresholds. Both of these areas are also requirements for review and data collection under QPP (*i.e.* the Eligible Clinician-Initiated Other Payer Advanced APM Determination form and All-Payer QP

Submission form), and therefore similar forms have been prepared and reviewed under the QPP.

Given these similarities in forms, burden estimates for the MAQI Demonstration PRA package were derived from burden analyses and formulation done in conjunction with the QPP forms; more specifically the estimated burden associated with the submission of payment arrangement information for Other Payer Advanced APM Determinations. CMS estimates the total hour burden per respondent for the MAQI demonstration to be 15 hours or less, to match the hours listed in the equivalent QPP forms. Full detail of how these estimates were derived can be found in the published (83 FR 59452).

Based on public comments, we have revised the collection instruments to include modifications to allow Taxpayer Identification Numbers (TIN) level participation and greater functionality for organization/authorized representatives to submit on behalf of their clinicians. *Form Number:* CMS–10673 (OMB control number: 0938–1354; *Frequency:* Annually; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses*: 100,000; *Total Annual Hours:* 1,500,000. (For policy questions regarding this collection contact John Amoh at *john.amoh@cms.hhs.gov*.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The Fiscal Soundness Reporting Requirements; *Use:* All contracting organizations must submit audited annual financial statements one time per year. In addition, to the audited annual submission, Health Plans with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must file quarterly financial statements for fiscal soundness monitoring. Part D organizations are required to submit three (3) quarterly financial statements. Lastly, PACE organizations are required to file four (4) quarterly financial statements for the first three (3) years in the program. After the first three (3) years, PACE organizations with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must submit quarterly financial statements for fiscal soundness monitoring. CMS is responsible for overseeing the ongoing financial performance for all Medicare Health Plans, PDPs, and PACE organizations. Specifically, CMS needs the requested information collected in order to establish that contracting entities within those programs maintain fiscally sound operations. *Form Number:* CMS–906 (OMB control number: 0938–0469); *Frequency:* Yearly; *Affected Public:* Business or other for-profits, Not-for profits institutions; *Number of Respondents:* 767; *Total Annual Responses:* 1589; *Total Annual Hours:* 530. (For policy questions regarding this collection contact Christa Zalewski at 410–786–1971.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; *Use:* Sections 2723 and 2761 of the Public Health Service Act (PHS Act) direct the Centers for Medicare and Medicaid Services (CMS) to enforce a provision (or provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 144, 146, 147, and 148 of title 45 of the Code of Federal Regulations) with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the group and individual market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. Section 2723 of the PHS Act directs CMS to enforce an applicable provision (or applicable provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 146 and 147 of title 45 of the Code of Federal Regulations) with respect to group health plans that are non-Federal governmental plans. This collection of information includes requirements that are necessary for CMS to conduct compliance review activities.

The Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (collectively, the Departments) issued proposed regulations titled ''Health Reimbursement Arrangements and Other Account-Based Group Health Plans'' under section 2711 of the PHS Act and the health nondiscrimination provisions of HIPAA, Public Law 104–191 (HIPAA nondiscrimination provisions.) The proposed regulations are intended to expand the usability of health reimbursement arrangements and other account-based group health plans (collectively referred to as HRAs). In general, the proposed regulations would expand the usability of HRAs by eliminating the current prohibition on integrating HRAs with individual health insurance coverage, thereby permitting employers to offer HRAs to employees enrolled in individual health insurance coverage. Under the proposed regulations employees would be permitted to use amounts in an HRA integrated with individual health insurance coverage to pay expenses for medical care (including premiums for individual health insurance coverage), subject to certain requirements. This collection includes the requirements related to substantiation of individual health insurance coverage by an HRA prior to making reimbursements and the notice that HRAs would be required to provide to each participant. *Form Number:* CMS–10430 (OMB control number: 0938–0702); *Frequency:* Annually; *Affected Public:* State Governments, Private Sector, State or local governments; *Number of Respondents:* 2,785; *Total Annual Responses:* 298,175; *Total Annual Hours:* 7,737. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.)

5. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Prepaid Health Plan Cost Report; *Use:* Health Maintenance Organizations and Competitive Medical Plans (HMO/CMPs) contracting with the Secretary under Section 1876 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, 4th Quarter interim report (CMS has waived this annual submission), and a final certified cost report in accordance with 42 CFR 417.572–417.576. The submission, receipt and processing of the cost reports is imperative to determine if MCOs are paid on a reasonable basis for the covered services furnished to Medicare enrollees. CMS reviews the data submitted within the cost reports to establish monthly payment rates, monitor interim rates, and determine the final reimbursement. Health Care Prepayment Plans (HCPPs) contracting with the Secretary under Section 1833 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, and final cost report in accordance with 42 CFR 417.808 and 42 CFR 417.810. *Form Number:* CMS–276 (OMB control number: 0938–0165); *Frequency:* Quarterly; *Affected Public:* Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 57; *Total Annual Responses:* 67; *Total Annual Hours:* 1,800. (For policy

questions regarding this collection, contact Bilal Farrakh at 410–786–4456.)

6. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Testing of Web Survey Design and Administration for CMS Experience of Care Surveys; *Use:* This collection is a new generic clearance request which encompasses an array of research activities to add web administration protocols to a series of surveys conducted by the Centers for Medicare & Medicaid Services (CMS). This request seeks burden hours to allow CMS and its contractors to conduct cognitive in-depth interviews, focus groups, pilot tests, and usability studies to support a variety of methodological studies around web modes of data collection for programs such as the Emergency Department Experience of Care (EDPEC), Fee-for-Service (FFS) Consumer Assessment of Healthcare Providers and Systems (CAHPS), Hospital CAHPS (HCAHPS), Medicare Advantage and Prescription Drug (MA & PDP) CAHPS, Home Health (HH) CAHPS, Hospice CAHPS, In-Center Hemodialysis (ICH) CAHPS, the Health Outcomes Survey (HOS), and the Medicare Advantage and Part D Plan Disenrollment Reasons surveys. Providers. *Form Number:* CMS–10694 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 75,250; *Total Annual Responses:* 75,250; *Total Annual Hours:* 17,000. (For policy, questions regarding this collection contact Elizabeth H. Goldstein at 410–786–6665.)

7. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey; *Use:* CMS is the largest single payer of health care in the United States. The agency plays a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. A critical aim for CMS is to be an effective steward, major force, and trustworthy partner in supporting innovative approaches to improving quality, accessibility, and affordability in healthcare. CMS also aims to put patients first in the delivery of their health care needs.

The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is an in-person, nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Enterprise Data and Analytics (OEDA). The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (*e.g.* fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 26 years, encompassing over 1 million interviews and more than 100,000 survey participants. Respondents participate in up to 11 interviews over a four year period. This gives a comprehensive picture of health care costs and utilization over a period of time.

The MCBS continues to provide unique insight into the Medicare program and helps CMS and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. Beginning in 2020, this proposed revision to the clearance will add a few new measures to existing questionnaire sections. The revisions will result in a slight decrease in respondent burden of 4%, due to fewer projected completed cases each round. *Form Number:* CMS–P–0015A (OMB control number: 0938–0568); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 13,656; *Total Annual Responses:* 35,998; *Total Annual Hours:* 42,610. (For policy questions regarding this collection contact William Long at 410–786–7927.)

Dated: January 28, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–00433 Filed 1–30–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–262, CMS–224–14, CMS–R–240, CMS–10164, CMS–2552–10, CMS–R–306, CMS–10684, CMS–10237, CMS–10524 and CMS–10511]

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 March 4, 2019.

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) 395–5806 *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' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/*