containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Abiraterone acetate.
Acetaminophen; Butalbital.
Albuterol sulfate.
Alectinib hydrochloride.
Amantadine hydrochloride.
Amifampridine.
Aspirin.
Azilsartan kamedoxomil.
Azilsartan kamedoxomil; Chlorthalidone.
Betamethasone acetate; Betamethasone sodium phosphate.
Betaxolol hydrochloride.
Brimonidine tartrate (multiple reference listed drugs).
Brimonidine tartrate; Brinzolamide.
Brinzolamide.
Cabotegravir.
Cabotegravir; Rilpivirine.
Carglumic acid.
Clevidipine.
Clotrimazole.
Cobicistat; Elvitegravir; Emtricitabine; Tenofovir disoproxil fumarate.
Cyclobenzaprine hydrochloride.
Dorzolamide hydrochloride.
Fluticasone furoate.
Fluticasone furoate; Umeclidinium bromide; Vilanterol trifenatate.
Fluticasone furoate; Vilanterol trifenatate.
Fluticasone propionate.
Fluticasone propionate; Salmeterol xinafoate.
Glatiramer acetate.
Hydroxyurea.
Isavuconazonium sulfate.
Lasmiditan succinate.
Latanoprost.
Levomilnacipran hydrochloride.
Lumateperone tosylate.
Medroxyprogesterone acetate (multiple reference listed drugs).
Metformin hydrochloride.
Methylprednisolone acetate.
Metoprolol succinate.
Miconazole nitrate.
Naftifine hydrochloride (multiple reference listed drugs).
Oxiconazole nitrate (multiple reference listed drugs).
Paliperidone palmitate.
Penicillin G benzathine.
Phentermine hydrochloride; Topiramate.
Ponatinib hydrochloride.
Posaconazole.
Progesterone.
Ranitidine hydrochloride.
Risperidone.
Semaglutide.
Topiramate (multiple reference listed drugs).
Torsemide.
Trazodone hydrochloride.
Triamcinolone acetonide.
Umeclidinium bromide.
Umeclidinium bromide; Vilanterol trifenatate.
Venlafaxine hydrochloride.
Zonisamide.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

IV. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

V. Electronic Access

Persons with access to the internet may obtain the draft 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. 2025–19345 Filed 10–1–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding to the National Rural Health Policy, Community, and Collaboration Program

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA provided supplemental funds to the sole award recipient for the National Rural Health Policy, Community, and Collaboration Program under HRSA–24–003.

FOR FURTHER INFORMATION CONTACT: Alexa Ofori, Senior Advisor, Federal Office of Rural Health Policy, HRSA, at *aofori@hrsa.gov* and 301–945–3986.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: The National Rural Health Association (NRHA).

Amount of Non-Competitive Award: One award for $644,000.

Project Period: August 1, 2024, to July 31, 2029.

Assistance Listing Number: 93.155.

Award Instrument: Non-competitive supplement for services.

Authority: Section 711 of the Social Security Act (42 U.S.C. 912).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, state	Award amount
U16RH03702	National Rural Health Association	Leawood, KS	$644,000

Justification: NRHA was provided supplemental funds to identify, engage, educate, and collaborate with rural stakeholders on national rural health issues and promising practices to improve health care in rural areas nationwide. These activities build on past and ongoing NRHA projects supported by the Federal Office of Rural

Health Policy and align with the goals of the program to educate rural stakeholders and facilitate collaboration with key stakeholders to improve the exchange of information and promising practices that support rural health.

Thomas J. Engels,

Administrator.

[FR Doc. 2025–19249 Filed 10–1–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding to the National Rural Health Information Clearinghouse Program

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA provided supplemental funds to the sole award recipient of the National Rural Health Information Clearinghouse Program under HRSA–25–009 to provide information, data, and tools related to rural health to support improving health care in rural areas.

FOR FURTHER INFORMATION CONTACT: Sarah Scott, Federal Office of Rural Health Policy, HRSA, at *sscott2@hrsa.gov* and (301) 287–2619.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: The University of North Dakota.

Amount of Non-Competitive Award: One award for $545,000.

Project Period: June 1, 2025, to May 31, 2030.

Assistance Listing (CFDA) Number: 93.223.

Award Instrument: Cooperative Agreement Supplement for Services.

Authority: Social Security Act § 711(b) (42 U.S.C. 912(b)).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Supplemental award amount
U56RH05539	University of North Dakota	Grand Forks, ND	$545,000

Justification: This funding provided a one-time supplement to the University of North Dakota via the National Rural Health Information Clearinghouse Program with a budget period of June 2025 through May 2026. This supplement allows the University of North Dakota to build on past and ongoing projects supported by HRSA to improve health care in rural areas by advancing the knowledge base regarding strategies to support and enhance rural community health. The University of North Dakota is the recipient of the only award under the program and has longstanding experience identifying, developing, and disseminating resources like toolkits and webinars to support a broad range of rural health topics. The supplement will allow the University of North Dakota to create new toolkits and resources on important topics related to rural community health and health care.

Thomas J. Engels,

Administrator.

[FR Doc. 2025–19250 Filed 10–1–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding, Rural Health Innovation and Transformation Technical Assistance

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA provided supplemental funds to the Rural Health Innovation and Transformation Technical Assistance (RHIT–TA) Cooperative Agreement.

FOR FURTHER INFORMATION CONTACT: Lawrencia Afagbedzi, Health Insurance Specialist, Federal Office of Rural Health Policy, HRSA, at *lafagbedzi@hrsa.gov* and 301–443–3196.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: The University of Iowa.

Amount of Non-Competitive Award: One award for $150,000.

Project Period: August 1, 2023, to July 31, 2027.

Assistance Listing Number: 93.155.

Award Instrument: Cooperative Agreement Supplement.

Authority: Section 711 of the Social Security Act (42 U.S.C. 912).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant number	Award recipient name	City, state	Supplemental award amount
UB7RH25011	University of Iowa	Iowa City, IA	$150,000

Justification: This funding provides a one-time supplement to the University of Iowa through the RHIT–TA Cooperative Agreement with a budget period of August 2025 through July 2026. This supplement allows the University of Iowa to build on past and ongoing projects supported by HRSA to support health care in rural areas by advancing the knowledge base regarding the unique considerations and barriers facing rural providers implementing value-based care and innovative payment models. The University of Iowa is the recipient of the only award under the RHIT–TA program and has established relationships with rural stakeholders and has longstanding experience developing resources related to rural value-based care. The supplement to the RHIT–TA Cooperative Agreement will allow the University of Iowa to provide additional technical assistance and develop