TABLE 1—PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS) AND INCLUSION/EXCLUSION CRITERIA—Continued

PICOTS	Inclusion	Exclusion
	○ Harms specific to pregnancy and breastfeeding (infertility, miscarriage, abruption, preterm labor/preterm birth, preeclampsia, gestational hypertensive disorders, glucose intolerance/gestational diabetes mellitus, reduced milk production in breastfeeding/undesired weaning). ○ Danger to self or infant. ○ Misuse of prescription medication. ○ Serious adverse events related to treatment. ○ Death. • Fetal/infant/child harms. ○ Preterm birth/small for gestational age or large for gestational age. ○ Congenital anomalies. ○ Perinatal complications (low APGAR, withdrawal, respiratory distress, neonatal intensive care unit time, persistent pulmonary hypertension). ○ Poor infant attachment/bonding*†. ○ Delayed social, emotional, and cognitive development*. ○ Death.	
Time frame ...	*Followup* KQ 1, KQ 2: From conception up to 1 year postpartum for maternal outcomes. KQ 3, KQ 4: All	*Followup* • KQ 1, KQ 2: More than 12 weeks preconception for maternal preconception outcomes, more than 1 year for maternal postpartum outcomes • KQ 3, KQ 4: None.
Settings§	*Clinical setting* All settings	*Clinical setting* None.
Study design	• RCTs, CCTs, case-control studies, cohort studies with comparison arms. • Reference lists of relevant systematic reviews published in 2013 or later will be used to ensure our search strategies captured all relevant studies.	All other designs and studies using included designs that do not meet the sample size criterion.
Language	Studies published in English	Studies published in languages other than English.

*We will limit included outcomes to those using validated measures. Another potential exclusion, depending on volume of yield, includes studies that fail to control for confounding.
† Drugs such as brexanolone that are awaiting FDA approval will be included in the review once they are approved
‡ We will focus strength of evidence (SOE) grades on outcomes prioritized by the Technical Expert Panel (TEP).
§ Depending on volume, we may limit the primary analysis to studies from geographic settings with resources comparable or applicable to the United States.

Dated: December 4, 2019.

Virginia Mackay-Smith,

Associate Director.

[FR Doc. 2019–26510 Filed 12–9–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Statement of Organization, Functions, and Delegations of Authority

Part J (Agency for Toxic Substances and Disease Registry) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (50 FR 25129–25130, dated June 17, 1985, as amended most recently at 82 FR 42555, dated September 8, 2017) is amended to reflect the Order of Succession for the Agency for Toxic Substances and Disease Registry.

Section J–C, Order of Succession:

Delete in its entirety the Section J–C, Order of Succession, and insert the following:

During the absence or disability of the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), or in the event of a vacancy in that office, the first official listed below who is available shall act as Administrator, except during a planned period of absence, the Administrator may specify a different order of succession:

1. Assistant Administrator, ATSDR
2. Deputy Director for Non-Infectious Diseases
3. Principal Deputy Director
4. Chief Medical Officer
5. Director, Center for Preparedness and Response

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–26494 Filed 12–9–19; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10221, CMS–10344 and CMS–10137]

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 January 9, 2020.

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/PaperworkReductionActof1995/PRA-Listing.html*

1. Email 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:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Independent Diagnostic Testing Facilities (IDTFs) Site Investigation Form Revisions; *Use:* The data collection is used by Medicare contractors and/or their subcontractors on site visits to verify compliance with required IDTF performance standards. If a subcontractor is used, the subcontractor collects the information from the IDTF through an interview and forwards it to the Medicare contractor for evaluation.

The collection and verification of this information defends and protects our beneficiaries from illegitimate IDTFs. These procedures also protect the Medicare Trust Fund against fraud. The data collected also ensures that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare. *Form Number:* CMS–10221 (OMB control number: 0938–1029); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 727; *Total Annual Responses:* 727; *Total Annual Hours:* 1,454. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Elimination of Cost-Sharing for full benefit dual-eligible Individuals Receiving Home and Community-Based Services; *Use:* Each month CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration (SSA). The SSA sends a monthly file of Supplementary Security Income-eligible beneficiaries to CMS. Similarly, the State Medicaid agencies submit Medicare Modernization Act files to CMS that identify full subsidy beneficiaries. CMS deems the beneficiaries as having full subsidy and auto-assigns these beneficiaries to bench mark Part D plans. Part D plans receive premium amounts based on the monthly assessments.

State MMA Phase Down (SPD) exchange enables CMS to implement the Medicare Prescription Drug, Improvement, and Modernization Act, also called the Medicare Modernization Act (MMA), which was enacted into law in 2003. This data exchange allows the State Medicaid Agency (SMA) to identify Medicare beneficiaries with coverage under the Medicaid program. The SMAs also identify other low-income Medicare beneficiaries who have applied for the Part D Low-Income Subsidy (LIS). As a result of the identification of these two groups of beneficiaries, CMS auto-assigns and/or facilitates enrollment of the appropriate beneficiaries into Part D plans.

Section 1860 D–14 of the Social Security Act sets forth requirements for premium and cost-sharing subsidies for low-income beneficiaries enrolled in Medicare Part D. Based on this statute, 42 CFR 423.771, provides guidance concerning limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in Part D plans. 42 CFR 423.771 (b) establishes requirements for determining a beneficiary's eligibility for full subsidy under the Part D program. Regulations set forth in 423.780 and 423.782 outline premium and cost sharing subsidies to which full subsidy eligible are entitled under the Part D program. *Form Number:* CMS–10344 (OMB control number: 0938–1127); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 612. (For policy questions regarding this collection contact Roland O. Herrera at 410–786–0668.)

3. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Title Solicitation for Applications for Medicare Prescription Drug Plan 2021 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled ''*Application Procedures and Contracts with PDP Sponsors.*''

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB control number: 0938–0936); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 243; *Total Annual Responses:* 290; *Total Annual Hours:* 1,384.79. (For policy questions regarding this collection contact Arianne Spaccarelli at 410–786–5715.)

Dated: December 5, 2019.

William N. Parham, III,

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

[FR Doc. 2019–26595 Filed 12–9–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–304/–304a and CMS–368/–R–144]

Agency Information Collection Activities: Proposed Collection; 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 (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 February 10, 2020.

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 the 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–304/–304a Reconciliation of State Invoice and Prior Quarter Adjustment Statement

CMS–368/–R–144 Medicaid Drug Rebate Program Forms

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:* Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use:* Form CMS–304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS–304a (PQAS) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS–304 and –304a (OMB control number: 0938–0676); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 1,255; *Total Annual Responses:* 5,020; *Total Annual Hours:* 227,416. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate State Reporting Program Forms; *Use:* We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS–R–144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during