EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Total burden hours	Average hourly wage rate *	Total cost burden
4. Data File(s) Submission	85	64.58	5,489
Total	308	NA	19,891

* Mean hourly wage rate of $64.58 for Medical and Health Services Managers (SOC code 11–9111) was obtained from the May 2023 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100—Offices of Physicians located at *https://www.bls.gov/oes/current/naics4_621100.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 26, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–22578 Filed 10–1–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10844 and CMS–10157]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 November 1, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

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 of a currently approved collection; *Title of Information Collection:* Small Biotech Exception and Biosimilar Delay Information Collection Request (ICR) for Initial Price Applicability Year 2027; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). The Information Collection Request Forms for the Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027 must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2027.

Small Biotech Exception: In accordance with section 1192(d)(2) of the Act, the term ''negotiation-eligible drug'' excludes, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the ''Small Biotech Exception,'' or ''SBE'').

This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act. To ensure that only covered Part D drugs that meet the requirements for the SBE are excluded from the term ''negotiation-eligible drug,'' a manufacturer that seeks the SBE for its covered Part D drug (''Submitting Manufacturer'') must submit information to CMS about the company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the SBE for a covered Part D drug it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021. If the Submitting Manufacturer was acquired by another entity after December 31, 2021, the Submitting Manufacturer must provide information regarding that acquiring entity for CMS to assess whether the acquisition triggers the limitation at section 1192(d)(2)(B)(ii) of the Act.

Biosimilar Delay: In accordance with section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product (''Biosimilar Manufacturer'' of a ''Biosimilar'') may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a ''Reference Drug'') on the selected drug list for a given initial price applicability year (the ''Biosimilar Delay''). This information is required in order for CMS to accurately determine if a drug meets the criteria for the Biosimilar Delay for initial price applicability year 2027 in accordance with section 1192(f) of the Act. To ensure that the delay of selection and negotiation of biologics is only applied if there is a high likelihood of biosimilar market entry that meets the requirements for the Biosimilar Delay, a Biosimilar Manufacturer that seeks the Biosimilar Delay must submit information to CMS related to the Biosimilar. This information includes identifying information for the Biosimilar and the Reference Drug; the licensure status of the Biosimilar; attestations that the Biosimilar Manufacturer is not the same or treated as the same entity as the Reference Manufacturer, that the Biosimilar Manufacturer and the Reference Manufacturer (who is the manufacturer of the Reference Drug) have not entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit the Biosimilar Delay, or directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time; and documentation specified under section 1192(f)(3) of the Act to demonstrate there is a high likelihood of Biosimilar market entry within two years of the statutorily-defined selected drug publication date for initial price applicability year 2027. *Form Number:* CMS–10844 (OMB control number: 0938–1443); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 415; (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The HIPAA Eligibility Transaction System (HETS); *Use:* CMS created the HIPAA (Health Insurance Portability and Accountability Act of 1996) Eligibility Transaction System (HETS) to provide HIPAA Accredited Standards Committee X12 270/271 health care eligibility inquiries (270) and responses (271) on a real-time basis. HETS allows health care providers or their designees to check Medicare beneficiary eligibility data in real-time. They use HETS to prepare accurate Medicare claims, determine beneficiary liability, or check eligibility for specific services. HETS allows users to submit HIPAA compliant 270 eligibility request over a secure connection and receive 271 responses in real-time. In creating the HETS system, federal law requires that CMS take precautions to minimize the security risk to federal information systems. Accordingly, CMS requires that trading partners who wish to connect to the HETS 270/271 system via the CMS Extranet and/or internet to agree to the HETS Rules of Behavior and the HETS Authorized Representative Roles and Responsibilities terms as a condition of receiving Medicare eligibility information. Applicants complete the entire Trading Partner Agreement form to indicate agreement with CMS trading partner terms and provide sufficient information to establish connectivity to the service and assure that those entities that access the Medicare eligibility information are aware of applicable provisions and penalties for the misuse of information.

CMS uses the Trading Partner Agreement Form to capture certain information whereby a person certifies that they are fully aware of all penalties related to the use of PHI and their access to this data from the HETS application. The information is an attestation by the authorized representative of an entity that wishes to access the Medicare eligibility information to conduct real-time eligibility transactions. The authorized representative is a person responsible for business decisions on behalf of the Organization who is submitting the access request. The data captured includes the authorized representative's name, title contact number and the name of the submitting entity. Other data captured is the submitter's National Provider Identifier, business name, billing address, physical address, and telephone number.

The Trading Partner Agreement Form is also used by CMS to capture certain information whereby a person identifies the particular connectivity protocol that they will use to connect to CMS and specific organization information which is reviewed and authorized prior to the access being granted. *Form Number:* CMS–10157 (OMB control number: 0938–0960); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 250. (For policy questions regarding this collection contact William Money at 410–786–1956).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–22547 Filed 10–1–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4489]

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Supplemental Biologics License Application 125586/546 From AstraZeneca AB for Andexxa (Coagulation Factor Xa (Recombinant), Inactivated -zhzo); November 21, 2024

AGENCY: Food and Drug Administration, HHS.