Institute for Occupational Safety and Health (NIOSH) is to conduct research and investigations on work-related disease and injury and to disseminate information for preventing identified workplace hazards (Sections 20(a)(1) and (d)). This dual responsibility recognizes the need to translate research into workplace application if it is to impact worker safety and well-being. The goal of this project is to assess the relevance and impact of NIOSH's contribution to guidelines and risk mitigation practices for safe handling of engineered nanomaterials in the workplace. The intended use of this data is to inform NIOSH's research agenda to enhance its relevance and impact on worker safety and health in the context of engineered nanomaterials.

The research under this project will survey companies who manufacture, distribute, fabricate, formulate, use or provide services related to engineered nanomaterials. The analysis will describe the survey sample, response rates, and types of company by industry and size. Further analysis will focus on identifying the types of engineered nanomaterials being used in industry and the types of occupational safety and health practices being implemented. The analysis will be used to develop a final report which evaluates the influence of NIOSH products, services, and outputs on industry occupational safety and health practices.

Under this project, the following activities and data collections will be conducted:

(1) Company Pre-calls. Sampled companies will be contacted to identify the person who will complete the survey and to ascertain whether or not the company handles engineered nanomaterials.

(2) Survey. A web-based questionnaire, with a mail option, will be administered to companies. The purpose of the survey is to learn directly from companies about their use of NIOSH materials and their occupational safety and health practices concerning engineered nanomaterials.

A sample of 600 companies will be compiled from lists of industry associations, research reports, marketing databases, and web-based searches. Of the 600 selected companies we anticipate that 500 will complete the survey. The company pre-call is expected to require five minutes to complete. The survey is expected to require 20 minutes to complete; including the time it may take respondents to look-up and retrieve needed information. The estimated annualized burden hours for the respondents' time to participate in this information collection is 108 hours. There are no costs to the responders other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
Receptionist	Pre-call	300	1	5/60
Occupational health and safety specialists	Survey	100	1	20/60
Industrial Production Managers	Survey	75	1	20/60
Natural Sciences Managers	Survey	75	1	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–19633 Filed 9–10–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10261, CMS–10556, CMS–R–305, CMS–10328 and CMS–10079]

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 October 11, 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/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:* Revision with change of a previously approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); *Use:* Section 1852(m) of the Social Security Act (the Act) and CMS regulations at 42 CFR 422.135 allow Medicare Advantage (MA) plans the ability to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits. MA additional telehealth benefits are limited to services for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act. In addition, MA additional telehealth benefits are services that been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (or ''electronic exchange'') when the physician (as defined in section 1861(r) of the Act) or practitioner (as defined in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. Per § 422.135(d), MA plans may only furnish MA additional telehealth benefits using contracted providers.

The changes for the 2020 Reporting Requirements will require plans to report Telehealth benefits. The data collected in this measure will provide CMS with a better understanding of the number of organizations utilizing Telehealth per contract and to also capture those specialties used for both in-person and Telehealth. This data will allow CMS to improve its policy and process surrounding Telehealth. In addition, the specialist and facility data we are collecting aligns with some of the provider and facility specialty types that organizations are required to include in their networks and to submit on their HSD tables in the Network Management Module in Health Plan Management System. *Form Number:* CMS–10261 (OMB control number 0938–1054); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 594; *Total Annual Responses:* 4,752; *Total Annual Hours:* 187,926. (For policy questions regarding this collection contact Mark Smith at 410–786–8015.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Necessity and Contract Amendments Under Mental Health Parity; *Use:* Upon request, regulated entities must provide a medical necessity disclosure. Receiving this information will enable potential and current enrollees to make more educated decisions given the choices available to them through their plans and may result in better treatment of their mental health or substance use disorder (MH/SUD) conditions. States use the information collected and reported as part of its contracting process with managed care entities, as well as its compliance oversight role. In states where a Medicaid Managed Care Organization (MCO) is responsible for providing the full scope of medical/surgical and MH/SUD services to beneficiaries, the state will review the parity analysis provided by the MCO to confirm that the MCO benefits are in compliance. CMS uses the information collected and reported in an oversight role of State Medicaid managed care programs. *Form Number:* CMS–10556 (OMB control number: 0938–1280); *Frequency:* Once and occasionally; *Affected Public:* Individuals and households, the Private sector, and State, Local, or Tribal Governments; *Number of Respondents:* 47,468,596; *Total Annual Responses:* 285,444; *Total Annual Hours:* 48,057. (For policy questions regarding this collection contact Juliet Kuhn at 410–786–2480.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs) and Supporting Regulations; *Use:* State agencies must provide to the external quality review organization (EQRO) information obtained through methods consistent with the protocols specified by CMS. This information is used by the EQRO to determine the quality of care furnished by an MCO. Since the EQR results are made available to the general public, this allows Medicaid/CHIP enrollees and potential enrollees to make informed choices regarding the selection of their providers. It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid/CHIP MCOs. States use the information during their oversight of these organizations. *Form Number:* CMS–R–305 (OMB control number 0938–0786); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 629; *Total Annual Responses:* 4,869; *Total Annual Hours:* 426,492. (For policy questions regarding this collection contact Jennifer Sheer at 410–786–1769.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Self-Referral Disclosure Protocol; *Use:* Section 6409 of the ACA requires the Secretary to establish a voluntary self-disclosure process that allows providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. In addition, section 6409(b) of the ACA gives the Secretary authority to reduce the amounts due and owing for the violations. To determine the nature and extent of the noncompliance and the appropriate amount by which an overpayment may be reduced, the Secretary must collect relevant information regarding the arrangements and financial relationships at issue from disclosing parties. The Secretary may also collect supporting documentation, such as contracts, leases, communications, invoices, or other documents bearing on the actual or potential violation(s). Most of the information and documentation required for submission to CMS in accordance with the SRDP is information that health care providers of services and suppliers keep as part of customary and usual business practices. *Form Number:* CMS–10328 (OMB control number: 0938–1106); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 5,000. (For policy questions regarding this collection contact Matthew Edgar at 410–786–0698.)

5. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Hospital Wage Index Occupational Mix Survey; *Use:* Section 304(c) of Public Law 106–554 mandates an occupational mix adjustment to the wage index, requiring the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. The proposed data collection that is

included in this submission complies with this statutory requirement. The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor. *Form Number:* CMS–10079 (OMB control number: 0938–0907); *Frequency:* Yearly; *Affected Public:* Business or Other for-Profits, Not-for-Profit Institutions; *Number of Respondents:* 3,300; *Total Annual Responses:* 3,300; *Total Annual Hours:* 1,584,000. (For policy questions regarding this collection contact Tehila Lipschutz at 410–786–1344.)

Dated: September 6, 2019.

William N. Parham, III,

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

[FR Doc. 2019–19677 Filed 9–10–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Child Support Enforcement Direct Funding Request: (OMB #0970–0218)

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS

ACTION: Request for Public Comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF) is requesting a 3-year extension of the Tribal IV–D plan (OMB #0970–0218, expiration 3/21/2020). There are no changes requested to this form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street, SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The final rule within 45 CFR part 309, published in the **Federal Register** on March 30, 2004, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV–D program a Tribe or Tribal organization must submit a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity; establishing, modifying, and enforcing support orders; and locating noncustodial parents. The plan is required for all Tribes requesting funding; however, once a Tribe has met the requirements to operate a comprehensive program, a new plan is not required annually unless a Tribe makes changes to its title IV–D program. If a Tribe or Tribal organization intends to make any substantial or material changes, a Tribal IV–D plan amendment must be submitted for approval. Tribes and Tribal organizations must have an approved plan and submit any required plan amendments in order to receive funding to operate a Tribal IV–D program. This paperwork collection activity is set to expire in March 2020.

Respondents: Tribes and Tribal Organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
45 CFR 309-Plan	60	1	120	7,200
45 CFR 309-New Plan	2	1	480	960

Estimated Total Annual Burden Hours: 8,160.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 45 CFR 309.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–19580 Filed 9–10–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–E–0298; FDA–2018–E–0299; FDA–2018–E–0301; and FDA–2018–E–0321]

Determination of Regulatory Review Period for Purposes of Patent Extension; Edwards Pericardial Aortic Bioprosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has