should sunset, or whether the limited wraparound pilot program should be made permanent. *Form Number:* CMS–10571 (OMB control number: 0938–NEW); *Frequency:* Once; *Affected Public:* Private Sector; *Number of Respondents:* 8; *Total Annual Responses:* 8; *Total Annual Hours:* 24. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.)

Dated: March 22, 2018.

William N. Parham, III,

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

[FR Doc. 2018–06082 Filed 3–26–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10341, CMS–10538, CMS–R–153, CMS–10561 and CMS–10336]

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 May 29, 2018.

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 *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 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–10341 Affordable Care Act Information and Collection Requirements for Section 1115 Demonstration Projects

CMS–10538 Hospice Information for Medicare Part D Plans

CMS–R–153 Medicaid Drug Use Review (DUR) Program

CMS–10561 Essential Community Provider Data Collection to Support QHP Certification for PYs 2021–2023

CMS–10336 Medicare and Medicaid Programs; Electronic Health Record Incentive Program

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:* Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428; *Use:* This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. *Form Number:* CMS–10341 (OMB control number 0938–1162); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 37; *Total Annual Responses:* 300; *Total Annual Hours:* 24,092. (For policy questions regarding this collection contact Tonya Moore at 410–786–0019.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Information for Medicare Part D Plans; *Use:* The form would be completed by the prescriber or the beneficiary's hospice, or if the prescriber or hospice provides the information verbally to the Part D sponsor, the form would be completed by the sponsor. Information provided on the form would be used by the Part D sponsor to establish coverage of the drug under Medicare Part D. Per statute, drugs that are necessary for the palliation and management of the terminal illness and related conditions are not eligible for payment under Part D. The standard form provides a vehicle for the hospice provider, prescriber or sponsor to document that the drug prescribed is ''unrelated'' to the

terminal illness and related conditions. It also gives a hospice organization the option to communicate a beneficiary's change in hospice status and care plan to Part D sponsors. *Form Number:* CMS–10538 (OMB control number 0938–1269); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 424; *Total Annual Responses:* 376,487; *Total Annual Hours:* 31,374. (For policy questions regarding this collection contact Shelly Winston at 410–786–3694.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.,* allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The State must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons and trends related to States' experiences with DUR. The States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports. *Form Number:* CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Emeka Egwim at 410–786–1092.)

4. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Essential Community Provider Data Collection to Support QHP Certification for PYs 2021–2023; *Use:* For plan years beginning on or after January 1, 2021, Health and Human Services (HHS) intends to continue collecting more complete provider data for inclusion on the HHS Essential Community Provider (ECP) list to ensure a more accurate reflection of the universe of qualified available ECPs in a given service area that can be counted toward an issuer's satisfaction of the ECP standard. HHS intends to continue collecting these data on qualified and available ECPs directly from providers through the online ECP petition. Providers will submit an ECP petition to be added to the HHS ECP list or update required data fields to remain on the list. *Form Number:* CMS–10561 (OMB Control Number: 0938–1295); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit Institutions); *Number of Respondents:* 14,260; *Total Annual Responses:* 14,260; *Total Annual Hours:* 7,468. (For policy questions regarding this collection contact Deborah Hunter at (202) 309–1098).

5. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Medicare and Medicaid Programs; Electronic Health Record Incentive Program; *Use:* The American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 111–5) was enacted on February 17, 2009. The Recovery Act includes many measures to modernize our nation's infrastructure, and improve affordable health care. Expanded use of health information technology (HIT) and certified electronic health record (EHR) technology will improve the quality and value of America's health care. Title IV of Division B of the Recovery Act amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified EHR technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the ''Health Information Technology for Economic and Clinical Health Act'' or the ''HITECH Act.''

The HITECH Act creates incentive programs for EPs and eligible hospitals, including CAHs, in the Medicare Fee-for-Service (FFS), MA, and Medicaid programs that successfully demonstrate meaningful use of certified EHR technology. In their first payment year, Medicaid EPs and eligible hospitals may adopt, implement or upgrade to certified EHR technology. It also, provides for payment adjustments in the Medicare FFS and MA programs starting in FY 2015 for EPs and eligible hospitals participating in Medicare that are not meaningful users of certified EHR technology. These payment adjustments do not pertain to Medicaid providers.

The first final rule for the Medicare and Medicaid EHR Incentive Program, which was published in the **Federal Register** on July 28, 2010 (CMS–0033–F), specified the initial criteria EPs, eligible hospitals and CAHs, and MA organizations must meet in order to qualify for incentive payments; calculation of incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs, eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology beginning in 2015; and other program participation requirements. On the same date, the Office of the National Coordinator of Health Information Technology (ONC) issued a closely related final rule (45 CFR part 170, RIN 0991–AB58) that specified the initial set of standards, implementation specifications, and certification criteria for certified EHR technology. ONC has also issued a separate final rule on the establishment of certification programs for health information technology (HIT) (45 CFR part 170, RIN 0991–AB59). The functionality of certified EHR technology should facilitate the implementation of meaningful use. Subsequently, final rules have been issued by CMS (77 FR 53968) and ONC (77 FR 72985) to create a Stage 2 of meaningful use criteria and other changes to the CMS EHR Incentive Programs and the 2014 Edition Certification Criteria for EHR technology.

The information collection requirements contained in this information collection request are needed to implement the HITECH Act. In order to avoid duplicate payments, all EPs are enumerated through their National Provider Identifier (NPI), while all eligible hospitals and CAHs are

enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider's tax identification number and NPI or CCN combination in order to make payment, validate payment eligibility and detect and prevent duplicate payments for EPs, eligible hospitals and CAHs. *Form Number:* CMS–10336 (OMB Control Number: 0938–1158); *Frequency:* Occasionally; *Affected Public:* Private sector; *Number of Respondents:* 214,694; *Total Annual Responses:* 214,694; *Total Annual Hours:* 2,034,740. (For policy questions regarding this collection contact Steven Johnson at (410) 786–3332).

Dated: March 22, 2018.

William N. Parham, III,

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

[FR Doc. 2018–06081 Filed 3–26–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0073]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by April 26, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0704. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

OMB Control Number 0910–0704—Extension

This information collection supports the above captioned Agency guidance document. FDA recommends that producers who use biotechnology in the manufacture or development of foods and food ingredients work cooperatively with FDA to ensure that products derived through biotechnology are safe and comply with all applicable legal requirements and has instituted a voluntary consultation process with industry. To facilitate this process the Agency has issued a guidance entitled, ''Guidance on Consultation Procedures: Foods Derived From New Plant Varieties,'' which is available on our website at *https://www.fda.gov/FoodGuidances.* The guidance describes FDA's consultation process for the evaluation of information on new plant varieties provided by developers. The Agency believes this consultation process will help ensure that human food and animal feed safety issues or other regulatory issues (*e.g.,* labeling) are resolved prior to commercial distribution. Additionally, such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development, and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

In the **Federal Register** of December 13, 2017 (82 FR 58619), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. Two comments were received in response to the notice. Overall, the comments supported FDA's need for the information collection and neither comment suggested revising our estimate of the associated burden. However, both comments reminded us that significant resources were invested into developing data upon which respondents rely to bring information to FDA regarding the development of foods derived from new plant varieties. All the more reason, the comments said, FDA should identify mechanisms by which it can better incorporate its experience over time and, where possible, implement more efficient, streamlined review processes for those products similar to those the Agency has reviewed in the past. The comments recommended FDA compare efficiencies with a process at the U.S. Department of Agriculture regarding the review of agricultural biotechnology products. We appreciate this suggestion. FDA strives to allocate its limited resources in ways that maximize protection to the public health and facilitate compliance with existing regulatory requirements implemented to do so. We also look for ways in which we might coordinate our efforts with those by other agencies who share these objectives.

Both comments also included the suggestion that FDA develop a less redundant review process (such as reciprocity if no material differences are identified) that better coordinates expertise across the Center for Food Safety and Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) into a single, efficient review. We appreciate this suggestion as well and, as discussed in the guidance, note the following:

[FDA's] Office of Premarket Approval of the CFSAN and the Office of Surveillance and Compliance of the CVM have established a Biotechnology Evaluation Team (BET) to facilitate, and to ensure consistency in the process by which firms consult under the 1992 policy and inform FDA regarding the marketing of bioengineered foods and food ingredients derived from new plant varieties including those developed using rDNA techniques. The BET oversees the consultation process, identifies regulatory and scientific issues that need to be addressed, and once all relevant issues have been adequately addressed, brings the consultation to closure.

At the same time, we have shared the comments received in response to this notice under the PRA with the BET. Consistent with our Good Guidance Practice regulations (21 CFR 10.115), FDA welcomes comments on our guidance documents at any time.

In consideration of these comments, we have retained the currently approved burden estimated associated with the information collection, which is as follows: