including Power Wheelchairs and Power-Operated Vehicles; *Use:* We are renewing our request for approval for the collection requirements associated with the final rule, CMS–3017–F (71 FR 17021), which published on April 5, 2006, and required a face-to-face examination of the beneficiary by the physician or treating practitioner, a written prescription, and receipt of pertinent parts of the medical record by the supplier within 45 days after the face-to-face examination that the durable medical equipment (DME) suppliers maintain in their records and make available to CMS and its agents upon request. *Form Number:* CMS–10116 (OMB control number: 0938–0971); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 55,700; *Number of Responses:* 55,700; *Total Annual Hours:* 11,140. (For policy questions regarding this collection contact Rachel Katonak at 410–786–2118).

4. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* State Medicaid Eligibility Quality Control Sample Selection Lists; *Use:* The Medicaid Eligibility Quality Control (MEQC) program provides states a unique opportunity to improve the quality and accuracy of their Medicaid and Children's Health Insurance Program (CHIP) eligibility determinations. The MEQC program is intended to complement the Payment Error Rate Measurement (PERM) program by ensuring state operations make accurate and timely eligibility determinations so that Medicaid and CHIP services are appropriately provided to eligible individuals. Current regulations require that states review equal numbers of active cases and negative case actions (*i.e.,* denials and terminations) through random sampling. Active case reviews are conducted to determine whether or not the sampled cases meet all current criteria and requirements for Medicaid or CHIP eligibility. Negative case reviews are conducted to determine if Medicaid and CHIP denials and terminations were appropriate and undertaken in accordance with due process. State Title XIX and Title XXI agencies are required to submit MEQC case level and CAP reports based on pilot findings in accordance with 42 CFR 431.816 and 431.820, respectively. The primary users of this information are state Medicaid (and where applicable CHIP) agencies and the Centers for Medicare & Medicaid Services. *Form Number:* CMS–319 (OMB control number: 0938–0147); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 34; *Total Annual Responses:* 34; *Total Annual Hours:* 1,900. For policy questions regarding this collection contact Camiel Rowe 410–786–0069.

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Quality Improvement Strategy Implementation Plan, Progress Report Form and Modification Summary Supplement. *Use:* Section 1311(c)(1)(E) of the Patient Protection and Affordable Care Act requires qualified health plans (QHPs) offered through an Exchange must implement a quality improvement strategy (QIS) as described in section 1311(g)(1). Section 1311(g)(3) of the Affordable Care Act specifies the guidelines under Section 1311(g)(2) shall require the periodic reporting to the applicable Exchange the activities that a qualified health plan has conducted to implement a strategy which is described as a payment structure providing increased reimbursement or other incentives for improving health outcomes of plan enrollees, implementing activities to prevent hospital readmissions, improving patient safety and reducing medical errors, promoting wellness and health, and/or implementing activities to reduce health and health care disparities. CMS has created a separation of the QIS form into a separate Implementation Plan, Progress Report and Modification Summary which is intended to decrease overall burden on issuers. With these separate forms, issuers would no longer need to complete and resubmit an Implementation Plan every year (which is currently the process). Issuers would only submit the Implementation Plan form in the first year of a QIS, and then issuers would submit the Progress Report form in each subsequent year (with the Modification Summary Supplement as necessary). This adjustment will eliminate the need for issuers to enter and submit unchanged data, and allow them to focus their time on reporting new progress achieved for the QIS.

The QIS form will allow: (1) The Department of Health & Human Services (HHS) to evaluate the compliance and adequacy of QHP issuers' quality improvement efforts, as required by Section 1311(c) of the Affordable Care Act, and (2) HHS will use the issuers' validated information to evaluate the issuers' quality improvement strategies for compliance with the requirements of Section 1311(g) of the Affordable Care Act. *Form Number:* CMS–10540 (OMB Control Number: 0938–1286); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 250 respondents; *Total Annual Responses:* 250 responses; *Total Annual Hours:* 11,000. For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.

Dated: September 21, 2020.

William N. Parham, III,

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

[FR Doc. 2020–21092 Filed 9–23–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–43, CMS–40B, CMS–R–285, and CMS–10175]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 November 23, 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 following:

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

2. 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–43 Application for Health Insurance Benefits Under Medicare for Individual with Chronic Renal Disease and Supporting Regulations in 42 CFR

CMS–40B Application for Enrollment in Medicare the Medical Insurance Program

CMS–R–285 Request for Retirement Benefit Information

CMS–10175 Certification Statement for Electronic File Interchange Organizations that Submit NPI Data to the National Plan and Provider Enumeration System

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 without change of a currently approved collection; *Title of Information Collection:* Application for Health Insurance Benefits Under Medicare for Individual with Chronic Renal Disease and Supporting Regulations in 42 CFR; *Use:* Individuals with End-Stage Renal Disease (ESRD) have the opportunity to apply for Medicare benefits and obtain premium-free Part A if they meet certain criteria outlined in statute. Sections 226A of the Act authorizes entitlement for Medicare Hospital Insurance (Part A) if the individual with ESRD files an application for benefits and meets the requisite contributions through one's own employment or the employment of a related individual to meet the statutory definition of a ''currently insured'' individual outlined in section 214 of the Act. Further, for individuals who meet the requirements for premium-free Part A entitlement, Medicare coverage starts based on the dates in which the individual started dialysis treatment or had a kidney transplant. These statutory provisions are codified at 42 CFR 406.7(c)(3) and 407.13.

The CMS–43 form is used (in conjunction with the CMS–2728, OMB control number 0938–0046) to establish entitlement to Medicare Part A and enrollment in Medicare Part B for individuals with ESRD. Form CMS–43 is only used for initial applications for Medicare by individuals diagnosed with ESRD. Form CMS–2728 provides the medical documentation that the individual has ESRD, and it accompanies Form CMS–43.

Form CMS–43 is completed by the person applying for Medicare or by an SSA representative using information provided by the Medicare enrollee during an in-person interview. The majority of the forms are completed by an SSA representative on behalf of the individual applying for Medicare benefits. The form is owned by CMS, but not completed by CMS staff. *Form Number:* CMS–43 (OMB control number: 0938–0080); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 20,382; *Total Annual Responses:* 20,382; *Total Annual Hours:* 8,560. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Application for Enrollment in Medicare the Medical Insurance Program; *Use:* Section 1836 of the Act, and regulations at 42 CFR 407.10, provide the eligibility requirements for enrollment in Part B. Section 407.11 lists the CMS–40B as the application to be used by individuals who wish to apply for Part B if they already have initial entitlement to premium-free Part A. Under the regulations, individuals may also enroll in Medicare Part B by signing a statement requesting Part B, if eligible for enrollment at that time. Individuals use the standardized Form CMS–40B to request enrollment.

The CMS–40B provides the necessary information to determine eligibility and to process the beneficiary's request for enrollment for Medicare Part B coverage. This form is only used for enrollment by beneficiaries who already have Part A, but not Part B. Form CMS–40B is completed by the person with Medicare or occasionally by an SSA representative using information provided by the Medicare enrollee during an in-person interview. The form is owned by CMS, but not completed by CMS staff. SSA processes Medicare enrollments on behalf of CMS. *Form Number:* CMS–40B (OMB control number: 0938–1230); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 400,000; *Total Annual Responses:* 400,000; *Total Annual Hours:* 100,000. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Retirement Benefit Information; *Use:* Section 1818(d)(5) of the Social Security Act (the Act) provides that certain former State and local government employees (and their current or former spouses) may have the Part A premium reduced to zero.

Form CMS–R–285, ''Request for Retirement Benefit Information,'' is used to obtain information regarding whether

a beneficiary currently purchasing Medicare premium Part A coverage, is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan is subsidizing the individual's Part A premium.

Form CMS–R–285 provides the necessary information regarding the prior state or local government employment to process the individual's request for premium Part A reduction based on their employment by a state or local government.

The form is completed by the state or local government employer on behalf of the individual seeking the Medicare premium reduction. The SSA—CMS' agent for processing Medicare enrollments and premium amount determinations will use this information to help determine whether a beneficiary meets the requirements for reduction of the Part A premium. The form is owned by CMS but not completed by CMS staff. *Form Number:* CMS–R–285 (OMB control number: 0938–0769); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 125. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Certification Statement for Electronic File Interchange Organizations (EFIOs) that submit National Provider Identifier (NPI) data to the National Plan and Provider Enumeration System (NPPES); *Use:* The EFI process allows organizations to submit NPI application information on large numbers of providers in a single file. Once it has obtained and formatted the necessary provider data, the EFIO can electronically submit the file to NPPES for processing. As each file can contain up to approximately 25,000 records, or provider applications, the EFI process greatly reduces the paperwork and overall administrative burden associated with enumerating providers. It is essential to collect this information from the EFIO to ensure that the EFIO understands its legal responsibilities as an EFIO and attests that it has the authority to act on behalf of the providers for whom it is submitting data. In short, the certification statement, which must be signed by an authorized official of the EFIO, serves as a safeguard against EFIOs attempting to obtain NPIs for illicit or inappropriate purposes. *Form Number:* CMS–10175 (OMB control number 0938–0984); *Frequency:* Once, Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 32; *Number of Responses:* 32; *Total Annual Hours:* 8. For questions regarding this collection contact DaVona Boyd at 410–786–7483.

Dated: September 21, 2020.

William N. Parham, III,

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

[FR Doc. 2020–21095 Filed 9–23–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0810]

Food and Drug Administration Equivalence Determination Regarding Implementation by Spain and the Netherlands of the European Union System of Food Safety Control Measures for Raw Bivalve Molluscan Shellfish With Additional Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a final determination that the adoption and implementation by Spain and the Netherlands of the European Union's (EU's) system of food safety control measures for raw bivalve molluscan shellfish (''shellfish''), along with their application of additional measures specifically adopted for this purpose, *i.e.,* for export to the United States, provides at least the same level of sanitary protection as comparable food safety measures in the United States and is therefore equivalent. This final equivalence determination will permit the importation of raw shellfish harvested from certain production areas in Spain and the Netherlands from establishments that have been listed by FDA on the Interstate Certified Shellfish Shippers List (ICSSL).

DATES: The determination becomes final on September 24, 2020.

FOR FURTHER INFORMATION CONTACT: Melissa Abbott, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1401; or Robert Tuverson, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1586.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

FDA is responsible for protecting public health by ensuring, among other things, the safety of our nation's food supply, including imported foods. This includes raw bivalve molluscan shellfish (oysters, clams, mussels, roe-on scallops, and whole scallops, referred to as ''shellfish'' throughout this notice) imported into the United States. In the **Federal Register** of March 9, 2018 (83 FR 10487), we published a notice that announced and explained the basis for our proposed equivalence determination that the EU system of food safety control measures for shellfish, along with the application of additional measures specifically adopted for this purpose, *i.e.,* for export to the United States, as adopted and implemented in Spain and the Netherlands, provides at least a level of sanitary protection as comparable food safety measures in the United States. This notice announces that, after considering comments we received on the proposed equivalence determination, we are finalizing the equivalence determination as proposed, except that we are narrowing the scope of this final equivalence determination so that it only encompasses two EU Member States, Spain and the Netherlands. FDA will use this determination as a basis to evaluate additional EU Member States that adopt and implement these measures.

In the future, we will evaluate and recognize as equivalent, as appropriate, other EU Member States in separate determinations. In addition, we further clarify and explain our basis for the final equivalence determination in response to the comments. We note that, in the March 9, 2018, notice, we used both ''production area'' and ''growing area'' in referring to beds or sites that support or could support the propagation of bivalve molluscan shellfish. For purposes of this notice, we continue to use the same terminology.

B. Basis for Equivalence Determination

Under section 432 of the Uruguay Round Agreements Act (URAA), Public Law 103–465, U.S. Agencies may not find foreign sanitary and phytosanitary measures (SPS measures) equivalent to comparable SPS measures in the United States unless the Agency determines that the foreign measures provide at least the same level of sanitary or phytosanitary protection as the