For policy questions regarding this collection contact Lucia Patrone at 410–786–8621.

William N. Parham, III,

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

[FR Doc. 2026–16455 Filed 8–12–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5547–N]

Medicare Program; Alternative Payment Model (APM) Incentive Payment Advisory for Clinicians—Request for Current Billing Information for Qualifying APM Participants

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Payment advisory.

SUMMARY: This advisory is to alert certain clinicians who are Qualifying Alternative Payment Model (APM) participants (QPs) and eligible to receive an APM Incentive Payment that the Centers for Medicare & Medicaid Services (CMS) does not have the current billing information needed to disburse the payment. This advisory provides information to these clinicians on how to update their billing information to receive this payment for the 2026 payment year.

DATES: This notice is applicable on August 13, 2026.

FOR FURTHER INFORMATION CONTACT: Tanya Dorm, (667) 290–9530.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare Quality Payment Program, an eligible clinician who participates in an Advanced Alternative Payment Model (APM) and meets or exceeds the applicable payment amount or patient count thresholds for a performance period is a qualifying APM participant (QP) for that year. For payment years 2019 through 2026, which respectively correspond to the QP performance periods for 2017 through 2024, an eligible clinician who attains QP status for a year earns a lump sum APM incentive payment that is paid in the payment year. For payment years 2021 through 2024, the amount of the APM incentive payment is equal to 5 percent of the estimated aggregate paid amounts for covered professional services furnished by the QP during the calendar year immediately preceding the payment year. The APM incentive payment percentage is 3.5 percent for the 2023 performance year and 2025 payment year, and 1.88 percent for the 2024 performance year and 2026 payment year.

II. Provisions of the Advisory

The Centers for Medicare & Medicaid Services (CMS) has identified those eligible clinicians who attained QP status in the 2024 performance period and earned a 1.88 percent APM incentive payment for the 2026 payment year based on aggregate paid amounts for the covered professional services they furnished in the calendar year 2025 base period.

When CMS processed the 2026 APM incentive payments, CMS was unable to identify a taxpayer identification number (TIN) or TINs associated with some QPs and was therefore unable to disburse the payment. To successfully issue the APM incentive payment for the 2026 payment year, CMS is requesting assistance identifying current Medicare billing information for these QPs in accordance with 42 CFR 414.1450(c)(8).

CMS has compiled a list of QPs for whom we were unable to identify any associated TIN to which we can make the APM incentive payment. These QPs, and any others who anticipated receiving an APM Incentive Payment but have not, should follow the instructions to provide CMS with updated Medicare billing information at the following web address: 2026 QP Notice for APM Incentive Payment.

If you have any questions concerning submission of information through the Quality Payment Program (QPP) website, please contact the QPP Help Desk at 1–866–288–8292.

All information must be received by October 13, 2026. After that date, any claim to an APM incentive payment for the 2026 payment period based on an eligible clinician's QP status for the 2024 QP performance period will be forfeited. To facilitate payment, please include all required documentation as specified in the previous link.

All submissions received on or before October 13, 2026, will be held and processed after the close of the response period. CMS will not accept requests for additional payment review or reprocessing after October 13, 2026. Any claim related to a 2025 APM Incentive that is submitted after October 13, 2026, will be forfeited and will not be considered for review. If your banking information has changed within the last year, we strongly recommend submitting a voided check and CMS Form 588 [1] to help avoid payment delays. Please note that CMS will not notify you if there is an issue processing your payment.

III. Collection of Information Requirements

This advisory is intended to alert certain QPs that CMS is requesting assistance identifying current Medicare billing information so that we can disburse APM incentive payments. This request for follow-up information is exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) as specified under implementing regulation 5 CFR 1320.3(h)(9) with regard to the clarification of responses.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–16472 Filed 8–12–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6530]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry titled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' This guidance outlines the recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of new drug or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This guidance

[1] Form CMS–588 is currently approved under OMB control number 0938–0626.

finalizes the draft guidance of the same title issued on September 22, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on August 13, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2017–D–6530 for ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' Received comments 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Mercier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5390, Silver Spring, MD 20993–0002, 301–796–0957; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry titled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' This guidance outlines the recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of drug or biological products as agreed upon during the Prescription Drug User Fee Act (PDUFA) VII negotiations. This guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings. The guidance describes the different meeting types, formats, and timelines associated with those requests. It also provides industry with the information necessary to have a complete meeting request and background package to help facilitate the meeting to gain useful feedback for product development. The guidance provides examples to help guide stakeholders on selecting and requesting the proper meeting type for a given scenario.

This guidance finalizes the draft guidance titled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' issued on September 22, 2023 (88 FR 65395). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include additional scenarios for Type D meetings, clarification on Initial Targeted Engagement for Regulatory Advice on CDER and CBER ProducTs meetings, and the addition of information on meeting formats that FDA may grant. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' It does not establish any rights for any person and is not binding on FDA or the public.

You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 relating to submission of investigational new drug applications and related meetings, including pre-IND meetings, INTERACT meetings, meetings at the ''End-of-phase 2'' and ''pre-NDA'' stages, pre-new drug application (pre-NDA/pre-sNDA)/pre-biologics license application (pre-BLA/pre-sBLA) meetings governed by 21 CFR 312.47, and dispute resolution meetings under 21 CFR 312.48, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to submission of new drug applications, amendments and supplemental applications and related meetings, including meetings between sponsors or applicants and FDA under 21 CFR 314.102, meetings requested within 30 days of FDA issuance of a refuse-to-file letter under 21 CFR 314.101, and dispute resolution meetings under 21 CFR 314.103, as well as the guidance ''Formal Dispute Resolution: Sponsor Appeals Above the Division Level,'' have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to the submission of biologics license applications and related meetings, including formal meetings between sponsors or applicants and FDA, have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16452 Filed 8–12–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3120]

Kremers Urban Pharmaceuticals, Inc.; Grant of Hearing Request Regarding a Proposal To Withdraw Approval of an Abbreviated New Drug Application for Extended-Release Methylphenidate Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a formal evidentiary public hearing on the proposal to withdraw approval of the abbreviated new drug application (ANDA) 091695, submitted by Kremers Urban Pharmaceuticals, Inc. (Kremers) for methylphenidate hydrochloride extended-release tablets. On October 18, 2016, the Director of FDA's Center for Drug Evaluation and Research (CDER) published a notice of opportunity for hearing on a proposal to withdraw approval of ANDA 091695. Kremers submitted a timely request for hearing on that proposal. This notice of hearing provides factual and legal information concerning CDER's proposal to withdraw approval of ANDA 091695 and identifies the factual issues that will be the subject of the evidentiary hearing.

DATES: A prehearing conference will be held on September 28, 2026, beginning at 10:00 a.m. Eastern Daylight Time. Any person wishing to participate in this hearing shall submit a written notice of participation by September 14, 2026. Disclosure of data and information as required by 21 CFR 12.85(b) must be made by October 13, 2026.

ADDRESSES: You may submit a written notice of participation and data and information required under 21 CFR 12.85 by either of the following methods:

Electronic Submissions

Submit electronically in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting information. Information submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your information will be made public, you are solely responsible for ensuring that your information 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 information, that information will be posted on *https://www.regulations.gov.*
- If you want to submit any information with confidential information that you do not wish to be made available to the public, submit the information as a written/paper submission and in the manner detailed (see ''Written/Paper Submission'' 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 submissions sent to the Dockets Management Staff, FDA will post your submission, as well as any attachments, except for the information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–3120 for ''Kremers Urban Pharmaceuticals, Inc.; Grant of Hearing Request Regarding a Proposal to Withdraw Approval of an Abbreviated New Drug Application for Extended-Release Methylphenidate Tablets.'' Received submissions 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 make a submission with confidential information that you do not wish to be made publicly available, send your submissions 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 any decisions on this matter. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and