218171 was approved on December 18, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04491 Filed 3–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1001]

Developing Specifications for In-Home Disposal Systems for Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of a docket to solicit public comment on what specifications for in-home disposal systems, if application holders are required to make them available under the Opioid Analgesic Risk Evaluation and Mitigation Strategy, would be necessary to show that these systems may mitigate the serious risks of abuse or overdose involving these medications.

DATES: Submit either electronic or written comments by April 6, 2026.

ADDRESSES: FDA is establishing a docket for public comment on this notice. The docket number is FDA–2026–N–1001. The docket will close on April 6, 2026. Submit either electronic or written comments by April 6, 2026. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 6, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–1001 for ''Developing Specifications for In-Home Disposal Systems That May Be Made Available Through the Opioid Analgesic Risk Evaluation and Mitigation Strategy For Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://*

www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Purpose of Notice

The Agency is currently considering exercising its authority to require, through a Risk Evaluation and Mitigation Strategy (REMS), that a drug be dispensed to certain patients with safe disposal packaging or a safe disposal system (21 U.S.C. 355–1(e)(4)). Specifically, the Agency is considering whether to further modify the Opioid Analgesic (OA) REMS to require application holders of opioid analgesics dispensed in outpatient settings to make in-home disposal systems available to pharmacies and other outpatient dispensers. The purpose of this notice is to seek public comment on what specifications would be necessary to show that in-home disposal systems may mitigate the serious risks of abuse or overdose involving these medications.

II. Background

A. Public Health Need

Despite latest trends indicating decreased prescribing of opioid analgesics, abuse, misuse, accidental exposure, and overdose associated with prescription opioid analgesics remain serious problems in the United States. In 2024, prescription pain relievers, such as opioid analgesics, remained the most common class of prescription drugs misused (*i.e.,* used in any way not directed by a doctor) in the United States, with approximately 8.0 million people aged 12 years and older reporting past-year misuse (Ref. 1). Patients commonly report having unused opioid analgesics after treatment of acute pain, such as pain following surgical procedures (Refs. 2, 3, 4 and 5). Patients who are prescribed opioid analgesics to treat chronic pain may also have unused opioids when changing opioid therapy (new opioid ingredient or tablet strength), upon discontinuation of opioid therapy, or upon death. Accordingly, removing unused opioids from a home is an important public health intervention, and FDA's efforts to address the opioid crisis include a focus on encouraging appropriate disposal of unused opioid analgesics.

B. SUPPORT Act and REMS Authority

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271), signed into law on October 24, 2018, provided FDA several new authorities to address the opioid crisis. As enacted in 2018, section 505–1(e)(4)(B) of the Food, Drug, and Cosmetic Act (FD&C Act) authorized FDA to require through a REMS that safe disposal packaging or a safe disposal system for the purposes of rendering the drug non-retrievable [1] be dispensed to certain patients with opioids or other drugs that pose a serious risk of abuse or overdose if, among other conditions, FDA determines that such safe disposal packaging or system may mitigate such risks and is sufficiently available (21 U.S.C. 355–1(e)(4) (referencing 355–1(b)(1)(B) and (C))).[2] In December 2022, Congress removed the ''nonretrievable'' requirement, thereby expanding the scope of potential disposal options available for FDA to require through a REMS (Consolidated Appropriations Act, 2023, Pub. L. 117–328). Subsequently, in late 2025, Congress reauthorized the SUPPORT Act (the 2025 SUPPORT Act Reauthorization), which directs the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration, to publish guidance to facilitate the use of in-home safe disposal systems for applicable drugs (SUPPORT for Patients and Communities Reauthorization Act, 2025, Pub. L. 119–44).

C. FDA Previously Exercised SUPPORT Act Authority

FDA previously exercised its SUPPORT Act authority to expand disposal options through the OA REMS. When deciding whether to take this action, FDA considered the opioid disposal options available at the time and the impact and benefits of FDA requiring application holders, through the OA REMS, to provide a safe disposal option when those drugs are dispensed. The Agency solicited input from stakeholders at multiple points during its evaluation, including through an April 21, 2022, **Federal Register** notice entitled ''Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments'' (87 FR 23869) in which FDA solicited public comment on a potential modification to the OA REMS to require application holders of opioid analgesics dispensed in outpatient settings to make available prepaid mail-back envelopes.

In April 2023, the FDA notified application holders of opioid analgesics dispensed in outpatient settings that the OA REMS would require them to make available prepaid mail-back envelopes to outpatient pharmacies and other dispensers as an additional disposal option for patients. FDA approved that REMS modification in October 2024. Beginning March 31, 2025, outpatient pharmacies and dispensers could order prepaid mail-back envelopes from opioid analgesic application holders, free of charge, which they then could provide to patients prescribed opioid analgesics.

In choosing to require prepaid mail-back envelopes, the Agency recognized that mail-back envelopes, in particular, are one disposal option that has ''multiple favorable characteristics'' (87 FR 23872, Apr. 21, 2022): First, mail-back envelopes are relatively simple to use; their use involves fewer steps than in-home disposal systems, and, unlike collection kiosks, many people can use them without leaving the home. Second, mail-back envelopes are subject to longstanding, existing federal regulation and oversight, administered by the U.S. Drug Enforcement Administration (DEA) and United States Postal Service (USPS), which requires that mail-back envelopes be nondescript, fit for purpose, and be able to safely and

[1] Under the SUPPORT Act, *nonretrievable* was defined with an explicit cross-reference to a Drug Enforcement Agency (DEA) regulation, 21 CFR 1300.05. (Pub. L. 115–271). That regulation defines *non-retrievable,* in pertinent part, as: ''. . . the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes.'' 21 CFR 1300.05(b).

[2] The Agency interprets the term *abuse* as the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects. We interpret the term *overdose* to include fatal or non-fatal poisoning resulting from accidental (*e.g.,* in young children) or intentional exposure (*e.g.,* in settings of abuse or therapeutic misuse) to opioid analgesics. Though we recognize that certain language may perpetuate stigma and negative bias toward individuals who use substances or who have substance use disorders, we use *abuse* and *overdose* throughout this notice to align with language in the FD&C Act.

securely transport unused medicines from the patient's home to the location where they will be destroyed (87 FR 23872 at 23872, Apr. 21, 2022); 21 CFR 1300.05(b), 1317.70, 1317.90. Last, ''unlike other alternatives,'' the mail-back envelopes could meet the nonretrievability requirement that was in place at the time because DEA regulations require mail-back envelopes to be disposed of in a manner that renders them ''non-retrievable'' (87 FR 23872. 87 FR at 23872, Apr. 21, 2022). At the time of the modification, FDA expected (and still expects) that the mail-back envelope modification to the OA REMS provides patients with an added and underutilized safe disposal option that complements and does not displace disposal options already available outside of the REMS (87 FR 23872 at 23872 and 23870, Apr. 21, 2022).

The REMS modification also required OA REMS application holders to create a new written educational document for patients about the risks of unused opioid analgesics and the importance of their safe disposal that is provided to the patient with each mail-back envelope. FDA expects that any future modifications to the OA REMS to include additional safe disposal systems would be operationalized the same way: outpatient dispensers would have the ability to order mail-back envelopes and/or in-home disposal systems, and an educational document would accompany all disposal options.

III. Potential Further Modification to the OA REMS To Require In-Home Disposal Systems

FDA is now considering whether to further modify the OA REMS, using the same SUPPORT Act authority, to require that application holders also make commercially available in-home disposal systems available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option for patients. That analysis, currently underway, includes consideration of the public health need for additional opioid disposal options in the context of the ongoing opioid crisis and any new data regarding the impact that provision of in-home disposal options has on patients' opioid analgesic disposal behaviors.

Should FDA decide to require that commercially available in-home disposal systems, in addition to mail-back envelopes, be made available under the OA REMS, the Agency plans to set out certain specifications for systems to meet REMS requirements. The opioid analgesic application holders would then be required, pursuant to the REMS, to identify a system or more than one system that meet those specifications and make them available to patients in outpatient settings. For mail-back envelopes, the OA REMS was modified to require application holders to make available mail-back envelopes that meet specifications set out in USPS and DEA regulations (as described above). In contrast, no federal agency currently regulates in-home disposal systems for purposes of disposing of opioid analgesics. Thus, FDA plans to identify appropriate specifications for these systems.

The purpose of this notice is to seek input from the public on what specifications of in-home disposal systems under the OA REMS would be appropriate to show that these systems may mitigate the serious risk of opioid analgesic abuse and/or overdose, considering all the relevant factors that may affect these risks.[3] These inputs will also inform our implementation of the 2025 SUPPORT Act Reauthorization requirement that the Secretary publish guidance to facilitate the use of in-home safe disposal systems for applicable drugs.

A. FDA's Current Recommendations for Opioid Analgesic Disposal

FDA primarily recommends disposing of opioids using a take-back option (*i.e.,* kiosks in pharmacies, take-back events, or mail-back envelopes) (Ref. 6). If a take-back option is not readily available, FDA currently recommends that most opioids be flushed down the toilet. This recommendation differs from most other prescription drugs, which FDA recommends disposing by mixing them with an unpalatable substance and disposing of them in trash if a take-back option is not readily available. There are 11 opioids on FDA's ''Flush List,'' which lists those products that should be disposed of by flushing down the toilet. (Ref. 6). FDA does not recommend that opioid analgesics on the Flush List be disposed of in household trash because of their serious risk of abuse and fatal overdose. Given that in-home disposal systems are intended to be put in household trash, FDA's determination that these systems may mitigate the serious risks of abuse and/or overdose would therefore constitute a substantial change in FDA's recommendations for disposal of opioid analgesics.

[3] This notice is not soliciting input on how commercially available in-home disposal systems should be regulated beyond FDA's REMS authority.

B. Information About These Systems Obtained Thus Far

FDA has undertaken multiple efforts to obtain information about in-home disposal systems' capabilities and usability to inform a potential further modification to the OA REMS.

First, in June 2021, FDA requested information from nine commercially available in-home disposal system manufacturers to gain a better understanding of how their systems work and what testing, including validation studies, they had undertaken. In response to these requests, FDA received some information from six of the manufacturers, and a subset of the information was evaluated by an independent lab. It remains challenging to validate data on in-home disposal systems because there are no industry-wide agreed upon tests to evaluate in-home disposal systems for their intended purpose of disposing of opioid analgesics. Further, these systems use varying mechanisms to render the opioid unavailable, adding another layer of complexity in evaluating the submitted data.

Second, on April 4, 2023 (88 FR 19959), FDA issued a request for public comment about in-home disposal systems and announced the June 2023 National Academies of Sciences, Engineering, and Medicines' (NASEM) Forum on Drug Discovery, Development, and Translation public workshop entitled ''Defining and Evaluating In-Home Disposal Systems for Opioid Analgesics'' (''In-Home Disposal Systems for Opioid Analgesics; Request for Information'') (Docket No. FDA–2023–N–0917). The workshop featured invited experts to discuss the types of in-home drug disposal options that could be used to remove unused opioid analgesics from the home. The workshop included, among other things, presentations about and a discussion of the scientific, behavioral, and policy considerations for assessing the safety, use, and effectiveness of in-home drug disposal systems (see *https://www.nationalacademies.org/our-work/advancing-regulatory-science-for-defining-and-evaluating-in-home-safe-disposal-systems-a-workshop*). Comments submitted to the docket and made at the NASEM meeting identified some recommended assessments of these systems, including evaluating whether they are capable of rendering opioid analgesics sufficiently unavailable for abuse (assuming the in-home disposal system is used according to instructions) or overdose. Comments suggested that relevant specifications could include whether the system

changes the physical integrity of the drug formulation, renders the active ingredient unusable, is non-toxic and non-hazardous, timely deactivates the drug, and has an acceptable ease-of-use. Additionally, some manufacturers of in-home disposal systems submitted data about their in-home disposal systems to the docket.

Third, FDA reviewed the limited information available on real-world use experiences with commercially available in-home disposal systems. As discussed above, neither FDA nor any other federal agency regulates these systems for purposes of disposing of opioid analgesics, and thus, there are no requirements that in-home disposal system manufacturers or any other party report adverse events or other problems associated with use of these systems to FDA or any other agency. Nonetheless, available information from U.S. poison center cases and social media posts reflects some instances of accidental pediatric exposure to in-home disposal systems (without mention of exposure to opioids or other medications), as well as other exposures associated with unclear or misunderstood directions or inadequate patient counseling (*e.g.,* reports of patients who thought the disposal system was a separate medication that should be ingested, it should be used as a vehicle to administer a medication, or it could be ingested as an antidote to counteract adverse effects associated with opioid medications) and apparent system malfunction (*e.g.,* bags not sealing appropriately and foaming out before the bag could be resealed). When outcomes of such instances were shared, they were generally minor in severity.

Finally, FDA has commissioned a study by the University of Maryland-Baltimore (UMB) through the Center of Excellence in Regulatory Science and Innovation (CERSI) to assess commercially available in-home drug disposal products (''The Assessment of Commercially Available In-Home Drug Disposal Products,'' available at *https://www.fda.gov/science-research/advancing-regulatory-science/assessment-commercially-available-home-drug-disposal-products*). The overall goal of the project is to gain an understanding of the mechanisms of action, ingredients, safety, usability, and range of capabilities of commercially available in-home drug disposal systems. The CERSI project will evaluate various commercially available in-home disposal systems by testing them with multiple opioid analgesics, including immediate-release and extended-release formulations. Depending on each system's mechanism of action, the system will be analyzed for its ability to inactivate, sequester, and/or adsorb the opioid analgesic at various time intervals after the drug is placed into the in-home disposal system, following the manufacturer's instructions. The in-home disposal systems will also be tested to determine if the opioid analgesic can be recovered from the used disposal systems with commonly available household solvents such as lemon juice or alcohol. Additionally, a human factors study will be conducted to evaluate how users interact with a sample of commercially available in-home disposal systems and assess if they can correctly and safely use these systems. The results of the CERSI study will inform the appropriate specifications for these systems.

C. Additional Information Needed To Support a Modification To Require Safe In-Home Disposal Systems

Commercially available in-home disposal systems have differing characteristics that may impact their ability to mitigate the serious risks of opioid analgesic abuse and overdose. Although all in-home disposal systems are intended to render opioids or other medications safe for disposal in household trash, they vary in their mechanism of action (*e.g.,* carbon binding, chemical deactivation, sequestration), formulation (powder in envelopes, liquids in bottles), instructions for use, and the types and formulations of medications for which they can be used. Thus, the Agency intends to consider the specific characteristics of the disposal system to determine whether requiring application holders make it available through the OA REMS may mitigate a serious risk of abuse and/or overdose. Foremost, an in-home disposal system's ability to mitigate those risks depends on the extent to which it makes the opioid unavailable and the speed with which this occurs. The risk of accidental pediatric exposure may also be impacted by a disposal system's use of child-resistant packaging (recognizing that most in-home disposal systems require removing the opioid medication from its original, child-resistant packaging). In addition, if the used disposal system package is readily identifiable or if the opioid analgesic product can be readily identified within the used system (*e.g.,* because a prescription vial label identifies the contents or because tablet or capsule imprint codes remain readable), there may be a greater risk of attempted opioid retrieval from the system. These factors take on further importance considering that a modification to the OA REMS that promotes the use of in-home disposal systems would likely result in an increased number of used systems with potentially available opioid analgesics in household trash. Finally, in-home disposal systems vary in the complexity of use (*e.g.,* requiring the addition of water to a certain level or of a certain temperature, shaking for a specified period); if patients have difficulty using an in-home disposal system correctly, the capability of the systems to achieve their intended purpose may be adversely impacted or patients may be harmed. All these factors may be relevant for the Agency to consider when deciding whether to modify the OA REMS to require that in-home disposal systems be made available as an additional safe disposal option and, if so decided, what specifications should apply to those systems.

IV. Questions for Comment

The Agency is seeking public input on the specifications in-home disposal systems would need to meet in order for FDA to require OA application holders to make these systems available under the REMS. Please explain your rationale for your input.

1. What amount of an opioid product's active ingredient would an in-home disposal system need to render unavailable, when used according to the system's instructions? For example, should we require that the system render at least 95% of the opioid unavailable? If not, would a lower threshold, such as 80%, be acceptable?

- How does the variation in opioid product dosage strength, dosage form, and potency affect this consideration?

2. What should be the maximum time for an in-home disposal system to make the specified percentage of opioid product's active ingredient unavailable? For example, would the threshold percentage contemplated in Question 1 need to be achieved within 2 hours in order to minimize the time the opioid is available for abuse and/or overdose? 8 hours? 24 hours?

3. Should FDA consider the in-home disposal system's susceptibility to manipulation after it is used? If so, how should this be assessed? For example, should FDA require that the opioid product's active ingredient remain unavailable after manipulating the used in-home disposal system with commonly available household solvents (*e.g.,* alcohol, lemon juice)? If so, to what extent? For example, would 75% of the opioid product's active ingredient need to remain unavailable? Should it be higher, or would a lower threshold, such as 50%, be acceptable?

- How does the variation in opioid product dosage strength, dosage form, and potency affect this consideration?

4. How should we consider the following characteristics in determining the specifications for any in-home disposal system?

- Whether, or the extent to which, it is apparent that the used disposal system may contain opioids.
- The potential risks associated with accidental exposure to the in-home disposal system (*e.g.,* ingestion, skin/eye exposure, inhalation). Consider difference in risk for adults, children, and pets.
- Use of child-resistant packaging.
- User interface of an in-home disposal system: *i.e.,* does its design support safe and correct use of the system.
- Robustness in light of expected use error: *i.e.,* does the system still work sufficiently well in real world use scenarios, which may include some reasonably anticipated use errors (*e.g.,* overfilling, incorrect water temperature, insufficient shaking).

5. Are there any other specifications FDA should require or characteristics that FDA should consider? Discuss other actions FDA could take in addition to, or in support of, an in-home disposal system REMS requirement to increase safe disposal of unused opioid analgesics.

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some references may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the web addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. * Substance Abuse and Mental Health Services Administration, ''Key Substance Use and Mental Health Indicators in the United States: Results from the 2024 National Survey on Drug Use and Health'' (HHS Publication No. PEP25–07–007, NSDUH Series H–60), Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration (2025), available at *https://www.samhsa.gov/data/sites/default/files/reports/rpt56287/2024-nsduh-annual-national/2024-nsduh-annual-national-html-071425-edited/2024-nsduh-annual-national.htm*.
2. Mallama, C.A., C. Greene, A.A. Alexandridis, et al., ''Patient-Reported Opioid Analgesic Use After Discharge From Surgical Procedures: A Systematic Review,'' *Pain Medicine,* vol. 23(1), pp. 22–29, 2022, *https://doi.org/10.1093/pm/pnab244*.
3. Bicket, M.C., J.J. Long, P.J. Pronovost, et al., ''Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review,'' *JAMA Surgery,* vol. 152(11), pp. 1066–1071, 2017, *https://doi.org/10.1001/jamasurg.2017.0831*.
4. Collins, C.L., K. England, SW Conrad, et al., ''Patient-Reported Duration of Opioid Analgesic Use After Discharge from Surgical Procedures or Other Types of Acute Pain: A Scoping Review,'' *Pain Medicine,* vol. 26(9), pp. 503–514, 2025, *https://doi.org/10.1093/pm/pnaf029*.
5. Atwood, K., T. Shackleford, W. Lemons, et al., ''Post Discharge Opioid Use After Total Hip and Total Knee Arthroplasty,'' *Arthroplasty Today,* vol. 7, 2021, pp. 126–129, *https://doi.org/10.1016/j.artd.2020.12.021*.
6. * FDA, ''Disposal of Unused Medicines: What You Should Know—Learn How to Dispose of Unused or Expired Drugs,'' accessed October 31, 2021, available at *https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04479 Filed 3–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to the Office of Management and Budget (OMB) for Review and Approval; Public Comment Request; Standardized Work Plan Form for Use with Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements, OMB No. 0906–0049—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to OMB. Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than May 5, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983. Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Standardized Work Plan (SWP) Form for Use with Applications to HRSA's Bureau of Health Workforce (BHW) Research and Training Grants and Cooperative Agreements, OMB No. 0906–0049—Revision

Abstract: HRSA BHW requires applicants for training and research grants and cooperative agreements to submit work plans via the SWP form. Information in the SWP describes the timeframes and progress required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement. Applicants use the SWP form when they submit their proposals, and award recipients and Project Officers use the SWP information to assist in monitoring progress once HRSA makes the awards. After awards are made, recipients complete a Quarterly Progress Update (QPU) to provide information to BHW on a quarterly basis on each activity listed in the SWP.

Need and Proposed Use of the Information: The QPU is completed via HRSA's Electronic Handbook system and prompts recipients to report on progress of activities that were submitted using the SWP in the original application. The QPU automatically populates activities from the recipient's SWP form on a quarterly basis. For each activity listed in the submitted SWP for any particular quarter within the project period, recipients select and submit a single selection response for each activity status from a pull-down menu with five options: (1) Activity is on