approved collection; *Title of Information Collection:* PACE State Plan Amendment Preprint; *Use:* If a state elects to offer PACE as an optional Medicaid benefit, it must complete a state plan amendment preprint packet described as ''Enclosures 3, 4, 5, 6, and 7.'' CMS will review the information provided in order to determine if the state has properly elected to cover PACE services as a state plan option. In the event that the state changes something in the state plan, only the affected page must be updated. *Form Number:* CMS–10227 (OMB control number: 0938–1027); *Frequency:* Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 7; *Total Annual Responses:* 2; *Total Annual Hours:* 140. (For policy questions regarding this collection contact Angela Cimino at 410–786–2638.)

13. *Type of Information Collection Request:* Extension 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:* This collection eliminates Part D cost-sharing for full benefit dual-eligible beneficiaries who are receiving home and community based services. In this regard, states are required to identify the affected beneficiaries in their monthly Medicare Modernization Act Phase Down reports. *Form Number:* CMS–10344 (OMB control number: 0938–1127); *Frequency:* Monthly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 612. (For policy questions regarding this collection contact Roland Herrera at 410–786–0668.)

14. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; *Use:* The collected baseline data is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children (by age group and basis of Medicaid eligibility) who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state's results in attaining the participation goals set for the state. The information gathered from this report, permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. *Form Number:* CMS–416 (OMB control number 0938–0354); *Frequency:* Yearly and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 1,624. (For policy questions regarding this collection contact Kimberly Perrault at 410–786–2482.)

15. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Programs for All-inclusive Care of the Elderly (PACE) and Supporting Regulations in 42 CFR part 460; *Use:* This information collection addresses all operational components of the PACE program (as defined in 42 CFR part 460) with the exception of the application process (§ 460.12). We are removing the application requirements and burden since this CMS–R–244 package is lengthy and we recognize that it can be somewhat time consuming to review. We believe the change will help streamline the public and OMB's review of the application as well as the remaining requirements and burden under the CMS–R–244 package.

The application is being moved under a new information collection request with a new CMS identification number (CMS–10631). An OMB control number specific to the application process is pending. The CMS–10631 information collection request was submitted to OMB on October 6, 2016, under ICR Reference No: 201610–0938–001. When approved, the control number can be found on *www.reginfo.gov/public/.*

Form Number: CMS–R–244 (OMB control number: 0938–0790); *Frequency:* Once and occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 130; *Total Annual Responses:* 145,455; *Total Annual Hours:* 61,350. (For policy questions regarding this collection contact Debbie Van Hoven at 410–786–6625).

16. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Healthcare Effectiveness Data and Information Set (HEDIS®) Data Collection for Medicare Advantage; *Use:* We use the collected data to: monitor Medicare Advantage organization performance, inform audit strategies, and inform beneficiary choice through their display in our consumer-oriented public compare tools and Web sites. Medicare Advantage organizations use the data for quality assessment and as part of their quality improvement programs and activities. Quality Improvement Organizations and our contractors use HEDIS® data in conjunction with their statutory authority to improve quality of care. Consumers use the information to help make informed health care choices. In addition, the data is made available to researchers and others as public use files at *www.cms.hhs.gov. Form Number:* CMS–10219 (OMB control number: 0938–1028); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 576; *Total Annual Responses:* 576; *Total Annual Hours:* 184,320. (For policy questions regarding this collection contact Lori Teichman at 410–786–6684.)

Dated: February 14, 2017.

William N. Parham, III,

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

[FR Doc. 2017–03235 Filed 2–16–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–304/304a, CMS–368/CMS–R–144, CMS–R–308, CMS–10151, CMS–10199, CMS–R–13, and CMS–10279]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 18, 2017.

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

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: Reports Clearance Office at (410) 786–1326.

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/CMS–R–144	Medicaid Drug Rebate Program Forms.
CMS–R–308	State Children's Health Insurance Program and Supporting Regulations.
CMS–10151	Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death.
CMS–10199	Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy.
CMS–R–13	Conditions of Coverage for Organ Procurement Organizations and Supporting Regulations ate Children's Health Insurance Program and Supporting Regulations.
CMS–10279	Ambulatory Surgical Center Conditions for Coverage.

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 of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Use:* Form CMS–304 (Reconciliation of State Invoice) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS–304a (Prior Quarter Adjustment Statement) 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:* 1,037; *Total Annual Responses:* 4,148; *Total Annual Hours:* 187,880. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate 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 that quarter. Form CMS–368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. *Form Number:* CMS–368 and –R–144 (OMB control number: 0938–0582); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Children's Health Insurance Program and Supporting Regulations; *Use:* States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. *Form Number:* CMS–R–308 (OMB control number: 0938–0841);

Frequency: Yearly, Once, and Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 28,294,596; *Total Annual Hours:* 1,473,885. (For policy questions regarding this collection contact Amy Lutzky at 410–786–0721).

4. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; *Use:* We provide coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, we consider coverage for ICDs reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, we issued a ''Decision Memo for Implantable Defibrillators'' on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). *Form Number:* CMS–10151 (OMB control number: 0938–0967); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 1,600; *Total Annual Responses:* 80,000; *Total Annual Hours:* 20,000. (For policy questions regarding this collection contact JoAnna Baldwin at 410–786–7205.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy; *Use:* We provide coverage for carotid artery stenting (CAS) with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis between 50 percent and 70 percent or have asymptomatic carotid artery stenosis ≥ 80 percent in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1, or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7). Accordingly, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the Social Security Act). However, evidence for use of CAS with embolic protection for patients with high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis ≥ 70 percent who are not enrolled in a study or trial is less compelling. To encourage responsible and appropriate use of CAS with embolic protection, we issued a Decision Memo for Carotid Artery Stenting on March 17, 2005, indicating that CAS with embolic protection for symptomatic carotid artery stenosis ≥ 70 percent will be covered only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. In accordance with this criteria, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the Social Security Act). *Form Number:* CMS–10199 (OMB control number: 0938–1011); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

6. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations and Supporting Regulations; Use: Section 1138(b) of the Social Security Act, as added by section 9318 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509), sets forth the statutory qualifications and requirements that organ procurement organizations (OPOs) must meet in order for the costs of their services in procuring organs for transplant centers to be reimbursable under the Medicare and Medicaid programs. An OPO must be certified and designated by the Secretary as an OPO and must meet performance-related standards prescribed by the Secretary. The corresponding regulations are found at 42 CFR part 486 (Conditions for Coverage of Specialized Services Furnished by Suppliers) under subpart G (Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations).

Since each OPO has a monopoly on organ procurement within its designated service area (DSA), we must hold OPOs to high standards. Collection of this information is necessary for us to assess the effectiveness of each OPO and determine whether it should continue to be certified as an OPO and designated for a particular donation service area by the Secretary or replaced by an OPO that can more effectively procure organs within that DSA. *Form Number:* CMS–R–13 (OMB control number: 0938–0688); *Frequency:* Occasionally; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 13,546. (For policy questions regarding this collection contact Diane Corning at 410–786–8486.)

7. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Ambulatory Surgical Center Conditions for Coverage; *Use:* The Ambulatory Surgical Center (ASC) Conditions for Coverage (CfCs) focus on a patient-centered, outcome-oriented, and transparent processes that promote quality patient care. The CfCs are designed to ensure that each facility has properly trained staff to provide the appropriate type and level of care for that facility and provide a safe physical environment for patients. The CfCs are used by Federal or state surveyors as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare. We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS–10279 (OMB control number: 0938–1071); *Frequency:* Annual; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 5,500; *Total Annual Responses:* 5,500; *Total Annual Hours:* 209,000. (For policy questions regarding this collection contact Jacqueline Leach at 410–786–4282.)

Dated: February 14, 2017.

William N. Parham, III,

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

[FR Doc. 2017–03234 Filed 2–16–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Food and Drug Administration/Xavier University PharmaLink Conference—Leadership in a Global Supply Chain

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in co-sponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University PharmaLink Conference: Leadership in a Global Supply Chain.'' The PharmaLink conference seeks solutions to important and complicated issues by aligning with the strategic priorities of FDA, and includes presentations from key FDA officials and industry experts.

DATES: The public conference will be held on March 15, 2017, from 8:30 a.m. to 5 p.m.; March 16, 2017, from 8:30 a.m. to 5 p.m.; and March 17, 2017, from 8:30 a.m. to 12:20 p.m. The conference is preceded by a Welcome Reception on March 14, 2017, from 5 p.m. to 7 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3483.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: Nicholas Paulin, Food and Drug Administration, Cincinnati South Office, 36 East 7th St., Cincinnati, OH 45202, 513–246–4134, email: *nicholas.paulin@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207–5471, 513–745–3073, email: *phillipsm4@xavier.edu.*

SUPPLEMENTARY INFORMATION:

I. Background

The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The most pressing challenges of the global pharmaceutical industry require solutions which are inspired by collaboration to ensure the on-going health and safety of patients. These challenges include designing products with the patient in mind, building quality into the product from the starting point, selecting the right suppliers, and considering total product lifecycle systems. Meeting these challenges requires vigilance, innovation, supply chain strategy, relationship management, proactive change management, and a commitment to doing the job right the first time. FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices.

The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

The conference includes the following:

- Welcome Reception at the Hilton Netherland Plaza.
- Lunch Networking by Topic.
- The Solution ''Xchange''.
- Case Studies and Small Group Discussions.
- Action Plans.

II. Topics for Discussion at the Public Conference

The public conference will engage those involved in FDA-regulated global supply chain quality and management through the following topics:

- FDA Metrics Program—Path Forward to Reduce Risks Within FDA and Across Industry.
- Predictive Capabilities Through a Living Metrics Model.
- How Big Data and Artificial Intelligence Can Enhance Your Proactive Risk Monitoring Programs.
- Connecting Culture to Performance.
- Data Integrity—Detection and Successful Practices.
- Building a Bridge Across Generations.
- Good Supply Practices (GSPs)—Paradigm Shifting Solutions.
- How to Develop and Execute a Robust Risk-Based Due Diligence Plan.
- Maximizing Post-Merger Success.
- Your Company Bought a New Business—Now What?
- Supply Chains in China—Strategies for Regulatory Success.
- Top 3 Challenges for Successful Serialization Implementation Across Your Supply Chain.
- Strategic Direction of the Food & Drug Administration, Center for Drug Evaluation and Research (CDER), Office of Manufacturing Quality.
- Office of Regulatory Affairs Key Initiatives.
- FDA Investigator Case Study Insights.

III. Registration for the Public Conference

Registration: To register online for the public conference, please visit the ''Registration'' link on the conference Web site at *http://www.XavierPharmaLink.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. FDA has verified the Web site address in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Marla Phillips, 3800 Victory Pkwy., Cincinnati, OH 45207–5471. An email will be sent confirming your registration.

If you need special accommodations due to a disability, please contact Marla Phillips (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the conference.

There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2.5 days of the conference, including the Welcome Reception that precedes the conference. There will be onsite registration if space is available. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee type	Standard rate
Industry	$1,895
Small Business (<100 employees)	1,295
Start-up Manufacturer	300
Academic	300
Media	Free