Administration, 301–796–2031, *OCE-Guidances@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, Institutional Review Boards (IRBs), and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. Specifically, this guidance includes recommendations regarding expanding eligibility criteria to include patients with a wider range of performance status, and is intended to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

This guidance finalizes the draft guidance entitled ''Cancer Clinical Trial Eligibility Criteria: Performance Status'' issued on April 26, 2024 (89 FR 32442). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include updates on additional considerations for sponsors (*i.e.,* impact of including patients with lower performance status on trial retention and sample size) and minor revisions for 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 ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' 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. This guidance is also being issued consistent with FDA regulations in 21 CFR 312.145, 314.445, and 601.29, which provide that FDA will make guidance documents available to facilitate compliance with certain requirements in 21 CFR parts 312, 314, and 601, respectively.

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 Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15185 Filed 7–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–3406]

Fee Rate for Using a Priority Review Voucher in Fiscal Year 2026; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is amending a notice entitled ''Fee Rate for Using a Priority Review Voucher in Fiscal Year 2026'' that appeared in the **Federal Register** on September 18, 2025. The notice established the FY 2026 priority review fee rate applicable to submission of eligible applications for review of human drug or biological products using a rare pediatric disease, material threat medical countermeasure, or tropical disease priority review voucher and outlined the payment procedures for such fees. This amendment is being made to reflect that on February 3, 2026, Congress amended section 529 of the FD&C Act, including to require a sponsor of a human drug application that is the subject of a rare pediatric disease priority review voucher to submit a priority review user fee ''upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used.''

FOR FURTHER INFORMATION CONTACT: Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993–0002, 301–796–2771, *CDER_ARC_Program@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 18, 2025 (90 FR 45041), in FR Doc. 2025–18075, the following corrections are made:

1. On page 45041, in the third column, the second sentence in footnote #1 is revised to state only the following: ''Section 529(b)(5) of the FD&C Act provides that after September 30, 2029, FDA may not award any rare pediatric disease priority review vouchers.''

2. On page 45043, in the second column, in section IV.B titled ''Priority Review Voucher User Fee Due Date,'' the first sentence is revised to state, ''Under sections 524(c)(4)(A) (tropical disease priority review user fee), 529(c)(4)(A) (rare pediatric disease priority review user fee), and 565A(c)(4)(A) (material threat MCM priority review user fee) of the FD&C Act, the priority review user fee is due (*i.e.,* the obligation to pay the fee is incurred) upon submission of a human drug application for which the priority review voucher is used.'' The second paragraph in section IV.B is removed. A new paragraph is inserted: ''Given the recent amendment to section 529, FDA is updating the electronic Form FDA 3397, Prescription Drug User Fee Coversheet to allow sponsors the option to select for use of a rare pediatric disease priority review voucher. Generally, if a sponsor selects for use of a tropical disease, material threat MCM, or rare pediatric disease priority review voucher on Form FDA 3397, the form will be placed on hold while FDA completes its review of the priority review voucher redemption. Once the hold is lifted, a sponsor can proceed with submission of the completed Form FDA 3397 and payment of the applicable fees.'' Footnote #7 is revised to state, ''In the case of a ''rolling review'' application (as discussed in FDA's May 2014 guidance entitled Expedited Programs for Serious

Conditions—Drugs and Biologics, available at: *https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf*) for which a tropical disease priority review voucher, rare pediatric disease priority review voucher, or material threat MCM priority review voucher is redeemed, FDA considers the application to be submitted on the date FDA receives the final portion of the application that the applicant identifies as complete.''

3. On page 45043, in the third column, in section V.B titled ''Wire Transfer Payment Process,'' the second sentence is deleted, and the third sentence is revised as follows: ''For all priority reviews, please use the unique user fee ID number generated for the *Pay.gov* feature.)''

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15147 Filed 7–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form

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 the Office of Management and Budget (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 September 28, 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.

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

Information Collection Request Title: Applicant Organizational National Provider Identifiers and Centers for Medicare & Medicaid Services Certification Numbers Form, OMB No. 0906–xxxx New.

Abstract: HRSA is proposing a new form to collect organizational National Provider Identifiers (Type 2 NPIs) and CMS Certification Numbers (CCNs) from organizations that apply for HRSA award funding through *Grants.gov*. The form will be completed as part of the *Grants.gov* funding application. This collection is limited to organizational identifiers and will only collect an NPI and/or CCN only from organizations that already have one. An organization is not required to have, or to obtain, an NPI or CCN in order to apply for or receive HRSA funding, and individual applicants (persons) are not asked to provide an individual (Type 1) NPI. Organizational NPIs are issued by the Centers for Medicare & Medicaid Services (CMS) through the National Plan and Provider Enumeration System. CCNs are issued by CMS to providers and suppliers that obtain Medicare or Medicaid certification.

The purpose of this proposed collection is to strengthen the evidence HRSA uses to understand how it meets its mission of improving health outcomes through access to quality services, a skilled health workforce, and innovative, high-value programs. This collection is authorized under section 301 of the Public Health Service Act (42 U.S.C. 241), which authorizes the Secretary of Health and Human Services to conduct and support research, investigations, experiments, demonstrations, and studies relating to the causes; diagnosis; treatment; control; and prevention of disease, and to collect and make available information on those activities, including the provision of technical assistance on statistical methods.

HRSA collects this information to support research, program evaluation, and evidence-building consistent with its broader obligations to measure whether award recipients meet program objectives (*e.g.,* 2 CFR 200.301(a)) and to ensure the data underlying HRSA's performance reporting are reliable and accurate (*e.g.,* 31 U.S.C. 1115(b)(7)–(8)), and consistent with the agency evidence-building plan obligations of the Foundations for Evidence-Based Policymaking Act of 2018 (see 5 U.S.C. 312). These provisions inform why reliable provider identity data are useful to HRSA; the authority for this collection is 42 U.S.C. 241. Further, collecting information will enhance accountability in HRSA funding and enable the agency to minimize fraud, waste, and abuse by ensuring that its funding of entities is non-duplicative with funding provided by CMS.

Linking HRSA program data to other datasets, and particularly to datasets at CMS, is currently difficult because HRSA lacks an identifier that reliably and consistently identifies funded organizations across its many programs and across externally available health-care delivery-system data. The Unique Entity Identifier (UEI) obtained from *SAM.gov* identifies the legal entity that receives an award, but it is not used in health-care transactions and does not appear in CMS claims, encounter, certification, or quality datasets. Organizational NPIs and CCNs address this gap because they are already embedded as standard provider-identity keys in widely used, publicly available CMS datasets. The organizational NPI is the standard unique identifier for organization health care providers used in HIPAA-standard transactions and is therefore a stable, externally recognized organizational key; this descriptive fact about how NPIs are used is the reason HRSA considers the NPI a reliable identifier, and is not the legal authority for this collection. CCNs identify Medicare- and Medicaid-certified institutional providers and are the standard key for linking certified facilities to CMS institutional claims, certification files, cost reports, and facility-level quality data.

Need and Proposed Use of the Information: All applicants for HRSA funding through *Grants.gov* must obtain a UEI from *SAM.gov* before beginning a funding application. Because UEI does not appear in CMS provider and claims data, collecting organizational NPIs and CCNs from organizations that already have them allows HRSA to link its program and award data to publicly available external datasets that use those identifiers. Such linkage supports more accurate, efficient, and credible agency analyses of program reach, utilization, cost, quality, and outcomes.

For organizational applicants, the organizational NPI and CCN function as enterprise-level provider-identity keys