

HRSA’s assessment of the financial stability of your organization. HRSA reserves the right to conduct site visits and/or use the current compliance status to inform final funding decisions.

Award Notice: HRSA anticipates issuing the Notice of Award approximately 30 days prior to your budget period start date.

Thomas J. Engels,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Pediatric Mental Health Care Access Program

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

ACTION: Announcing supplements for Pediatric Mental Health Care Access Program (PMHCA) award recipients to continue expansion activities and

ensure consistent funding is offered across all award recipients.

SUMMARY: HRSA is announcing supplemental funding for 19 PMHCA (U4A) award recipients to continue to address the national surge in behavioral health needs among children and adolescents. These supplemental awards, funded through fiscal year (FY) 2025 appropriations, will ensure consistent support across all 29 PMHCA recipients. While 10 recipients previously received forward funding of supplemental funds, 19 did not due to availability of funds; this supplemental funding will bring parity across the program. HRSA previously provided supplemental funding to these 19 recipients for similar activities in FY 2023 and FY 2024. With this support, recipients will continue to enhance the behavioral health workforce capacity in pediatric primary care, school settings, and emergency departments to address the growing behavioral health needs among children and adolescents.

FOR FURTHER INFORMATION CONTACT: Lauren Ramos, Director of Division of Maternal and Child Health Workforce Development, Health Resources and

Services Administration, at *Iramos@hrsa.gov* or 301–443–6091.

SUPPLEMENTARY INFORMATION: Intended Recipient(s) of the Award: Nineteen PMHCA award recipients will be eligible to receive supplemental awards to continue to address the national surge in behavioral health needs among children and adolescents. These award recipients are listed in Table 1. *Note:* These 19 PMHCA award recipients received \$115,291 of total available funds for this funding action in January 2025. HRSA will award the remaining \$139,709 available for the funding action upon the publishing of this **Federal Register** notice. A statutory requirement at 42 U.S.C. 254c–19(f) (§ 330M(f) of the Public Health Service Act) requires that PMHCA award recipients match federal funding with a 20 percent non-federal match.

Amount of Non-Competitive Award(s): Total \$2,654,471 for 19 awards (average \$139,709 per award).

Project Period: September 30, 2025, to September 29, 2026.

Assistance Listing Number: 93.110.

Award Instrument: Non-competitive Supplement for Services.

Authority: 42 U.S.C. 254c–19 (§ 330M of the Public Health Service Act).

TABLE 1—19 U4A RECIPIENTS AND AWARD AMOUNTS

Original award number	Organization name	Supplement/ increase to base for 19 U4A PMHCA awardees	Total funding (Federal + non-Federal)
U4AMC53375	My Health Resources of Tarrant County	\$139,709	\$167,651
U4AMC53368	Kentucky Cabinet for Health and Family Services	139,709	167,651
U4AMC53366	West Virginia Department of Health and Human Resources	139,709	167,651
U4AMC53370	New Mexico Department of Health	139,709	167,651
U4AMC53373	Indiana Family and Social Services Administration	139,709	167,651
U4AMC53377	Republic Of Palau	139,709	167,651
U4AMC53379	Red Lake Band of Chippewa Indians	139,709	167,651
U4AMC53384	Virgin Islands Department of Health Group	139,709	167,651
U4AMC53361	Illinois Department of Public Health	139,709	167,651
U4AMC53359	Commonwealth Healthcare Corporation	139,709	167,651
U4AMC53376	Oklahoma Department of Mental Health and Substance Abuse Services	139,709	167,651
U4AMC53374	Minnesota Department of Health	139,709	167,651
U4AMC53358	Chickasaw Nation	139,709	167,651
U4AMC53372	Vermont Agency of Human Services	139,709	167,651
U4AMC53381	South Carolina Department of Mental Health	139,709	167,651
U4AMC53382	Tennessee Department of Health	139,709	167,651
U4AMC53369	Louisiana Department of Health	139,709	167,651
U4AMC54741	Wyoming Department of Health	139,709	167,651
U4AMC53364	FSM Department of Health and Social Affairs	139,709	167,651

Purpose/Justification: HRSA is issuing non-competitive supplemental funds in FY 2025 for 19 PMHCA award recipients to continue to address behavioral health needs among children and adolescents. HRSA provided Bipartisan Safer Communities Act emergency expansion awards in FY

2022 to 29 PMHCA U4A award recipients to expand PMHCA services to new providers and practices and to school-based and emergency department settings. In FY 2023, 10 PMHCA award recipients received 36 months of forward funding of supplemental funds to continue

expansion activities for the remaining period of performance (September 30, 2023, to September 29, 2026). One award recipient received 12 months of forward funding of supplemental funds for the same purpose for FY 2023 (September 30, 2023, to September 29, 2024). Forward funding of supplemental

funds was offered to these recipients with the intent to offer the remaining 19 PMHCA award recipients with the same level of funding through annual supplements in FY 2024 and FY 2025.

HRSA will offer supplemental funding for all 29 PMHCA U4A current award recipients in a manner that ensures all 29 award recipients are offered the same total amount of funding over a 3-year timeframe. If PMHCA current award recipients decline supplemental funding, that declined funding will be distributed among remaining recipients as allowable. The intended date of supplemental funding is September 30, 2025, to September 29, 2026, which falls within the current period of performance. In FY 2025, annual appropriation funds for PMHCA award recipients will be tracked separately from concurrent PMHCA awards.

PMHCA program award recipients will continue to expand the reach and capacity of PMHCA programs started in FY 2022 to provide training and tele-consult support to pediatric primary care providers and providers in other settings, including emergency departments and educational agencies and schools. The above activities are within the original scope of the PMHCA program (HRSA–22–121, and HRSA–21–122).

Thomas J. Engels,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction

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

ACTION: Announcement of application process for the 340B Rebate Model Pilot Program and request for public comment; Correction.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Health Resources and Service Administration (HRSA), Office of Pharmacy Affairs (OPA), which administers the 340B Drug Pricing Program (340B Program), is issuing this Notice to announce the availability of a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying

drug manufacturers to effectuate the 340B ceiling price on select drugs to all covered entities, and to collect comments on the structure and application process of the 340B Rebate Model Pilot Program, as outlined in this Notice. OPA will consider comments received but is under no obligation to respond to or act on the comments. This Notice is effective immediately as published, unless revised by a future notice. OPA reserves the right to issue revisions or addenda to this Notice at a later date (including, but not limited to, revisions or addenda informed by public comment).

DATES: Submit comments no later than September 8, 2025.

ADDRESSES: Electronic comments should be submitted *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the instructions on the website for submitting comments. Include the HHS Docket No. HRSA–2025–14619 in your comments. All comments received will be posted without change to <https://www.regulations.gov>. Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

FOR FURTHER INFORMATION CONTACT: Chantelle Britton, Director, Office of Pharmacy Affairs, HRSA, 5600 Fishers Lane, Mail Stop 14W52, Rockville, MD 20857; email: 340Bpricing@hrsa.gov; telephone 301–594–4353.

SUPPLEMENTARY INFORMATION: OPA has received inquiries from manufacturers related to different proposed rebate models for the 340B Program, primarily to address 340B and Maximum Fair Price (MFP) deduplication,¹ but also to facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion.

A “rebate” for purposes of this pilot program, means a reimbursement made

¹ As stated in Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026, “in accordance with section 1193(d)(1) of the Social Security Act, the Primary Manufacturer of a selected drug is not required to provide access to the Maximum Fair Price (MFP) for a selected drug to MFP-eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the (Public Health Service (PHS)) Act if the selected drug is subject to an agreement described in section 340B(a)(1) of the PHS Act and the 340B ceiling price (defined in section 340B(a)(1) of the PHS Act is lower than the MFP for such selected drug. Under section 1193(d)(2) of the Social Security Act, the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a deduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug.”

from the manufacturer to the covered entity in the amount of the standard acquisition cost (*i.e.*, wholesale acquisition cost) of a covered outpatient drug less the statutory 340B ceiling price as defined at section 340B(a)(1) of the Public Health Service Act (PHSA).

Whereas the 340B Program has traditionally operated as an upfront discount program (*i.e.*, a covered entity purchases a covered outpatient drug at the discounted 340B price), under a rebate model, a covered entity would pay for the drug at a higher price upfront and then later receive a post-purchase rebate that reflects the difference between the higher initial price and the 340B price. Section 340B(a)(1) of the PHS Act states, “[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [designated prices].” As the Department has previously informed stakeholders, implementing a rebate model without Secretarial approval would violate section 340B(a)(1) of the PHS Act.

Due to the significant amount of feedback received from (or on behalf of) manufacturers and covered entities regarding implementation of rebate models, and in light of the fact that rebate models could fundamentally shift how the 340B Program has operated for over 30 years, OPA is inviting certain drug manufacturers, that meet the criteria described below, to apply for participation in a voluntary 340B Rebate Model Pilot Program for a minimum of 1 year. OPA is introducing this pilot program to test the rebate model on a select group of drugs (as described below) in a methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved. OPA is also implementing this pilot to better understand the merits and shortcomings of the rebate model from stakeholders’ perspectives, and to inform OPA consideration of any future 340B rebate models consistent with the 340B statute and the Administration’s goals.

The scope of this voluntary 340B Rebate Model Pilot Program will be limited to the NDC–11s included on the CMS Medicare Drug Price Negotiation Selected Drug List,² regardless of payer.

² Medicare Drug Price Negotiation Selected Drug List, available at <https://www.cms.gov/files/zip/medicare-drug-price-negotiation-selected-drug-list.zip>.