public parking in proximity to the Allyn Site; however, GSA may pursue options to provide additional parking, such as entering into a lease with a commercial parking operator.

The design of the new courthouse is anticipated to begin in mid-2026, and the 3-year construction period is likely to commence in 2027. The new courthouse is expected to be completed and fully occupied by 2030. The exact sequence and timeline of construction activities (*e.g.,* site preparation, excavation, etc.) will be determined during design.

GSA intends to implement and comply with all mitigation measures and best management practices as detailed in the ROD.

Further information about the project can be viewed at: *http://gsa.gov/hartfordcourthouse.*

Jesse Lafreniere,

Director, Design and Construction Division, U.S. General Services Administration, PBS New England Region.

[FR Doc. 2025–11337 Filed 6–18–25; 8:45 am]

BILLING CODE 6820–RB–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10501, CMS–10846 and CMS–10578]

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 (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 August 19, 2025.

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, 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 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–10501 Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange

CMS–10846 Medicare Part D Manufacturer Discount Program

CMS–10578 Emergency Preparedness Requirements for Medicare and Medicaid Providers Participating Providers and Suppliers

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 Collections

1. *Type of Information Collection Request:* Revision of currently approved collection; *Title:* Healthcare Fraud Prevention Partnership (HFPP) Data Sharing and Information Exchange; *Use:* Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a–7c(a)(2)) authorizes the Secretary and the Attorney General to consult, and arrange for the sharing of data with, representatives of health plans for purposes of establishing a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. The result of this authority has been the establishment of the HFPP. The HFPP was officially established by a Charter in the fall of 2012 and signed by HHS Secretary Sibelius and U.S. Attorney General Holder. In December 2020, President Trump signed into law H.R.133—Consolidated Appropriations Act, 2021, which amended Section 1128C(a) of the Social Security Act (42 U.S.C. 1320a–7c(a)) providing explicit statutory authority for the Healthcare Fraud Prevention Partnership including the potential expansion of the public-private partnership analyses.

Data sharing within the HFPP primarily focuses on conducting studies for the purpose of combatting fraud, waste, and abuse. These studies are intended to target specific vulnerabilities within the payment systems in both the public and private healthcare sectors. The HFPP and its committees design and develop studies in coordination with the TTP. The core function of the TTP is to manage and execute the HFPP studies within the HFPP. *Form Number:* CMS–10501 (OMB control number: 0938–1251); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 28; *Number of Responses:* 28; *Total Annual Hours:* 120. (For questions regarding this collection, contact Maricruz Bonfante at (410–786–5086).

2. *Type of Information Collection Request:* Revision with change of the currently approved collection; *Title:* Medicare Part D Manufacturer Discount Program; *Use:* Congress enacted the Inflation Reduction Act of 2022, Public Law 117–169 (IRA). Section 11201 of the IRA eliminates the coverage gap phase of the Part D benefit. It also sunsets the coverage gap discount program (CGDP) after December 31, 2024, and amends the Social Security Act (the Act) to add section 1860D–14C, requiring the Secretary to establish a new Medicare Part D manufacturer discount program (MDP) beginning January 1, 2025. Under the MDP, participating manufacturers are required to provide discounts on their ''applicable drugs'' (brand drugs, biologics, and biosimilars) both in the initial coverage phase and in the catastrophic coverage phase of the Part D benefit.

Information in this collection is needed to set up agreements between manufacturers and CMS. Under section 1860D–14C(a) of the Act, such agreements are required for manufacturers in order to participate in the MDP and, under section 1860D43(a) of the Act, for their applicable drugs to be covered under Part D beginning in 2025. The information collected from manufacturers in the Health Plan Management System (HPMS) (Appendix A) is needed to create and execute MDP agreements and to determine which manufacturers qualify as a specified manufacturer or specified small manufacturer for phased-in discounts under section 1860D–14C(g)(4) of the Act. Banking information collected by the TPA from manufacturers and plan sponsors (Appendix B) is needed to prepare invoices and process financial transactions (deposits and payments) through the ACH. *Form Number:* CMS–10846 (OMB control number: 0938–1451); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 200; *Number of Responses:* 200; *Total Annual Hours:* 320. (For questions regarding this collection, contact Maricruz Bonfante at (410–786–5086).

3. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Emergency Preparedness Requirements for Medicare and Medicaid Providers Participating Providers and Suppliers; *Use:* This is a reinstatement of the information collection request that expired on January 31, 2023. The previous iteration of this OMB Control Number: 0938–1325 had a burden of 1,260,474 annual hours. For this requested reinstatement, with changes, the total annual burden hours for industry is 1,251,158 hours and the annual burden costs are $401,106,506.

Emergency Preparedness information collections were established as a result of the Omnibus final rule ''*Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,*'' 81 FR 63860 (September 16, 2016) (hereinafter ''*2016 Final Rule*''). This information collection request captures the burden necessary for existing providers and suppliers to maintain their emergency preparedness collection of information requirements. This request also captures the burden to develop and implement the emergency preparedness requirements for newly approved Medicare and Medicaid providers and suppliers, also referred to as facilities.

This information collection (''IC'') is an ''Omnibus'' request. The emergency preparedness Conditions of Participation (CoPs) apply to the 19 Medicare and Medicaid providers that are listed in the next section. However, for reasons discussed below, this information collection request captures the burden for 17 of the affected Medicare and Medicaid providers and suppliers.

This is a departure, as we normally submit information collection requests (''ICRs'') by provider and supplier type. For example, the collection of information(s) stemming from the Conditions of Participation for the ''Hospital'' provider type are under OMB Control Number: 0938–0328. The collection of information(s) stemming from the Conditions of Participations for the ''Hospice'' provider type are under OMB Control Number: 0938–1067, etc. We make this exception for continuity and simplicity. We continue to cross reference this emergency preparedness IC in each provider type's individual information collection request.

In response to past terrorist attacks, natural disasters, and the subsequent national need to refine the nation's strategy to handle emergency situations, there continues to be a coordinated effort across Federal agencies to establish a foundation for development and expansion of emergency preparedness systems.

This reinstatement includes a new facility type, Rural Emergency Hospitals (REHs), which was created in 2021, after the prior reinstatement for this package had been approved in 2020. Congress introduced the designation Rural Emergency Hospitals (REHs) as part of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260), which is codified at 42 United States Code § 1395x(kkk)(1) or Section 1861(kkk)(1) of the Social Security Act. REHs are subject to the Emergency Preparedness CoPs per 42 CFR 485.542 and are similar to the Critical Access Hospital (CAH's) Emergency Preparedness CoPs. *Form Number:* CMS–10578 (OMB control number 0938–1325); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 60,712; *Total Annual Responses:* 80,915; *Total Annual Hours:* 1,251,158. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

William N. Parham, III,

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

[FR Doc. 2025–11324 Filed 6–18–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0206; FDA–2024–E–0207; FDA–2024–E–0208]

Determination of Regulatory Review Period for Purposes of Patent Extension; QALSODY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for QALSODY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by August 19, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 17, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.