

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.

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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 588¹ 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.

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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.