UNITED STATES DISTRICT COURT DISTRICT OF RHODE ISLAND

STATE OF COLORADO: STATE OF RHODE ISLAND; STATE OF CALIFORNIA; STATE OF MINNESOTA: STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA: STATE OF HAWAI'I: STATE OF ILLINOIS; OFFICE OF THE GOVERNOR ex rel. Andy Beshear, in his official capacity as Governor of the COMMONWEALTH OF KENTUCKY: STATE OF MAINE: STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF NEVADA; STATE OF NEW JERSEY: STATE OF NEW MEXICO: STATE OF NEW YORK; STATE OF NORTH CAROLINA: STATE OF OREGON: JOSH SHAPIRO, in his official capacity as Governor of the COMMONWEALTH OF PENNSYLVANIA; and STATE OF WISCONSIN, Plaintiffs.

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services, Defendants. Civil Action No. 25-cv-121-MSM-LDA

THE UNITED STATES OF AMERICA'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Twenty-three States and the District of Columbia (the "Plaintiffs" or "Plaintiff states") seek to compel the United States Department of Health and Human Services ("HHS") to pay billions of federal dollars in grants for programs and activities 1) that were originally funded in response to the COVID-19 pandemic; 2) where most of the allocated funding has already been spent by the recipient states; 3) where significant amounts of the funding Plaintiffs now claim is critical had been available but left unspent, for years in some cases; and 4) where the terminations permit payment for any expenses the states had validly incurred at the time of termination.

Critically, the Supreme Court made clear less than two weeks ago that this Court does not have jurisdiction to hear these claims where, as here, a group of plaintiff states seek a court order to compel government payments under awarded grants. In addition, this Court does not have jurisdiction to review—let alone countermand—an agency's discretionary decision on how to allocate funds. Nor does the Court have jurisdiction over claims seeking to compel the payment of money allegedly due under a contract, which is exactly what Plaintiffs seek here. And, even if the Court could review the agency's termination decisions, because the relevant regulations provide HHS with the authority to terminate these grants, HHS did not act contrary to law, nor were its actions arbitrary and capricious.

The Court may issue preliminary injunctive relief only in rare and drastic circumstances where, unlike here, plaintiffs meet the heavy burden of establishing both that they are likely to succeed on the merits and that they will suffer immediate and irreparable harm. In this case, Plaintiffs are not likely to succeed in this Court because the Court lacks jurisdiction over Plaintiffs' claims and because HHS acted within its authority. And Plaintiffs will not suffer any immediate harm apart from a delay in payment—a classic form of *reparable* injury. By contrast, interim relief will inflict irremediable harm on the federal government by forcing it to support activities that contravene Executive Branch priorities, and with funds that it likely cannot recoup should Defendants ultimately win this case, as they are likely to do.

Nonetheless, Plaintiffs demand a restart to this funding *now*, even though every dollar of the money that they seek would remain available to them *later* as money damages should they ultimately prove their entitlement to the funds. They do so without concrete evidence that their own governments could not absorb the costs of the grants in the interim, and with a universal request to require continued payment for every grant terminated by HHS. Plaintiffs expansively assert that "[k]ey health programs and initiatives will have to be dissolved or disbanded because the Plaintiff States do not have the wherewithal to run these programs with alternate funding midcycle...," ECF No. 60 at 1, without differentiating between the hundreds of grants they demand the Court order the federal government to fund.

Plaintiffs know full well that, if the Court enters preliminary relief requiring Defendants to release funds pursuant to the terminated grants, HHS will likely be unable to recover those funds once disbursed. Once the money is released it will be spent. And it will be spent on activities that the agency has deemed inconsistent with Congress's intent and the public interest—thus inflicting an antidemocratic harm on

the Executive Branch and the public. Defendants—not Plaintiffs—will suffer significant harm that cannot be undone at the conclusion of the case.

Rather than take the extraordinary step of issuing a preliminary injunction and essentially commandeering federal funds, the Court should chart a more cautious and prudent path and keep the funds with the agency for now. For these reasons and those explained below, the Court should deny Plaintiffs' motion.

BACKGROUND

This case involves grants awarded or supplemented by HHS with funding appropriated by Congress to address issues related to the onset of the COVID-19 public health emergency ("PHE"). In response to the coronavirus PHE, the federal government took unprecedented action to address the public health threat posed by COVID-19. To that end, Congress provided supplemental funds through six acts: Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146 (2020); Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (2020); The Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020) ("CARES"); The Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020); The Coronavirus Response and Relief Supplemental Appropriations Act ("CRRSAA"), (2021) Pub. L. No. 116-260, 134 Stat. 1182; and The American Rescue Plan Act of 2021 ("ARPA") Pub. L. No. 117-2, 135 Stat. 4 (2021). The grants at issue in this case fall under two sub-agencies of HHS: the Substance Abuse and Mental Health Services Administration ("SAMHSA") and the Centers for Disease Control And Prevention

("CDC"). These federal agencies expeditiously provided the Plaintiff states with critical funding through a variety of grant programs intended to timely respond to the crisis caused by the COVID-19 PHE.

CDC and SAMHSA either added these dollars to existing, open awards to quickly get money to states, or provided new grant funds to make sure states could respond quickly to the COVID-19 PHE. Those funds were used by many states, but in many cases, there was simply too much money to spend at one time, so funding could not readily or timely be used by recipients. The agencies therefore allowed, upon request by a recipient and consideration by the respective agency, no-cost extensions of the grant awards.

Over the past five years, HHS has, where appropriate, approved no-cost extensions or allowed carryover of funding through these grant programs, extending deadlines during which the funding could be spent as set out above. In the interim, the period of performance for several of the grants have also expired, frequently with remaining funds that had not been drawn down by the states, despite the availability of those funds. See Declaration of Jamie Legier ("Legier Decl.") and Declaration of Kurt John ("John Decl."). At the time of the grant terminations on March 24, 2025, approximately 70% of the allocated funding for the grants at issue in this case had either been spent by the Plaintiff states or had expired. Legier Decl. ¶ 8; John Decl. ¶ 7. With respect to grants where the period of performance had ended before March 24, 2025, the Plaintiff states had not even sought to draw down over \$160 million in

available funding before the grant terminations. Legier Decl. ¶ 9; John Decl. ¶ 8. 1

On March 24, 2025, HHS provided notification to the Plaintiff states that the remaining, active grants or funding lines under broader grants with COVID-19 supplemental funding were being terminated. The COVID-19 PHE is over. Yet, in many cases, there was still substantial grant funding remaining that the states had not drawn down for years. Pursuant to the underlying CDC and SAMHSA statutes and regulations, for the agencies to terminate future use of those funds. After the termination, Plaintiffs could continue to draw down grant funds for costs they already had incurred, but could no longer access federal grant funds for new expenditures.

On April 1, 2025, Plaintiffs sued HHS in the District of Rhode Island, claiming that the terminations of the grants violated the Administrative Procedure Act ("APA"). 5 U.S.C. §706(2)(A). ECF No. 1. The Complaint included the following causes of action: Violation of the APA – Contrary to Law SAMHSA Termination Notices (Count I); Violation of the APA – Contrary to Law CDC Termination Notices (Count II); and Substantive Violation of the APA – Arbitrary & Capricious All Public Health Terminations (Count III). Plaintiffs also filed a Motion for a Temporary Restraining

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¹ In an effort to provide the Court with context for Plaintiffs' claims, the government provides this preliminary data summary of the grants that it believes to be at issue based on Plaintiffs' filings. Given the short timeframe for the government to file this Opposition, these and other calculations presented in the Opposition are based on a preliminary review of the currently-available raw data provided by the agency and undersigned counsel's understanding of Plaintiffs' claims. While the government believes, to the best of its knowledge and understanding, that these preliminary calculations are accurate, they are subject to further review and confirmation by the agency.

Order ("TRO") the same day. (ECF No. 4). On April 3, 2025, the Court granted Plaintiffs' Motion for a TRO by Text Order. On April 5, 2025, the Court issued an opinion granting Plaintiffs' TRO. ECF No. 54. On April 7, 2025, HHS filed a Notice of Compliance with the TRO. ECF No. 55. That same day, HHS filed a Motion for Reconsideration of the TRO, based on the United States Supreme Court's decision in *Dep't of Educ. v. California*, 604 U.S. ---, --- S. Ct. ---, No. 24A910, 2025 WL 1008354, at *1-2 (Apr. 4, 2025) (per curiam). ECF No. 56. That Motion remains pending. On April 8, 2025, Plaintiffs filed an Amended Complaint, adding constitutional claims in addition to the APA claims, presumably in response to the Supreme Court's decision and HHS's Motion for Reconsideration. ECF No. 59.

STANDARDS OF REVIEW

I. Subject Matter Jurisdiction

To proceed on its claims, the Plaintiff states must first establish subject-matter jurisdiction in this Court—specifically, by showing whether Congress has waived sovereign immunity and, if so, whether this Court may hear their claims. See, e.g., Hanley v. United States, No. 94-1315, 1994 WL 723678, at *2 (1st Cir. Oct. 5, 1994) (per curiam) (affirming R. 12(b)(1) dismissal) ("A plaintiff has the burden of showing a waiver of sovereign immunity."). "Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit." F.D.I.C. v. Meyer, 510 U.S. 471, 475 (1994) (citing cases); United States v. Mitchell, 463 U.S. 206, 212 (1983) ("It is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction."); Griffith v. Bowen, 678 F. Supp.

942, 944 (D. Mass. 1988) ("[T]his Court must decide whether it has jurisdiction over the subject matter of the dispute before it may proceed any further.").

Federal courts "presume [they] lack jurisdiction unless the contrary appears affirmatively from the record." Renne v. Geary, 501 U.S. 312, 316 (1991) (cleaned up). The test for deciding whether sovereign immunity has been waived is "stringent," the waiver must be "unmistakably clear," and the Court must "indulge every reasonable presumption against" waiver. Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 527 U.S. 666, 675, 678, 682 (1999) (cleaned up); FAA v. Cooper, 566 U.S. 284, 290 (2012) ("A waiver of sovereign immunity must be unequivocally expressed in statutory text.").

Thus, the Plaintiff states have the burden of alleging facts sufficient to establish the Court's subject matter jurisdiction. See Aversa v. United States, 99 F.3d 1200, 1209 (1st Cir. 1996); see also Padilla-Mangual v. Pavía Hosp., 516 F.3d 29, 31 (1st Cir. 2008) ("Once challenged, the party invoking subject matter jurisdiction ... has the burden of proving by a preponderance of the evidence the facts supporting jurisdiction").

II. Preliminary Injunction

"A preliminary injunction is an extraordinary remedy never awarded as of right." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 24 (2008); see also Cushing v. Packard, 30 F.4th 27, 35 (1st Cir. 2022). A plaintiff must establish that: (i) it is likely to succeed on the merits; (ii) absent preliminary relief, it likely will suffer irreparable harm; (iii) the balance of the equities tips in its favor; and (iv) an injunction is in the public interest. New Jersey v. Trump, 131 F. 4th 27, 33 (1st Cir. 2025) (citing

Winter, 555 U.S. at 20). The third and fourth factors "merge when the government is the opposing party." Nken v. Holder, 556 U.S. 418, 435 (2009); see also Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982) ("In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction."). "In each case, a court must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." Amoco Prod. Co. v. Village of Gambell, 480 U.S. 531, 542 (1987)). "The party seeking the preliminary injunction bears the burden of establishing that these four factors weigh in its favor[,]" using evidence to support its conclusions. Esso Standard Oil Co. (Puerto Rico) v. Monroig-Zayas, 445 F.3d 13, 18 (1st Cir. 2006).

To evaluate whether the Plaintiffs have met the most important requirement—likelihood of success on the merits—the Court must keep in mind that the merits need not be "conclusively determine[d]"; instead, at this stage, decisions "are to be understood as statements of probable outcomes only." Akebia Therapeutics, Inc. v. Azar, 976 F.3d 86, 93 (1st Cir. 2020) (partially quoting Narragansett Indian Tribe v. Guilbert, 934 F.2d 4, 6 (1st Cir. 1991)). "To demonstrate likelihood of success on the merits, plaintiffs must show 'more than mere possibility' of success—rather, they must establish a 'strong likelihood' that they will ultimately prevail." Sindicato Puertor-riqueño de Trabajadores v. Fortuño, 699 F.3d 1, 10 (1st Cir. 2012) (per curiam) (quoting Respect Maine PAC v. McKee, 622 F.3d 13, 15 (1st Cir. 2010)).

ARGUMENT

I. The Court Lacks Jurisdiction Over Plaintiffs' Claims

A. Only the Court of Federal Claims has jurisdiction to hear claims seeking compulsion of payments of federal grants.

When a party seeks to compel funding that it believes the government is obligated to pay under a contract or grant, the proper remedy is suit under the Tucker Act, not the APA. The Tucker Act provides that the "United States Court of Federal Claims shall have jurisdiction to render judgment upon any claim against the United States founded" on "any express or implied contract with the United States." 28 U.S.C. § 1491(a); see, e.g., Burgos v. Milton, 709 F.2d 1, 3 (1st Cir. 1987) (vacating district court judgment; concluding district court lacked jurisdiction under 5 U.S.C. § 702 to award money judgment); id. ("[E]ven if we agreed with [claimant] that the award was equitable and did not constitute 'money damages,' we would still find that section 702 did not remove the defense of sovereign immunity."); Am. Sci. & Eng'g, Inc. v. Califano, 571 F.2d 58, 62-63 (1st Cir. 1978) (no district court jurisdiction under APA even where plaintiff alleged violations of the agency's regulations and due process of law because the Court of Claims provided "an adequate remedy" for the claims, which were grounded in contract).

And, under these circumstances, courts have routinely held that "grant agreements [are] contracts when the standard conditions for a contract are satisfied." See, e.g., Columbus Reg'l Hosp. v. United States, 990 F.3d 1330, 1338 (Fed. Cir. 2021); see also San Juan City Coll. v. United States, 391 F.3d 1357, 1360-62 (Fed. Cir. 2004)

(treating a "Program Participation Agreement" and related grants under the Higher Education Act as a contract).

In determining whether "a particular action" is "at its essence" a contract action that is subject to the Tucker Act or, instead, is a challenge properly brought under the APA, courts have looked at both "the source of the rights upon which the plaintiff bases its claims" and "the type of relief sought (or appropriate)." *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 968 (D.C. Cir. 1982); *see also, e.g., Cohen v. Postal Holdings, LLC*, 873 F.3d 394, 403 (2d Cir. 2017) (applying *Megapulse* test); *Califano*, 571 F.2d at 63 (evaluating whether "the essence of the action is in contract").

In short, "an injunction to compel the payment of money past due under a contract" is an action at law—not equity. *Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 210 (2002); *see Coggeshall Dev. Corp. v. Diamond*, 884 F.2d 1, 3 (1st Cir. 1989) ("Federal courts do not have the power to order specific performance by the United States of its alleged contractual obligations."). As the First Circuit has explained, the APA's waiver of sovereign immunity for claims seeking relief other than money damages does not extend to "specific performance for breach of contract." *Id.* Thus, this Court lacks jurisdiction to order HHS to pay money allegedly owed under the grants.

B. The Supreme Court recently stayed injunctive relief compelling payment of federal grants given the district court's likely lack of jurisdiction.

The Supreme Court has embraced the preceding analysis in a case decided within the last two weeks in which, like here, a group of plaintiff states sought a court order to compel government payments under awarded grants.

In California v. United States Department of Education, several States sued the Department of Education under the APA to try to compel such payments. No. CV 25-10548-MJJ, 2025 WL 760825, at *1 (D. Mass. Mar. 10, 2025). In the district court, the federal government argued that the APA's limited waiver of sovereign immunity, 5 U.S.C. § 702, does not extend to the termination of grant funding because challenges to such agency decision-making arise under contract—subject matter that Congress determined was the exclusive jurisdiction of the Court of Federal Claims pursuant to the Tucker Act. 28 U.S.C. § 1491. The district court rejected that argument, temporarily restrained the defendants, and more specifically ordered them to "immediately restore Plaintiff States to the pre-existing status quo prior to the termination under all previously awarded [] grants for recipients in Plaintiff States." 2025 WL 760825, at *5.

The United States appealed that order to the First Circuit, where the government presented the same jurisdictional challenge under the Tucker Act. The First Circuit refused to stay the district court's order. *California v. U.S. Dep't of Educ.*, No. 25-1244, 2025 WL 878431, at *1 (1st Cir. Mar. 21, 2025); *id.* at *2 (evaluating Tucker Act arguments).²

 2 The Plaintiffs in this case described the First Circuit's California decision as follows:

The First Circuit has soundly rejected this argument under identical circumstances. California v. U.S. Dep't of Educ., --- F.4th ----, 2025 WL 878431, at *2 (1st Cir. Mar. 21, 2025), application for stay pending, No. 24A910 (U.S. Mar. 26, 2025). Where, as here, 'the States challenge the Department's actions as insufficiently explained, insufficiently reasoned, and otherwise

The United States, however, appealed the First Circuit's decision to the Supreme Court, which granted the stay that the government had sought. 2025 WL 1008354, at *2. In doing so, the Supreme Court explained that the government is "likely to succeed in showing the District Court lacked jurisdiction to order the payment of money under the APA." *Id.* at *1. Instead, the Supreme Court explained, suits seeking relief like that sought by the *California* plaintiff states—namely, restoration of funding from allegedly improperly terminated grants—likely belong in the Court of Federal Claims. *See id.* The Supreme Court reasoned:

The APA's waiver of sovereign immunity does not apply "if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought." 5 U. S. C. § 702. Nor does the waiver apply to claims seeking "money damages." *Ibid.* True, a district court's jurisdiction "is not barred by the possibility" that an order setting aside an agency's action may result in the disbursement of funds. *Bowen v. Massachusetts*, 487 U. S. 879, 910 (1988). But, as we have recognized, the APA's limited waiver of immunity does not extend to orders "to enforce a contractual obligation to pay money" along the lines of what the District Court ordered here. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U. S. 204, 212 (2002). Instead, the Tucker Act grants the Court of Federal Claims jurisdiction over suits based on "any express or implied contract with the United States." 28 U. S. C. §1491(a)(1).

Id.; see also U.S. Conference of Catholic Bishops v. U.S. Dep't of State, No. 1:25-cv-465, 2025 WL 763738, at *2-4, (D.D.C. Mar. 11, 2025) (concluding the court lacked jurisdiction under APA to assess claims contesting State Department's termination

contrary to law—arguments derived from the Administrative Procedure Act (APA),' [the First Circuit held] those claims are not breach of contract claims covered by the Tucker Act and are instead properly heard in the district court under the APA's waiver of sovereign immunity. *Id*."

ECF No. 4 at 18 (emphases added).

of contracts funding plaintiffs' refugee resettlement) (injunction pending appeal denied, No. 25-5066 (D.C. Cir. March 28, 2025); *id.* at *5 ("A request for an order that the government must perform on its contract is one that must be resolved by the Claims Court.") (cleaned up); *cf. Diaz v. Johnson*, No. 19-1501, 2020 WL 9437887, at *2 (1st Cir. Nov. 12, 2020) (although "Diaz attempts to couch his claims in the language of equitable and declaratory relief," such as seeking "an order directing that his proposal be funded," a plaintiff "cannot manufacture an APA claim by asking the court to declare that the failure to fund his proposal was an arbitrary or capricious act"); *Dep't of State v. AIDS Vaccine Advoc. Coal.*, 145 S. Ct. 753, No. 24A831, 2025 WL 698083, at *2 (U.S. Mar. 5, 2025) (Alito, J., dissenting from denial of application to vacate order) (explaining that "the relief here more closely resembles a compensatory money judgment rather than an order for specific relief that might have been available in equity," and "[s]overeign immunity thus appears to bar the sort of compensatory relief that the District Court ordered here").

Importantly, in its recent *California* opinion, the Supreme Court also went beyond the jurisdictional question to assess the elements of a stay. 2025 WL 1008354, at *1. Those elements are the same for preliminary relief under Federal Rule of Civil Procedure 65, on which the Plaintiff states have the burden. *See also New York v. Trump*, No. 25-1236, 2025 WL 914788, at *10 (1st Cir. Mar. 26, 2025) (identifying elements for stay pending appeal).

In *California*, the Supreme Court concluded that the remaining stay factors were met, because the government will be harmed if it is unable to "recover the grant

funds once they are disbursed." 2025 WL 1008354, at *1. That harm to the federal government was likely because, the Supreme Court noted, "[n]o grantee 'promised to return withdrawn funds should its grant termination be reinstated,' and the District Court declined to impose bond." By contrast, grant recipients "would not suffer irreparable harm while the TRO is stayed" because if the Plaintiff states ultimately prevail, "they can recover any wrongfully withheld funds through suit in an appropriate forum." *Id.* The Court then stayed the district court's relief pending not only the outcome of any First Circuit appeal but also "disposition of petition for a writ of certiorari, if such writ is timely sought." *Id.* at *2.

The preceding authorities preclude preliminary relief because this Court lacks the jurisdiction to enter it. The Plaintiffs do not claim that any statute or regulation entitles them, in particular, to these grants; instead, their relief is purely a matter of contract. And, twice, the Plaintiffs characterized the facts of this case as indistinguishable from those in *California*, where the Supreme Court has stayed (and, thus, effectively denied) preliminary relief through the exhaustion of post-trial appeals.

Because the circumstances of the *California* matter are indistinguishable from those presented here, the same result should obtain in both: the Court should not order the government to pay out canceled grants.

C. Plaintiffs' changes in the Amended Complaint do not avoid their jurisdictional hurdles.

In an effort to circumvent the Tucker Act and the recent Supreme Court decision that claims for grant-specific relief belong in the Court of Federal Claims as a

breach of contract claim, Plaintiffs filed an Amended Complaint, attempting to reframe their argument by adding Constitutional claims and removing many of the terms used in the Complaint. For example, Plaintiffs originally asserted throughout the Complaint that HHS "abruptly and arbitrarily terminated \$11 billion of critical public health funding. . . .[,]" argued they were challenging "Defendants' unlawful withholding of funds," and used terms such as grants, cooperative agreements, terminations notices, and "Public Health Terminations." See, e.g., ECF. No 1, ¶¶ 1-6. Yet in the Amended Compliant, Plaintiffs removed most of those references including changing "funding" to a "policy shift" and "federal financial assistance," changing "Public Health Terminations" to "Public Health Funding Decisions," changing ""Defendants' unlawful withholding of funds" to "Defendants' unlawful actions," and replacing the terms "grants" and "cooperative agreements" with "programs." ECF No. 50, ¶¶ 1-6.

Plaintiffs' decision to change the language it uses to describe the grants and HHS's funding decisions merely serves to highlight that, underneath the veneer, what Plaintiffs are, in fact, seeking is for this Court to mandate continued payment of grants by HHS, precisely as in *California*. See also Catholic Bishops, 2025 WL 763738, at *5, ("Stripped of its equitable flair, the requested relief seeks one thing: The Conference wants the Court to order the Government to stop withholding the money due under the Cooperative Agreements. In even plainer English: The Conference wants the Government to keep paying up... But this Court cannot order the Government to pay money due on a contract."); Diaz v. Johnson, No. 19-1501,

2020 WL 9437887, at *2 (1st Cir. Nov. 12, 2020) (although "[plaintiff] attempts to couch his claims in the language of equitable and declaratory relief," a plaintiff "cannot manufacture an APA claim by asking the court to declare that the failure to fund his proposal was an arbitrary or capricious act").

Similarly, simply adding Constitutional claims in an attempt to recharacterize a claim for money neither alters the relief being sought nor this Court's jurisdiction. As the Federal Circuit has recognized, after *Bowen v. Massachusetts*, 487 U.S. 879 (1988), where the Supreme Court understood the term "money damages" to mean "compensation for the damage sustained by the failure of the Federal Government to pay as mandated," there has arisen a "cottage industry among lawyers attempting to craft suits, ultimately seeking money from the Government, as suits for declaratory or injunctive relief without mentioning the money." Suburban Mortg. Assocs., Inc. v. U.S. Dep't of Hous. & Urban Dev., 480 F.3d 1116, 1124 (Fed. Cir. 2007). Plaintiffs' reliance on Bowen, 487 U.S. 879, is therefore misplaced. As noted above, in California, 2025 WL 1008354, the Supreme Court specifically considered Bowen in determining that the Tucker Act applied to the circumstances identical to this case.

The Federal Circuit has thus emphasized, in order to "thwart" "forum shopping" by attorneys who are "ultimately seeking money from the Government," that "in determining whether a plaintiff's suit is to be heard in district court or the Court of Federal Claims, we must look beyond the form of the pleadings to the substance of the claim. We have cautioned litigants that dressing up a claim

for money as one for equitable relief will not remove the claim from Tucker Act jurisdiction to make it an APA case." Suburban Mortg. Assocs., 480 F.3d at 1124; see also Christopher Vill., L.P. v. United States, 360 F.3d 1319, 1328 (Fed. Cir. 2004) ("[A] party may not circumvent the Claims Court's exclusive jurisdiction by framing a complaint in the district court as one seeking injunctive, declaratory or mandatory relief where the thrust of the suit is to obtain money from the United States.") (citation omitted); Consol. Edison Co. of New York, Inc. v. U.S. Dep't of Energy, 247 F.3d 1378 (Fed. Cir. 2001) ("This court and its sister circuits will not tolerate a litigant's attempt to artfully recast its complaint to circumvent the jurisdiction of the Court of Federal Claims."); Village West Assocs. v. Rhode Island Hous. & Mortg. Fin. Corp., 618 F.Supp.2d 134, 139-40 (D.R.I. 2009) (rejecting as "without merit" the "familiar argument" that by seeking a prospective declaration regarding future agency actions, the Court of Federal Claims could not provide adequate relief in cases where the Tucker Act applies).

The real question, then, is not how Plaintiffs have characterized their claims, but "whether the cause is one over which the Court of Federal Claims has jurisdiction under the Tucker Act" and thus whether there is an adequate remedy in a court other than the district court, precluding APA jurisdiction under 5 U.S.C. § 704. Suburban Mortg. Assocs., 480 F.3d at 1125. "If the suit is at base a claim for money, and the relief available through the Court of Federal Claims under the Tucker Act—a money judgment—will provide an adequate remedy, the inquiry is at an end." Id.

Here, Plaintiffs state that they are seeking injunctive and equitable relief and have sought to evade the Tucker Act by adding Constitutional claims, but as made clear in both their original and amended pleadings, the relief they seek is for a court to order the government to keep paying them money. The equitable relief they seek is plainly "incident of and collateral to" the requested monetary relief in the form of ongoing grant funding, and thus can be part of any review by the Court of Federal Claims. See 28 U.S.C. § 1491(a)(2). Plaintiffs' own argument in their added counts is essentially that the defendants are required to pay them—that the Constitution requires monetary payments. Regardless of Plaintiffs' attempts at artful recasting, the Supreme Court has clarified that there is an adequate remedy for their cause—continued payment of grant funds—in the Court of Federal Claims, which has exclusive jurisdiction over their cause. Accordingly, by statute and per the Supreme Court, there is no APA jurisdiction over Plaintiff States' Complaint in federal district court.

D. Even if the APA were applicable, the APA would independently bar review.

Plaintiffs now assert that they are seeking "purely prospective relief under the APA..." ECF No. 60 at 22. But Plaintiffs' attempt to reframe this case as "agency actions to cut critical public health funding" still fails to establish that this Court has jurisdiction over this case. Because HHS's terminations were consistent with the applicable statutory and regulatory provisions, no further review under the APA is available. Even were these claims reviewable under the APA, not the Tucker Act, the APA itself would have precluded review of grant terminations. Such terminations are

quintessential agency actions "committed to agency discretion by law," for which the APA does not provide an avenue for review. 5 U.S.C. § 701(a)(2). An agency's determination of how to allot appropriated funds among competing priorities and recipients is classic discretionary agency action that is not susceptible to APA review.

In Lincoln v. Vigil, the Supreme Court held that the Indian Health Service's decision to discontinue a program it had previously funded and to instead reallocate those funds to other programs was committed to agency discretion by law and thus not reviewable under the APA's reasoned-decision-making standards. 508 U.S. 182, 185-88 (1993). The Supreme Court explained that the "allocation of funds from a lump-sum appropriation is" an "administrative decision traditionally regarded as committed to agency discretion," because the "very point of a lump-sum appropriation is to give an agency the capacity to adapt to changing circumstances and meet its statutory responsibilities in what it sees as the most effective or desirable way." Id. at 192.

Indeed, "an agency's allocation of funds from a lump-sum appropriation requires 'a complicated balancing of a number of factors which are peculiarly within its expertise': whether its 'resources are best spent' on one program or another; whether it 'is likely to succeed' in fulfilling its statutory mandate; whether a particular program 'best fits the agency's overall policies'; and, 'indeed, whether the agency has enough resources' to fund a program 'at all." *Id.* at 193 (quoting *Heckler v. Chaney*, 470 U.S. 821, 831 (1985)). "Congress may always circumscribe

agency discretion to allocate resources by putting restrictions in the operative statutes." *Id.* But as long as the agency abides by the relevant statutes (and whatever self-imposed obligations may arise from regulations or grant instruments), the APA "gives the courts no leave to intrude." *Id.*; *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Donovan,* 746 F.2d 855, 861 (D.C. Cir. 1984) (Scalia, J.) ("A lump-sum appropriation leaves it to the recipient agency (as a matter of law, at least) to distribute the funds among some or all of the permissible objects as it sees fit.")

Although *Lincoln* involved lump-sum appropriations, its logic extends to funding programs that leave to the agency "the decision about how the moneys" for a particular program "could best be distributed consistent with" the statute. *Milk Train, Inc.* v. *Veneman*, 310 F.3d 747, 751 (D.C. Cir. 2002). Such decisions—like decisions regarding how best to allocate lump-sum appropriations—"clearly require[] 'a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise.'" *Id.* at 752 (citation omitted); see *Policy & Research, LLC* v. *U.S. Dep't of Health & Human Servs.*, 313 F. Supp. 3d 62, 75-76 (D.D.C. 2018) (Jackson, J.); *Cmty. Action of Laramie Cnty., Inc. v. Bowen*, 866 F.2d 347, 354 (10th Cir. 1989) ("Funding determinations are 'notoriously unsuitable for judicial review, for they involve the inherently subjective weighing of the large number of varied priorities which combine to dictate the wisest dissemination of an agency's limited budget." (quoting *Alan Guttmacher Inst. v. McPherson*, 597 F. Supp. 1530, 1536-37 (S.D.N.Y. 1984))).

In this case, where the agency explained the reasons for its actions and followed its own regulations, as explained in more detail in Section II below. Thus, no further review under the APA is available, and the Court does not have jurisdiction to review and impede HHS's discretionary funding decisions.

II. Plaintiffs Have Not Established a Likelihood of Success on the Merits

Because this Court lacks jurisdiction over Plaintiffs' claims, Plaintiffs cannot succeed on the merits. As the First Circuit has often recognized, proving likelihood of success on the merits is the "sine qua non" of a preliminary injunction." New Comm Wireless Servs., Inc. v. SprintCom, Inc., 287 F.3d 1, 9 (1st Cir. 2002) Therefore, "[i]f the moving party cannot demonstrate that [it] is likely to succeed in [its] quest, the remaining factors become matters of idle curiosity." Id. Even apart from the jurisdictional obstacles, Plaintiffs have not shown a likelihood of success on the merits because the agency's actions were not contrary to law or arbitrary and capricious, nor did they violate the Constitution.

A. The termination of grants was not contrary to law.³

1. The applicable CDC regulations allow HHS to terminate grants for cause, including changed priorities.

Plaintiffs argue that HHS exceeded its statutory authority, in violation of the APA, by terminating the CDC's COVID-related grants. However, there is no

³ On April 10, 2025, the Court entered a text order directing the Defendants to "address, in their response to Plaintiffs' motion for a preliminary injunction, all legal and factual bases upon which the Defendants relied, could have relied, or might in the future might rely to terminate the grant funds at issue in this litigation." See April 10, 2025 Text Order. In addition to the bases discussed elsewhere in this Opposition, HHS' bases for the termination of grants included,

question that HHS has the express authority to terminate grants "for cause," as described in more detail by the applicable regulations.

Congress appropriated funding for the particular purpose of providing support to address the public health and economic crises caused by the global COVID-19 pandemic. See Executive Order 14002 (January 22, 2021); White House OMB Statement of Administration Policy, H.R. 1319 – American Rescue Plan Act of 2021 (February 26, 2021). CDC expeditiously provided funding to the Plaintiff states through many different types of grants specifically for the purpose of addressing the COVID-19 pandemic. For example, CDC provided grant funding that included a "National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities." CDC National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities, attached hereto as Exhibit A. Another set of CDC grants was designed with

could have included, or could in the future include the provisions of 2 C.F.R. § 200 et. seq.; 42 C.F.R. § 75.300, et. seq.; 42 U.S.C. § 300x, et. seq., as interpreted by any current or future caselaw; the bases listed in the notices of awards to the Plaintiff states, including all statutes, regulations, or guidance refenced in those notices; changes in Congressional funding or statutory authority; emergency circumstances; and violations of federal criminal or civil laws by grant recipients that may not yet be known to the Defendants, including all applicable fraud laws. Defendants provide this list in an attempt to respond to the Court's direction, but do not intend to waive their ability to raise additional bases in future litigation

or to terminate any grant based on facts not yet known to the Defendants.

the goal of "preventing COVID-19 and protecting the American people from related public health impacts . . . through training and deployment of community health workers (CHWs) to response efforts and by building and strengthening community resilience to fight COVID-19 through addressing existing health disparities." CDC Community Health Workers for COVID Response and Resilient Communities, attached hereto as **Exhibit B**. Another group of CDC grants was provided "to rapidly establish and monitor key activities related to COVID-19 in the areas of epidemiology, laboratory, and informatics." ELC CARES 2020 Emerging Issues Project funding for adjusting community mitigation in response to COVID-19, April 21, 2020, attached hereto as **Exhibit C**.

With respect to the CDC, as Plaintiffs admit, the regulations governing the grants at issue specifically allow HHS to terminate these grants "for cause" 42 C.F.R. § 75.372(a)(2). Separately, the regulation expressly contemplates and permits termination when a grant recipient "fails to comply with the terms and conditions of the award" as a basis for termination. 42 C.F.R. § 75.372(a)(1). Thus, a common-sense reading of the regulation makes clear that "for cause" is something distinct from non-compliance, and that the agency is permitted to terminate grants for reasons other than non-compliance. The agency exercised its authority to terminate the funding for cause after determining that the purpose for which the grants were awarded was superseded by the end of the public health emergency (the termination notices reflected this interpretation by stating that the pandemic was over).

In addition, HHS's Grants Policy Statement confirm the understanding that "for cause" includes reasons other than non-compliance, such as for "public health or welfare concerns." *See* HHS Grants Policy Statement, at 59 (effective Oct. 1, 2024), *available at* https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-october-2024.pdf (last visited April 14, 2024) ("The HHS awarding agency may terminate without first suspending the federal award if the problem is serious enough or if the public health or welfare concerns require immediate action. Termination for cause may be appealed under the HHS awarding agency and HHS's federal award appeals procedures.")

Plaintiffs attempt to sidestep the regulatory language by pointing to the fact that HHS has indicated that it will adopt the Office of Management and Budget ("OMB") Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in October of this year. See 89 Fed. Reg. 80055, 2024 WL 4360439 (Oct. 2, 2024) (effective October 2025); 89 Fed. Reg. 30046, 2024 WL 1702101 (April 22, 2024). The OMB regulations have not included "for cause" as an independent basis of termination of a federal award since August 2020. Compare 2 C.F.R. § 200.340 (effective October 1, 2024), with 2 C.F.R. § 200.339 (effective July 30, 2015 to August 12, 2020). But the OMB regulations are irrelevant because they do not yet apply to HHS and do not constrain HHS's current authority to terminate grants "for cause."

Nor do OMB's regulations support Plaintiffs' reading of HHS's regulations.

If it is ever appropriate to use one agency's regulations to interpret another

agency's regulations, it certainly is not appropriate here. HHS has, for years, maintained grant regulations independent of OMB's regulations. If anything, that suggests that HHS consciously departed from the OMB regime. And a plaintext reading of HHS's regulations confirms that the agency may terminate grants for cause, as distinct from violation of the grant terms and conditions. Here, the CDC grant terminations comported with that regulatory regime.

At the time of the grant terminations, approximately 74% of the original \$22 billion in CDC funding for COVID grants to the Plaintiff states had either been spent or had expired, with a remaining balance of approximately \$5.8 billion. Legier Decl., \P 8. The period of performance for many of the original grants had already ended, with remaining balances—totaling nearly \$79 million—that the Plaintiff states never drew down from available funds. Id \P 9. Plaintiffs contend that all the funding from these grants is essential, and that HHS's termination of them will cause immediate, irreparable harm. Their actions, however, confirm that in fact, the termination of these grants did not create emergencies for the Plaintiff states, as the Plaintiffs themselves chose to leave millions of these funds unspent while they were available.

In their Amended Complaint, although not in their preliminary injunction motion, Plaintiffs also allege that HHS "failed to follow the processes required by applicable law" citing to 45 C.F.R. § 75.374(a), which states that "[u]pon taking

⁴ It is possible that, for a subset of grants that expired within 90 days prior to March 24, 2025, not all submissions for expenses incurred prior to March 24, 2025, were complete. CDC is not withholding payment of any expenses incurred during the period of performance for these grants.

any remedy for non-compliance, the HHS awarding agency must provide the non-Federal entity an opportunity to object and provide information and documentation challenging the suspension or termination action, in accordance with written processes and procedures published by the HHS awarding agency." As noted above, HHS terminated the CDC grants at issue "for cause," as distinct from non-compliance, and thus this provision does not apply. Regardless, any administrative appeal of the grant terminations would have been fruitless because Plaintiffs could not reasonably challenge the end of the COVID-19 PHE. HHS fully complied with its own regulations and did not act contrary to law.

Moreover, the agency's "for cause" determination is supported by the fact over half of the Plaintiff states requested extensions of time to allow them to access funds they had not yet obligated or appeared to have a clear plan to spend. See Legier Decl., ¶ 7. The states' inability to use the funds in a timely manner, for the purpose for which they were awarded, is an independent "cause" for which the grants were terminated. Given the end of the public health emergency caused by COVID-19, the agency therefore determined that it was no longer consistent with HHS's priorities to allow the funds to remain with the grantees. In an effort to remain a good steward of federal tax dollars, the agency exercised its discretion, well within the bounds of the applicable regulations, to require the states to return grant money they could not spend. Nothing about the agency's actions prevents the Plaintiffs from drawing down funds for already-incurred obligations; they simply cannot no longer access funds for new obligations.

2. The SAMHSA grants were terminated in compliance with the applicable regulations.

As with the CDC, SAMHSA appropriately provided funding to the Plaintiff states through the Community Mental Health Services Block grants and Substance Abuse Prevention and Treatment Block grants "to assist in response to the COVID-19 pandemic." SAMHSA letter to State Mental Health Commissioner, March 11, 2021, attached hereto as **Exhibit D**. SAMHSA provided "supplemental COVID-19 Relief funding" to the states and instructed that they be used "to prevent, prepare for, and respond to [serious mental illness] and [serious emotional disturbance] needs and gaps due to the on-going COVID-19 pandemic." *Id.* SAMHSA also made funds available for states to develop a "COVID-19 Mitigation Funding Plan," instructing that the states' activities funded by the grants "must be directly related to COVID-19 testing and mitigation." SAMHSA letter to Single State Authority Directors and State Mental Health Authority Commissioners, August 10, 2021, attached hereto to **Exhibit E**.

To begin, this provision does not apply at all to the SAMHSA grant terminations. The trigger for that provision is a determination "that a State has materially failed to comply" with the grant terms or other conditions. *Id.* As explained, the cause HHS identified was wholly distinct from the States' compliance, or lack thereof, with grant terms: HHS cited the end of the COVID-19 pandemic. So, just as the regulations governing non-compliance do not apply to these terminations, the SAMHSA statutory requirements governing non-compliance do not apply.

The fact that the statute uses the words "for cause" does not change this conclusion. The statute merely provides one example of a for-cause termination—material non-compliance with the terms of the grant. The statute never says this is the only type of for-cause termination permitted, however. External factors, like the end of a pandemic or lack of appropriations by Congress, would likewise supply cause to terminate. But because any such terminations would not be for material non-compliance with grant terms, section 300x-55 would be irrelevant.

Even if section 300x-55 applied, however, Plaintiffs' argument still fails. Plaintiffs argue that the SAMHSA terminations did not provide an explanation of the States' "material failure to comply" with the agreements and other necessary conditions. However, HHS did provide an explanation of why the Plaintiffs could no longer comply with the necessary conditions for the disbursement of these funds: they were no longer necessary because of the end of the pandemic. The fact that the Plaintiff states were in fact not spending the money that had been allocated for COVID-19 relief purposes also represents a material failure to comply.

SAMHSA awarded funds under ARPA and CRRSA for the express purpose of implementing a behavioral health response to the COVID-19 pandemic by addressing the effects of the pandemic on Americans with mental illness or substance use disorders and to carry out COVID-19 testing and mitigation activities. See Exhibits D and E.

The agency exercised its authority on March 24, 2025, to terminate the funding after determining that the purpose for which the grants were awarded was superseded by the end of the public health emergency (the termination notices reflected this interpretation by stating that the pandemic was over) and demonstrated the lack of necessity. The agency's determination is supported by the fact that over half of the Plaintiff states requested and received extensions of time in which to expend unobligated CRRSA funds. See John Decl. ¶ 6. The Plaintiff states' inability to use the funds, in a timely manner, for the purpose for which they were awarded constituted a failure to materially comply with the requirement to expend the funds to prevent, prepare for, and respond to the COVID-19 public health emergency. In addition, a number of the SAMHSA COVID grants expired on March 14, 2025, which also ended the period of performance, and the grantees have 90 days from that date to close out the grants. So, for the grants under which the performance period ended on or before March 14, 2025, the terminations were inconsequential because the grants had already expired.

At the time of the grant terminations, approximately 74% of the \$2.7 billion in SAMHSA funding for COVID grants to the Plaintiff states had either been spent or had expired, with a remaining balance of approximately \$702 million.⁵ John Decl., ¶ 7. The period of performance for many of the grants had already ended, along with a remaining balance of over \$86 million that the Plaintiff states never drew down

⁵ It is possible for a subset of grants that expired on March 14, 2025, not all submissions for expenses incurred prior to March 14, 2025, were complete. SAMHSA is not withholding payment of any expenses incurred during the period of performance for these grants.

from available funds. Id. at ¶ 8. Although Plaintiffs claim that all the funding from these grants is essential, the termination of which they argue will cause immediate, irreparable harm, their actions confirm HHS's view that in fact, the necessary conditions for the disbursement of the funding no longer existed.

The States further contend that these termination notices were issued without the opportunity for a hearing and an investigation as required by § 300x-55(g). However, as shown in the exhibits to Plaintiffs' filings, Plaintiffs were given notice shortly after termination, and an opportunity to challenge the termination and receive a hearing. See, e.g., ECF 4-26 at 16, 22; ECF 4-41 at 54, 412, 440, 443. Plaintiffs do not allege or argue that they have requested such a hearing in response to the notice that was provided, nor that such a hearing was denied. Thus, Plaintiffs cannot contend that they suffered any concrete harm from the allegedly deficient notice.

B. The Agency's decision to terminate the COVID funding grants was not arbitrary and capricious.

For the reasons discussed above, the APA does not provide an avenue for review of the agency's action in this case. 5 U.S.C. § 701(a)(2). Even if arbitrary-and-capricious review were available, however, HHS's actions pass muster. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The scope of review under the "arbitrary and capricious" standard under § 706 is "narrow and a court is not to

substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

This standard "deems the agency action presumptively valid provided the action meets a minimum rationality standard." Sierra Club v. EPA, 353 F.3d 976, 978 (D.C. Cir. 2004) (citation omitted); see also Atieh v. Riordan, 797 F.3d 135, 138 (1st Cir. 2015) (noting narrowness of arbitrary-and-capricious standard and that "a reviewing court 'may not substitute its judgment for that of the agency, even if it disagrees with the agency's conclusions.") (citing River St. Donuts, LLC v. Napolitano, 558 F.3d 111, 114 (1st Cir. 2009)). At bottom, this deferential standard requires only that "agency action be reasonable and reasonably explained." F.C.C. v. Prometheus Radio Project, 592 U.S. 414, 423 (2021). The explanation need only be clear enough for "the agency's path [to] reasonably be discerned" and to facilitate effective review, not an explanation of "ideal clarity." Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc., 419 U.S. 281, 286 (1974).

Plaintiffs contend that the agency's actions were arbitrary and capricious because they contend HHS "did not provide a rational basis" for its decision, even as Plaintiffs acknowledge, as they must, that the agency explained it "changed its position and determined that the public health funding is no longer necessary based on the end of the COVID-19 pandemic. . . ." ECF No. 60 at 30, 32. HHS's determination that COVID-19 grant funding should no longer be a focus in light of the end of the pandemic was regular and lawful. See Dep't of Commerce v. New York, 588 U.S. 752,

781 (2019) ("[A] court may not set aside an agency's policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration's priorities. . . . Such decisions are routinely informed by unstated considerations of politics, the legislative process, public relactions, interest group relations, foreign relations, and national security concerns (among others)"). And because the agency's determinations about how it allocates funding are matters of policy discretion and not of "factual findings," such a shift does not require any additional explanation under the APA. See F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). The agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." Id.

Much of Plaintiffs' arbitrary and capricious argument boils down to their contention that the agency should not have provided the same explanation to all recipients for its termination of COIVD-19-related grants. But Plaintiffs cite no authority to suggest that it is arbitrary and capricious for an agency to provide the same explanation across multiple decisions if, as here, those decisions are all made for the same basic reason and with respect to funding Congress appropriated for similar purposes tied to one global pandemic. The agency, in fact, had the same reason for terminating the grants at issue and communicated that clearly to recipients.

Plaintiffs alternatively suggest that HHS failed to consider "the substantial reliance interests of the Plaintiff States and the tremendously harmful impact of the Public Health Funding Decision and its implementation" and that "longstanding policies may have engendered serious reliance interests that must be taken into account." *Id.* at 33. But that is an incorrect premise. HHS concluded that some grants—specifically, those related to the now-ended COVID-19 PHE—should be terminated, and that some should be retained. HHS also identified over \$86 million in SAMHSA funding and nearly \$79 million in CDC grant funding that the states had not obligated or drawn down while the funds were available. For the same reasons, Plaintiffs' arguments about their reliance on the availability of grants from the federal government are unavailing. They ignore the fact that the states failed to draw down over \$160 million of the funds while they were available, and that HHS continued to fund other grants that were consistent with the agency's priorities.

Plaintiffs' remaining arbitrary-and-capricious arguments fare no better. For example, they argue that the agency's decision to terminate certain grants fail to consider that Congress chose to keep funding some of the grants after the pandemic was over, and "appear simply to desire to overrule Congress' spending and judgment authority." ECF No. 60 at 3. But Plaintiffs' argument ignores the broad discretion that agencies have in creating, awarding, and terminating specific grants. See generally, Lincoln v. Vigil, 508 U.S. at 185-88, 192-93 (finding that the Indian Health Service's decision to discontinue a program it had previously funded and to instead reallocate those funds to other programs consistent with the agency's statutory responsibilities

was committed to agency discretion by law and thus not reviewable under the APA's reasoned-decision-making standards, noting that an agency's allocation of funds requires "a complicated balancing of a number of factors which are peculiarly within its expertise': whether its 'resources are best spent' on one program or another; whether it is likely to succeed' in fulfilling its statutory mandate; whether a particular program 'best fits the agency's overall policies'; and, 'indeed, whether the agency has enough resources' to fund a program 'at all.") (quoting *Heckler v. Chaney*, 470 U.S. 821, 831 (1985)); *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Donovan*, 746 F.2d 855, 861 (D.C. Cir. 1984) (Scalia, J.) ("A lump-sum appropriation leaves it to the recipient agency (as a matter of law, at least) to distribute the funds among some or all of the permissible objects as it sees fit.")

While Plaintiffs point generally to the sections of the Fiscal Responsibility Act of 2023 that rescinded some, but not all, of the funding that had been appropriated in the wake of COVID-19, they overlook that this occurred in part because HHS had not yet distributed all of the money appropriated by Congress. When Congress considered the fact that HHS had not distributed all of the money it had appropriated for COVID-19 relief, Congress did not mandate spending of all of the previously allocated funds or provide more specific requirements for the funding. Instead, Congress chose to take some portion of the funds back.

Two years later, the money had still not been spent. Plaintiffs do not argue that HHS exceeded its authority in allowing grants to expire, or by allowing Plaintiffs to use funding for purposes no longer directly tied to COVID-19, such as the prevention of other infectious diseases. Plaintiffs did not take issue with HHS's ongoing adjustments, as long as the Plaintiffs were still receiving as much money as they wanted; it was only when HHS acknowledged the reality of the end of the pandemic and the need to stop, any remaining funding tied to COVID-19 that Plaintiffs claimed overreach.

HHS determined that the grants that it had previously determined to be an appropriate use of the remaining COVID-19 funding are no longer an appropriate use. Congress may, as before, decide to take back the funding or appropriate it for a different use. But, as the Supreme Court has acknowledged, it is squarely within HHS's discretion to determine whether to fund any specific program at all, so long as it is consistent with its statutory responsibilities. *See generally, Lincoln*, 508 U.S. at 193.

III. Plaintiffs Have Not Proven Irreparable Harm

Plaintiffs' motion should be denied solely on the basis that they have failed to demonstrate irreparable harm. "Preliminary injunctions are strong medicine" and "should not issue except to prevent a real threat of harm." *Matos ex rel. Matos v. Clinton Sch. Dist.*, 367 F.3d 68, 73 (1st Cir. 2004). "A finding of irreparable harm must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store." *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004) ("In most cases—and the case at hand is no outlier—irreparable harm constitutes a necessary threshold showing for an award of preliminary injunctive relief."); *see also Narragansett Indian Tribe*,

934 F.2d at 6–7 ("[S]peculative injury does not constitute a showing of irreparable harm." (quoting *Pub. Serv. Co. of N.H. v. Town of W. Newbury*, 835 F.2d 380, 383 (1st Cir. 1987))).

Plaintiffs argue that they "have suffered and will suffer substantial harm," not irreparable harm, the standard for a preliminary injunction. ECF No. 60 at 12. They argue that the termination of funding "undermines [their] ability to fulfill their mission of protecting public health [,]" "will eliminate a wide range of health care services provided by Plaintiff States[,]" and "imperils Plaintiff States' public health infrastructure projects." Id. at 13-17. Plaintiffs' sweeping assertion of harm fails to address the fundamental problem that the relief they seek is monetary damages—the classic example of reparable harm—and that Plaintiffs themselves, along with the other states, failed to draw down over \$160 million of the very grant funds they now claim the absence of which would cause irreparable harm.

A. Monetary damages do not establish irreparable harm.

Plaintiffs' shifting characterization of the claims cannot hide the fact that, at bottom, they seek an order from the Court that would force the federal government to pay them money. Thus, their claims are for money damages. It is "well settled that economic loss does not, in and of itself, constitute irreparable harm." Wis. Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985); see also, e.g., Akebia Therapeutics, Inc. v. Azar, 443 F. Supp. 3d 219, 230 (D. Mass. 2020) ("[E]("economic loss alone does not usually rise to the level of irreparable harm which a party must establish to obtain a preliminary injunction") (cleaned up); Seafreeze Shoreside, Inc v. U.S. Dep't of Inte-

rior, No. 1:22-cv-11091-IT, 2023 WL 3660689, at *7 (D. Mass. May 25, 2023) ("Plaintiffs have not demonstrated 'irreparable harm,' but at most, economic loss"); see also e.g., Weinberger, 456 U.S. at 312 ("The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies."); Danielson v. Local 275, Laborers Int'l Union, 479 F.2d 1033, 1037 (2d Cir. 1973) ("Irreparable injury is suffered where monetary damages are difficult to ascertain or are inadequate.").

Plaintiffs argue that "[p]reliminiary relief is necessary to avoid such harm and protect the equities and public interest[]" citing *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005). ECF 60 at 37. That case, however, defines "irreparable injury" for the purposes of preliminary relief as "an injury that cannot adequately be compensated for either by a later-issued permanent injunction, after a full adjudication on the merits, or by a later-issued damages remedy." *Rio Grande*, 397 F.3d at 76. It also involves a suit under § 1983, and not under the APA. *Id*.

The Plaintiffs' purport to be unable to provide certain programming results solely from the loss of funding. But HHS has not taken any actions—other than withholding money—that impede Plaintiffs' ability to carry on with these programs. The only thing that HHS has done is stop footing the bill. That is an economic loss. Otherwise, one could always convert the relevant harm for purposes of a preliminary injunction from (i) an economic loss to (ii) the inability to do things that cost money—thus swallowing the general rule that "economic loss alone does not usually rise to the level of irreparable harm." Akebia, 443 F. Supp. 3d at 230. The Plaintiff states

have other open grant awards with HHS and will continue to able to apply for, and receive, new lines of funding from the agency. The Plaintiff states are only prevented from drawing down from the COVID-19-related grant awards for costs they incurred after those awards were terminated.

Finally, even if Plaintiffs were correct that the terminations did not comport with the APA, vindicating that right would involve remanding to the agency for further consideration or explanation. If that is the final relief Plaintiffs would theoretically be entitled to, it makes no sense to grant the broader relief of reinstating the grants in this preliminary posture. See Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 744 (1985) ("the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation"); Dist. Hosp. Partners, L.P. v. Burwell, 786 F.3d 46, 60 (D.C. Cir. 2015) ("bedrock principles of administrative law preclude us from declaring definitively that the Secretary's decision was arbitrary and capricious without first affording her an opportunity to articulate, if possible, a better explanation").

Ultimately, even if Plaintiffs can claim some threat of harm, there is no reason why they cannot vindicate that alleged harm through individualized, specific lawsuits challenging particular funding denials for specific grants. Those suits would be properly brought in the Court of Federal Claims. Plaintiffs' declarations do not establish the need for broad relief in a single lawsuit, particularly because they demonstrate the wide varied grants and programs at issue.

B. If the Court enters a preliminary injunction, the harm to the federal government cannot be remedied.

A federal court may not issue an equitable remedy that is "more burdensome to the defendant than necessary to [redress] the plaintiff's injuries." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979); *see also Gill v. Whitford*, 585 U.S. 48, 68 (2018) ("[A] 'remedy must ... be limited to the inadequacy that produced the injury in fact that the plaintiff has established'"). The "universal injunctive relief" Plaintiffs seek defies foundational and equitable principles. *See Labrador v. Poe*, 601 U.S.——,—, —, No. 23A763 (April 15, 2024) (Gorsuch, J., concurring in grant of stay).

If an injunction is granted, and allows Plaintiffs to use the terminated funds, the government "is unlikely to recover the grant funds once they are dispersed." *California*, Slip Op. 2. As the Supreme Court noted in *California*, '[n]o grantee "promised to return withdrawn funds should its grant termination be reinstated," and the Court did not impose a bond to guarantee recovery of such funds if Defendants later prevail. *Id.* Given the exceptionally broad relief that Plaintiffs seek, the harm to the federal government would be tremendous. Therefore, relief should be denied.

IV. The Balance of the Equities and the Public Interest Weigh in the Federal Government's Favor

Even if Plaintiffs could establish irreparable harm, they have not shown that "the balance of equities and consideration of the public interest" favor a preliminary injunction. *Winter*, 555 U.S. at 32. Traditionally, a court first determines whether the movant's likely harm "will outweigh the harm which granting the injunction would inflict on [the defendant]." 7-Eleven, Inc. v. Grewal, 60 F. Supp. 3d 272, 283 (D. Mass. 2014). Thus, Plaintiffs must demonstrate that their claimed injury outweighs any

harm that granting the injunctive relief would inflict upon Defendants. *Lancor v. Lebanon Hous. Auth.*, 760 F. 2d 361, 362 (1st Cir. 1985). Next, courts consider whether "[t]he public interest weighs in favor of granting" the preliminary injunction. 7-*Eleven, Inc.*, 60 F. Supp. 3d at 285.. But where, as here, the government is the defendant, these factors simply "merge." *Nken*, 556 U.S. at 435.

If the Court does not issue a preliminary injunction, HHS will hold the grant money at issue during the pendency of the case, and the Plaintiffs can still obtain it as money damages at the end of the case if they are ultimately successful. But the opposite is not true—if the grantees are given access now, and draw down the funds throughout the litigation, Defendants will be left with no meaningful recourse even if they prevail. Accordingly, HHS will bear all the risk if the Court enters a preliminary injunction. The Supreme Court recognized precisely that dynamic in *California* when it stayed the TRO granted by the district court in that case. 2025 WL 1008354, at *1.

The relevant harm to the federal government is not merely the forced expenditure of (unrecoverable) money during the pendency of this litigation. The harm is also the forced expenditure of money in support of causes that are inconsistent with Executive Branch's policy objectives. Put another way, it is not just a loss of money, but also a loss of control that has been vested by statute in the Secretary, who in turn answers to the President and thus the public at large. Forcing the government to

financially support causes at odds with its own policies, and Congress's express purpose for the funds, inflicts a distinct and irremediable harm on the public that goes beyond the expenditure of appropriated funds.

V. The Court Should Limit Any Injunctive Relief to the Grants Plaintiffs Specifically Cite

Relief under the APA is limited; courts may either "compel agency action unlawfully withheld or unreasonably delayed" or "hold unlawful and set aside agency action." 5 U.S.C. § 706; see also Norton v. S. Utah Wilderness All., 542 U.S. 55, 66-67 (2004) (explaining how the APA's limits on relief are intended to "protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements").

Injunctive relief should not provide "a remedy beyond what [is] necessary to provide relief" to injured parties. Lewis v. Casey, 518 U.S. 343, 360 (1996). Accordingly, to the extent the Court intends to grant the Plaintiffs' request for a preliminary injunction, such relief should be narrowly tailored to apply only to the grants identified in Plaintiffs' declarations accompanying their motion for a temporary restraining order. See Univ. of Tex. v. Camenisch, 451 U.S. 390, 395 (1981) ("The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held."); Dep't of Homeland Sec. v. New York, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring) ("Universal injunctions have little basis in traditional equitable practice."); Florida v. Dep't of Health & Hum. Servs., 19 F.4th 1271, 1282 (11th Cir. 2021) (noting that the "appropriate circumstances" for issuing a nationwide injunction "are

rare"). Accordingly, the Court should—at a minimum—limit any relief to grant awards about which the Plaintiffs have provided information in their various declarations. And it should clarify that the agency may continue to subject draw down requests to its normal checks and procedures.

VI. Any Injunctive Relief Should Be Stayed Pending Appeal and be Accompanied by a Bond

If the Court grants Plaintiffs' Motion for a Preliminary Injunction, it should stay any such order pending any appeal, because Defendants are likely to succeed on appeal and will face irreparable harm absent a stay. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987) (setting forth the factors "regulating the issuance of a stay"). On the whole, as argued above, a stay is warranted. At a minimum, the Court should administratively stay any injunctive relief it intends to order for a period of seven days to allow the United States to seek an emergency, expedited stay from the Court of Appeals if an appeal is authorized.

The Defendants also respectfully requests that any injunctive relief accompany a bond under Federal Rule of Civil Procedure 65(c), which provides that "[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." A bond is appropriate here given that any preliminary relief would potentially mandate that HHS spend money that may not be recouped once distributed.

Dated: April 14, 2025 Respectfully submitted,

THE UNITED STATES OF AMERICA,

By its Attorneys,

SARA MIRON BLOOM Acting United States Attorney

/s/ Kevin Love Hubbard

KEVIN LOVE HUBBARD Assistant United States Attorney One Financial Plaza, 17th Floor Providence, RI 02903 (401) 709-5000 Kevin.Hubbard@usdoj.gov

CERTIFICATION OF SERVICE

I hereby certify that, on April 14, 2025, I filed the foregoing document through this Court's Electronic Case Filing (ECF) system, thereby serving it upon all registered users in accordance with Federal Rule of Civil Procedure 5(b)(2)(E) and Local Rules Gen 304.

/s/ Kevin Love Hubbard KEVIN LOVE HUBBARD Assistant United States Attorney

UNITED STATES DISTRICT COURT DISTRICT OF RHODE ISLAND

STATE OF COLORADO: STATE OF RHODE ISLAND; STATE OF CALI-FORNIA; STATE OF MINNESOTA; STATE OF WASHINGTON: STATE OF ARIZONA; STATE OF CON-NECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAI'I; STATE OF ILLINOIS; OFFICE OF THE GOVERNOR ex rel. Andy Beshear, in his official capacity as Governor of the COMMON-WEALTH OF KENTUCKY: STATE OF MAINE; STATE OF MARYLAND; COMMONWEALTH OF MASSACHU-SETTS; STATE OF MICHIGAN; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA: STATE OF OREGON: JOSH SHAPIRO, in his official capacity as Governor of the COMMONWEALTH OF PENNSYLVANIA; and STATE OF WISCONSIN,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services,

Defendants.

Civil Action No. 25-cv-121-MSM-LDA

DECLARATION OF JAMIE LEGIER

Pursuant to 28 U.S.C. § 1746, I, Jamie Legier, declare as follows:

- 1. I am the Director of the Office of Grants Services at the Centers for Disease Control and Prevention (CDC), the United States Department of Health and Human Services ("HHS").
- 2. In that capacity, my official duties include providing fiscal stewardship across the agency, and I serve as the agency's principal advisor and liaison on all aspects of grants, including grants financial management activities.
- 3. I have experience with HHS's record systems regarding grant awards issued by CDC, a sub-agency of HHS. These records are made in the course of regularly conducted business activity at or near the time of relevant events by a person with knowledge of these events.
- 4. In the course of preparing this declaration, I have examined the office records available to me regarding grants awarded by CDC.
- 5. At issue in this litigation are grants provided by CDC to prevent, prepare for, and mitigate against COVID-19. These grants were issued in the midst of the COVID-19 pandemic, utilizing supplemental funds appropriated through a number of appropriations acts passed by Congress in response to the COVID-19 pandemic.
- 6. CDC expeditiously provided the Plaintiff States with critical funding through a variety of grant programs intended to timely respond to the crisis caused by the COVID-19 Public Health Emergency ("PHE").
 - 7. Over the past five years, CDC has approved no cost extensions or

Case 1:25-cv-00121-MSM-LDA Document 68-1 Filed 04/14/25 Page 3 of 3 PageID #:

allowed carryover of funding through these grant programs at the request of a Plain-

tiff State as a recipient and upon agency review, which allowed the recipients addi-

tional time to use available funding. In the interim, the period of performance for a

number of the grants also ended prior to March 24, 2025, many having remaining

COVID-19 funds that had not been drawn down by the states, despite the availability

of those funds.

8. The grants to Plaintiff States were terminated on March 24, 2025, for

cause. The cause cited in the termination letters was that the COVID-19 pandemic

was over. At the time of the grant terminations on March 24, 2025, approximately

74% of the original \$22 billion in CDC funding for COVID-19 grants to the states had

either been spent or had expired, with a remaining balance of approximately \$5.8

billion.

9. At the time of the grant terminations, the period of performance for

many of the original CDC grants had already expired, with remaining balances—

totaling nearly \$79 million—that the states never drew down from available funds.

I HEREBY DECLARE TO THE BEST OF MY KNOWLEDGE AND BELIEF,

UNDER PENALTY OF PERJURY under the laws of the United States of Amer-

ica, that the foregoing is true and correct.

EXECUTED this April 14, 2025, at Washington, DC.

UNITED STATES DISTRICT COURT DISTRICT OF RHODE ISLAND

STATE OF COLORADO: STATE OF RHODE ISLAND; STATE OF CALI-FORNIA; STATE OF MINNESOTA; STATE OF WASHINGTON: STATE OF ARIZONA; STATE OF CON-NECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAI'I; STATE OF ILLINOIS; OFFICE OF THE GOVERNOR ex rel. Andy Beshear, in his official capacity as Governor of the COMMON-WEALTH OF KENTUCKY: STATE OF MAINE; STATE OF MARYLAND; COMMONWEALTH OF MASSACHU-SETTS: STATE OF MICHIGAN; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA: STATE OF OREGON: JOSH SHAPIRO, in his official capacity as Governor of the COMMONWEALTH OF PENNSYLVANIA; and STATE OF WISCONSIN,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services,

Defendants.

Civil Action No. 25-cv-121-MSM-LDA

DECLARATION OF KURT JOHN

Pursuant to 28 U.S.C. § 1746, I, Kurt John, declare as follows:

- 1. I am the Director of the Office of Financial Resources, Substance Abuse and Mental Health Services Administration (SAMHSA), the United States Department of Health and Human Services ("HHS").
- 2. In that capacity, my official duties include provides fiscal stewardship across the agency and serves as the agency's principal advisor and liaison on all aspects of budget, grants, contracts, and financial management activities.
- 3. I have experience with HHS's/SAMHSA's record systems regarding grant awards. These records are made in the course of regularly conducted business activity at or near the time of relevant events by a person with knowledge of these events.
- 4. In the course of preparing this declaration, I have examined the office records available to me regarding grants awarded by SAMHSA.
- 5. SAMHSA expeditiously provided the Plaintiff states with critical funding through a variety of grant programs intended to timely respond to the crisis caused by the COVID-19 Public Health Emergency ("PHE").
- 6. Over the past five years, SAMHSA has continued to provide ongoing no cost extensions or allow carryover of funding through these grant programs, frequently extending deadlines during which the funding could be spent. In the interim, the period of performance for a number of the grants have also expired, frequently

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with remaining funds that had not been drawn down by the states, despite the avail-

ability of those funds.

7. At the time of the grant terminations on March 24, 2025, approximately

74% of the \$2.7 billion in SAMSHA funding for COVID grants to the Plaintiff states

had either been spent or had expired, with a remaining balance of approximately

\$702 million.

8. With respect to grants where the period of performance had already ex-

pired at the time of the grant terminations, the states had not drawn down from the

more than \$86 million in available funding.

I HEREBY DECLARE TO THE BEST OF MY KNOWLEDGE AND BELIEF, UNDER

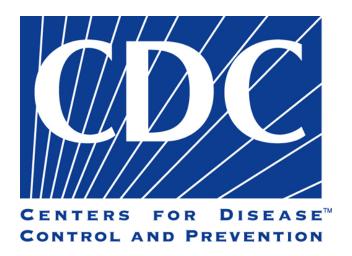
PENALTY OF PERJURY under the laws of the United States of America, that the foregoing is

true and correct.

EXECUTED this April 14, 2025, at Washington, DC.

/s/ Kurt John Kurt John

Exhibit A



Centers for Disease Control and Prevention

Office for State, Tribal, Local and Territorial Support

National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities

CDC-RFA-OT21-2103

05/03/2021

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Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-OT21-2103. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:

National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-OT21-2103

E. Assistance Listings Number:

93.391

F. Dates:

1. Due Date for Letter of Intent (LOI):

03/26/2021

2. Due Date for Applications:

05/03/2021

11:59 p.m. U.S. Eastern Standard Time, at <u>www.grants.gov</u>.

3. Due Date for Informational Conference Call:

CDC will host *two* informational conference calls for potential applicants:

Date: 03/30/2021

Times: 3:00pm to 4:00pm Eastern Standard Time

and

6:00pm to 7:00pm Eastern Standard Time

Meeting Details:

Join ZoomGov Meeting

https://cdc.zoomgov.com/j/16040976381?pwd=NmNjdFcrQlFVSjVPZ25nR0dHay9zdz09

Meeting ID: 160 4097 6381 Passcode: OT21-2103

One tap mobile

+16692545252,,16040976381#,,,,,0#,,708148093# US (San Jose) +16468287666,,16040976381#,,,,,0#,,708148093# US (New York)

Dial by your location

- +1 669 254 5252 US (San Jose)
- +1 646 828 7666 US (New York)
- +1 669 216 1590 US (San Jose)
- +1 551 285 1373 US

Meeting ID: 160 4097 6381

Passcode: 708148093

Find your local number: https://cdc.zoomgov.com/u/advmPjIAqk

Join by SIP

16040976381@sip.zoomgov.com

Join by H.323

161.199.138.10 (US West) 161.199.136.10 (US East) Meeting ID: 160 4097 6381 Passcode: 708148093

G. Executive Summary:

1. Summary Paragraph

The <u>Consolidated Appropriations Act, 2021</u> (P.L. 116-260), which contained the <u>Coronavirus Response and Relief Supplemental Appropriations Act, 2021</u> (P.L. 116-260, Section 2, Division M) provided, in part, funding for strategies to improve testing capabilities and other COVID-19 response activities in populations that are at high-risk and underserved, including racial and

ethnic minority groups and people living in rural communities. Strategies also include those to develop or identify best practices for states and public health officials to use for contact tracing.

#: 4997

To achieve these purposes, the Centers for Disease Control and Prevention (CDC) is announcing a non-competitive grant CDC-RFA-OT21-2103 titled "National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved, Including Racial and Ethnic Minority Populations and Rural Communities." This grant will provide funding to address COVID-19 and advance health equity (e.g., through strategies, interventions, and services that consider systemic barriers and potentially discriminatory practices that have put certain groups at higher risk for diseases like COVID-19) in racial and ethnic minority groups and rural populations within state, local, US territorial, and freely associated state health jurisdictions.

a. Eligible Applicants:

Open Competition

b. Funding Instrument Type:

G (Grant)

c. Approximate Number of Awards

108

d. Total Period of Performance Funding:

\$ 2,250,000,000

All funding will be disbursed during year one with a total performance period of two years.

e. Average One Year Award Amount:

\$0

Funding will vary by jurisdiction category. Average one-year award amount by applicant type:

- State Health Department: \$32,000,000
- Local Health Departments Serving a County or City with a Population of ≥2 Million: \$26,000,000
- Local Health Departments Serving a City with a Population of 400,000 or more, but less than 2 Million: \$5,000,000
- US Territories and Freely Associated States: \$3,000,000

f. Total Period of Performance Length:

2

g. Estimated Award Date:

June 01, 2021

h. Cost Sharing and / or Matching Requirements:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Coronavirus disease 2019 (COVID-19) has disproportionately affected populations placed at higher risk and who are medically underserved, including racial and ethnic minority groups, and people living in rural communities who are at higher risk of exposure, infection, hospitalization, and mortality. Additionally, racial and ethnic minority groups and people living in rural communities have disproportionate rates of chronic diseases that increase the severity of COVID-19 infection and might experience barriers to accessing testing, treatment, or vaccination against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes COVID-19.

To reduce the burden of COVID-19 among populations disproportionately affected, it is imperative that state, local, US territorial, and freely associated state health departments (or their bona fide agents) work collaboratively and develop partnerships with key partners who have existing community or social service delivery programs for African American, Hispanic, Asian American, Pacific Islander, Native American or other racial and ethnic minority groups or people living in rural communities. Such key partners may include:

- Community-based and civic organizations;
- Tribes, tribal organizations;
- Academic institutions, and universities (e.g., minority serving institutions Historically Black Colleges and Universities (HBCUs), Hispanic Association of Colleges and Universities (HACUs), American Indian Higher Education Consortium (AIHEC), Tribal Colleges and Universities (TCUs);
- Asian American and Pacific Islander Serving Institutions (AAPI);
- Faith-based organizations;
- Non-governmental organizations;
- Correctional facilities and institutions:
- Local governmental agencies and community leaders;
- Local businesses and business community networks and organizations, (e.g., employers, local chambers of commerce, small business community groups);
- Social services providers and organizations, including those that address social determinants of health (e.g., <u>community transportation</u>; anti-discrimination organizations; legal services);
- Health care providers, including community health centers (e.g., federally qualified health centers, (FQHCs);
- Health-related organizations, (e.g., pharmacies, testing centers, community health workers);
- State Offices of Rural Health (SORH) or equivalent, State Rural Health Associations (SRHAs);
- Rural Health Clinics (RHCs) and Critical Access Hospitals (CAHs); and
- Governmental organizations focused on non-health services (e.g., <u>Coordinating Council on Access and Mobility Department of Transportation</u>, <u>Supportive housing for the elderly Housing and Urban Development</u>).

To reach populations at higher risk, underserved, and disproportionately affected, including racial and ethnic minority groups and people living in rural communities, it is critical for funded recipients and key partners to implement a coordinated and holistic approach that builds on culturally, linguistically, and locally tailored strategies and best practices to reduce COVID-19 risk. In addition, a coordinated and holistic approach is essential to building and sustaining trust, ensuring equitable access to COVID-19 related services, and advancing health equity to address COVID-19 related health disparities among populations at higher risk, underserved, and disproportionately affected. ¹

b. Statutory Authorities

Section 317(k)(2) of the Public Health Service Act [42 USC 247b(k)(2), as amended] and the Consolidated Appropriations Act, 2021 (P.L. 116-260), which contained the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (P.L. 116-260, Section 2, Division M, Title III).

c. Healthy People 2030

This emergency funding opportunity focuses on emergency preparedness and response foundational capability and addresses the "*Healthy People 2030*" focus areas of <u>Preparedness</u>, <u>Vaccination</u>, <u>Health Communication</u>, <u>Respiratory Disease</u>, <u>Infectious Disease</u>, <u>Public Health Infrastructure</u>, and <u>Social Determinants of Health</u>.

For specific objectives within these topic areas, please visit www.healthypeople.gov.

d. Other National Public Health Priorities and Strategies

- Executive Order on Ensuring an Equitable Pandemic Response and Recovery (EO13995)
- Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (EO13985)
- National Strategy for the COVID-19 Response and Pandemic Preparedness (see Goal 6)
- CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity
- Centers for Disease Control and Prevention Coronavirus 2019 (COVID-19)
 Recommendations and Guidance for state, local, territorial and tribal health departments

e. Relevant Work

This NOFO is complementary and non-duplicative of the following CDC program activities, public health priorities, and strategies:

- CDC-RFA-CK19-1904: 2019 Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)
- ELC Enhancing Detection Emerging Issues (E) Project: Funding for the Enhanced Detection, Response, Surveillance, and Prevention of COVID-19 Supplement
- CDC-RFA-OT18-1802: Strengthening Public Health Systems and Services Through National Partnerships to Improvement and Protect the Nation's Health

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Due to the nature of this grant and public health crisis, there is not a predetermined logic model. It is expected that funds from this grant will be used to strengthen public health infrastructure, preparedness and response capabilities and services in state, local, US territorial and freely associated state health departments (or their bona fide agents) to address COVID-19 related health disparities and advance health equity in underserved and disproportionately affected populations through testing, contact tracing and other mitigation strategies. All applicants must define the populations disproportionately affected by COVID-19 within their respective jurisdiction, describe how they will reach these populations, and describe their experience working with communities that are underserved and at higher risk for COVID-19 disparities and health inequities.

Recipients will be required to include a financial carve out for rural communities, as applicable. As such, applicants who serve rural communities must define these communities and describe how they will provide direct support (e.g., funding, programs, or services) to those communities in their applications. State government applicants must also engage their State Office of Rural Health (SORH) or equivalent, in planning and implementing their activities and describe in their application how their SORHs or equivalent will be involved. To that end, CDC recommends state government applicants engage their respective SORH or equivalent, early in the application process. Contact information for SORHs can be found at: https://nosorh.org/nosorh-members-browse-by-state/.

In addition, applicants are strongly encouraged to develop partnerships and collaborate with key partners who have existing community or social service delivery programs for African American, Hispanic, Asian American, Pacific Islander, Native American or other racial and ethnic minority groups or people living in rural communities. Such key partners may include:

- Community-based and civic organizations;
- Tribes, tribal organizations;
- Academic institutions, and universities (e.g., minority serving institutions Historically Black Colleges and Universities (HBCUs), Hispanic Association of Colleges and Universities (HACUs), American Indian Higher Education Consortium (AIHEC), Tribal Colleges and Universities (TCUs);
- Asian American and Pacific Islander Serving Institutions (AAPI);
- Faith-based organizations;
- Non-governmental organizations;
- Correctional facilities and institutions;
- Local governmental agencies and community leaders;
- Local businesses and business community networks and organizations, (e.g., employers, local chambers of commerce, small business community groups);
- Social services providers and organizations, including those that address social determinants of health (e.g., <u>community transportation</u>; anti-discrimination organizations; legal services);
- Health care providers, including community health centers (e.g., federally qualified health centers, (FQHCs);

- Health-related organizations, (e.g., pharmacies, testing centers, community health workers);
- State Offices of Rural Health (SORH) or equivalent, State Rural Health Associations (SRHAs);
- Rural Health Clinics (RHCs) and Critical Access Hospitals (CAHs); and
- Governmental organizations focused on non-health services (e.g., <u>Coordinating Council on Access and Mobility Department of Transportation</u>, <u>Supportive housing for the elderly Housing and Urban Development</u>).

Through this collaborative approach, applicants will be better able to maximize the impact of their federal COVID-19 funding, strengthen implementation of strategies and activities, and align resources to better match the burden of COVID-19 among populations who are at higher risk and are underserved. This collaboration must be described in the application.

Applicants are encouraged to establish new funding relationships with partners and community organizations and may also continue funding relationships with partners and community organizations that have experience working with communities most affected by COVID-19 and have the capacity to implement strategies and activities outlined in this NOFO. To ensure resources reach the areas of greatest need, all applicants are strongly encouraged to use local epidemiologic, surveillance, and other available data sources to inform local resource allocation and program efforts, including program planning, implementation, and evaluation.

i. Purpose

Address COVID-19-related health disparities and advance health equity by expanding state, local, US territorial and freely associated state health department capacity and services to prevent and control COVID-19 infection (or transmission) among populations at higher risk and that are underserved, including racial and ethnic minority groups and people living in rural communities.

ii. Outcomes

The intended outcomes for this grant are:

- 1. Reduced COVID-19-related health disparities.
- 2. Improved and increased testing and contact tracing among populations at higher risk and that are underserved, including racial and ethnic minority groups and people living in rural communities.
- 3. Improved state, local, US territorial and freely associated state health department capacity and services to prevent and control COVID-19 infection (or transmission) among populations at higher risk and that are underserved, including racial and ethnic minority groups and people living in rural communities.

iii. Strategies and Activities

This grant program will address COVID-19-related health disparities and advance health equity by expanding state, local, US territorial and freely associated state health department capacity and services to prevent and control COVID-19 infection (or transmission) among populations at higher risk and that are underserved, including racial and ethnic minority groups and people living in rural communities. All strategies should aim to build infrastructures that both address disparities in the current COVID-19 pandemic and set the foundation to address future responses.

The program is composed of *four* overarching strategies:

1. Expand existing and/or develop new mitigation and prevention resources and services to reduce COVID-19 related disparities among populations at higher risk and that are underserved: Ensuring equitable access to critical COVID-19 personal protective equipment (PPE), testing, contact tracing, quarantine and isolation, vaccination, and other wrap-around services require deploying focused strategies, resources, and activities to meet the needs of individuals and mitigate the spread of COVID-19 among populations disproportionately

Priority activities for *Strategy 1* should include:

• Expand testing (including home test kits and mobile testing sites) and contact tracing among populations at higher risk and that are underserved, including racial and ethnic minority populations and people living in rural communities:

Additional activities may include but are not limited to:

- Vaccine coordination, quarantine and isolation options, and preventive care and disease management among populations that are underserved and at higher risk for COVID-19
- Tailor and adapt evidence-based policies, systems, and environmental strategies to mitigate social and health inequities related to COVID-19
- Identify and establish collaborations with critical partners affiliated with populations at higher risk and that are underserved, including racial and ethnic minority groups at higher risk for COVID-19 to:1) connect community members to programs, healthcare providers, services and resources (e.g., transportation, housing support, food assistance programs, mental health and substance abuse services, substance abuse) they might need and 2) lessen adverse effects of mitigation strategies
- 2. Increase/improve data collection and reporting for populations experiencing a disproportionate burden of COVID-19 infection, severe illness, and death to guide the response to the COVID-19 pandemic: Improving data systems and the collection, analysis, and use of racial, ethnic, and rural health data for COVID-19 prevention and control will help to better identify populations and communities disproportionately affected, track resource distribution, and evaluate the effectiveness of advancing health equity to address COVID-19related health disparities among disproportionately affected populations. Collection of data that contextualize racial, ethnic, and rural health data and robust analysis of these data are fundamental activities for improving data collection and reporting.

Priority activities for *Strategy 2* should include:

• Improve data collection and reporting for testing and contact tracing for populations at higher risk and that are underserved;

Additional activities may include but are not limited to:

• Build on plans for collecting and reporting timely, complete, representative, and relevant data on testing, incidence, vaccination, and severe outcomes by detailed race and ethnicity categories, taking into account age and sex differences between groups

Develop strategies to educate providers, community partners, and programs on: 1) the importance of the race and ethnicity data and appropriate strategies to collect it: 2) how to address mistrust/hesitancy about reporting personal information including race and ethnicity, and 3) why this information is important to prevent and control the spread of COVID-19

#: 5003

- Develop and implement plans to disseminate health equity-related data and related materials tailored to be culturally and linguistically responsive for diverse audiences
- Develop key principles and resources for collecting, analyzing, reporting, and disseminating health equity-related data to inform action during a public health
- Assure adequate resources for data infrastructure and workforce to ensure alignment with data modernization
- 3. Build, leverage, and expand infrastructure support for COVID-19 prevention and control among populations that are at higher risk and underserved: Sufficient workforce, infrastructure, and capacity are critical to providing equitable access to disproportionately affected populations. Where feasible, this short-term program will build, leverage, and expand the infrastructure and capacity within state, local, US territorial and freely associated state health departments (or their bona fide agents) to ensure and expand equitable access to critical COVID-19 testing and contact tracing, as well as PPE, quarantine and isolation, vaccination, and other wrap-around and supportive services.

Priority activities for *Strategy 3* should include:

• Expand the infrastructure to improve testing and contact tracing among populations at higher risk and that are underserved, including racial and ethnic minority populations and rural communities;

Additional activities may include but are not limited to:

- Establish, enhance, or implement leadership-level health equity offices, workgroups, task forces, or positions to guide addressing COVID-19 among communities at higher risk and that are underserved
- Convene and facilitate multi-sector coalitions or advisory groups that include members of underserved communities and organizations that serve the community. These groups may provide advice, guidance, and recommendations for addressing COVID-19 and advancing health equity among their communities
- Update jurisdictions' COVID-19 plans and health equity plans to support communities most at risk for COVID-19 with the intention of setting up systems that put in place infrastructures and plans that can also support future emergency responses
- Build and expand an inclusive public health workforce, including hiring people from the community (e.g., community health workers, social workers, other trusted community members) who are equipped to assess and address the needs of communities disproportionately affected by COVID-19
- 4. Mobilize partners and collaborators to advance health equity and address social determinants of health as they relate to COVID-19 health disparities among populations at higher risk and that are underserved: Identifying and addressing current gaps and factors that influence COVID-19-related health disparities requires a collaborative approach. Under this

strategy, collaborations between the primary applicant and key partners will broadly address health disparities and inequities related to COVID-19. (Please refer to Approach section of NOFO for a list of recommended key partners.)

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Priority activities for Strategy 4 should include:

• Build community capacity to reach disproportionately affected populations with effective culturally and linguistically tailored programs and practices for testing and contact tracing, and quarantine, including racial and ethnic minority populations and rural communities:

Additional activities may include but are not limited to:

- Build and implement cross-sectoral partnerships to align public health, healthcare, and non-health (e.g., housing, transportation, social service) interventions that decrease risk for COVID-19
- Develop mechanisms such as community advisory groups that include leaders representing racial and ethnic minority groups and rural community leaders and members representing underserved populations to inform COVID-19 and future emergency response activities
- Develop and disseminate culturally and linguistically responsive COVID-19 prevention communications through various channels (e.g., local media, local or community newspapers, radio, TV, trusted communications agents) written in plain language and in formats and languages suitable for diverse audiences—including people with disabilities, limited English proficiency, etc.—addressing and, as necessary, dispelling of misinformation and barriers to mitigation practices due to mistrust.
- Build community capacity that includes traditional organizations (e.g., public health, healthcare) and non-traditional partners (e.g., community health workers, churches, transportation providers, social workers) to reach disproportionately affected populations with effective culturally and linguistically tailored programs and practices for testing, contact tracing, isolating, vaccination, and healthcare strategies
- Identify and establish collaborations with critical partners affiliated with and who provide services to populations that are underserved and at higher risk for COVID-19 to disseminate scientifically accurate, culturally, and linguistically responsive information and facilitate access to health-related services

Applicants are not required to implement all four strategies, but rather they should select the strategies and activities that best address their jurisdiction's respective priorities and needs. Strategies should engage representatives of populations and communities to be served by this NOFO. CDC will also allow applicants to propose additional strategies and activities beyond those included in the NOFO to best achieve local outcomes. Any proposed new strategy or activity should include the rationale for the approach or a brief justification with evidence showing why it should be included. Applicants should not propose to allocate all funding to one activity (e.g. all funding will be used for one vaccination or testing event only).

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

Recipients are encouraged to collaborate, as appropriate, with CDC programs and centers, institutes, and offices (CIOs) to ensure that activities and funding are coordinated with, complementary of, and not duplicative of efforts supported under other CDC programs that support COVID-19 response.

To facilitate the identification and sharing of best practices, program evaluation, training, tool development, and communications of findings, recipients may receive tailored technical assistance from select national or regional partner organizations funded through CDC-RFA-OT18-1802: Strengthening Public Health Systems and Services through National Partnerships to Improvement and Protect the Nation's Health.

For questions about collaborating with CDC, please contact the CDC point of contact for this NOFO.

b. With organizations not funded by CDC:

It is a requirement of this opportunity to include a financial carve out for rural communities, as applicable. As such, applicants who serve rural communities must define these communities and describe how they will provide direct support (e.g., funding, programs and/or services) to those communities. State government applicants must also engage their State Office of Rural Health (SORH) or equivalent, in planning and implementing their activities and describe in their application how their SORHs or equivalent will be involved. To that end, CDC recommends state government applicants engage their respective SORH or equivalent, early in the application process. Contact information for SORHs can be found at: https://nosorh.org/nosorh-members-browse-by-state/.

In addition, applicants are strongly encouraged to develop partnerships and collaborate with key partners who have existing community or social service delivery programs for African American, Hispanic, Asian American, Pacific Islander, Native American or other racial and ethnic minority groups or people living in rural communities. Such key partners may include:

- Community-based and civic organizations;
- Tribes, tribal organizations;
- Academic institutions, and universities (e.g., minority serving institutions Historically Black Colleges and Universities (HBCUs), Hispanic Association of Colleges and Universities (HACUs), American Indian Higher Education Consortium (AIHEC), Tribal Colleges and Universities (TCUs);
- Asian American and Pacific Islander Serving Institutions (AAPI);
- Faith-based organizations;
- Non-governmental organizations;
- Correctional facilities and institutions:
- Local governmental agencies and community leaders;
- Local businesses and business community networks and organizations, (e.g., employers, local chambers of commerce, small business community groups);
- Social services providers and organizations, including those that address social determinants of health (e.g., <u>community transportation</u>; anti-discrimination organizations; legal services);

- Health care providers, including community health centers (e.g., federally qualified health centers, (FQHCs);
- Health-related organizations, (e.g., pharmacies, testing centers, community health workers);
- State Offices of Rural Health (SORH) or equivalent, State Rural Health Associations (SRHAs);
- Rural Health Clinics (RHCs) and Critical Access Hospitals (CAHs); and
- Governmental organizations focused on non-health services (e.g., <u>Coordinating Council on Access and Mobility Department of Transportation</u>, <u>Supportive housing for the elderly Housing and Urban Development</u>).

Through this collaborative approach, applicants will be better able to maximize the impact of their federal COVID-19 funding, strengthen implementation of strategies and activities, and align resources to better match the burden of COVID-19 among populations who are at higher risk and are underserved. This collaboration must be described in the application.

Applicants are encouraged to establish new funding relationships with partners and community organizations and may also continue funding relationships with partners and community organizations that have experience working with communities most affected by COVID-19 and have the capacity to implement strategies and activities outlined in this NOFO. To ensure resources reach the areas of greatest need, all applicants are strongly encouraged to use local epidemiologic, surveillance, and other available data sources to inform local resource allocation and program efforts, including program planning, implementation, and evaluation.

Memoranda of understanding (MOUs) or memoranda of agreement (MOAs) are encouraged, but not required.

2. Target Populations

This NOFO relates specifically to populations that have been placed at higher risk and are underserved, which, depending on the needs and priorities of the applicant, may include African American, Latino, and Indigenous and Native American people, Asian Americans and Pacific Islanders, and other people of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) people; people with disabilities; people who live in rural communities; people over the age of 65, and people otherwise adversely affected by persistent poverty or inequality.

Recipients are required to define and describe their respective population(s) of focus and describe how they will provide direct support (e.g., funding, services, or programs) to those communities within their application. Please include in the description the number of those you will serve broken out by applicable geographic area and/or community.

Recipients are also encouraged to include members of the populations and communities to be served in the planning, implementation, and evaluation of program activities.

a. Health Disparities

Evidence shows that COVID-19-related health disparities are inextricably linked to complex and widespread health and social inequities that have put many people from populations that are underserved —including racial and ethnic minority groups and people living in rural communities—at higher risk of exposure, infection, hospitalization, and mortality from COVID-19.2, 3, 4 Health equity requires striving for the highest possible standard of health for all people, giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

The intent of this funding opportunity is to address COVID-19-related health disparities and advance health equity by expanding state, local, US territorial and freely associated state health department capacity and services to prevent and control COVID-19 infection (or transmission) among populations at higher risk and that are underserved, including racial and ethnic minority groups and people living in rural communities.

To reduce the burden of COVID-19 among disproportionately affected populations applicants are strongly encouraged to develop partnerships and collaborate with key partners who have existing community or social service delivery programs for African American, Hispanic, Asian American, Pacific Islander, Native American or other racial and ethnic minority groups or people living in rural communities. Such key partners may include:

- Community-based and civic organizations;
- Tribes, tribal organizations;
- Academic institutions, and universities (e.g., minority serving institutions Historically Black Colleges and Universities (HBCUs), Hispanic Association of Colleges and Universities (HACUs), American Indian Higher Education Consortium (AIHEC), Tribal Colleges and Universities (TCUs);
- Asian American and Pacific Islander Serving Institutions (AAPI);
- Faith-based organizations;
- Non-governmental organizations;
- Correctional facilities and institutions;
- Local governmental agencies and community leaders;
- Local businesses and business community networks and organizations, (e.g., employers, local chambers of commerce, small business community groups);
- Social services providers and organizations, including those that address social determinants of health (e.g., <u>community transportation</u>; anti-discrimination organizations; legal services);
- Health care providers, including community health centers (e.g., federally qualified health centers, (FQHCs);
- Health-related organizations, (e.g., pharmacies, testing centers, community health workers);
- State Offices of Rural Health (SORH) or equivalent, State Rural Health Associations (SRHAs);
- Rural Health Clinics (RHCs) and Critical Access Hospitals (CAHs); and

Governmental organizations focused on non-health services (e.g., <u>Coordinating Council on Access and Mobility – Department of Transportation</u>, <u>Supportive housing for the elderly – Housing and Urban Development</u>).

To reach populations at higher risk, underserved, and disproportionately affected—including racial and ethnic minority groups, and people living in rural communities—it is critical for funded recipients and key partners to implement a coordinated and holistic approach that builds on culturally, linguistically, and locally tailored strategies and best practices to reduce COVID-19 risk. In addition, a coordinated and holistic approach is essential to build and sustain trust, ensure equitable access to COVID-19-related services, and advance health equity to address COVID-19-related health disparities among populations at higher risk, underserved, and disproportionately affected.

iv. Funding Strategy

The funding strategy will consist of three components aimed at decreasing health disparities. The components are defined by type of jurisdiction. The amount of funds available for each component are based on the overall population size for each type of jurisdiction. Funds will be awarded for each component using a separate formula that is: a) consistent with the intent of the legislation and purposes of the grant, and b) appropriate for the eligible recipients. The three jurisdiction-specific components include:

- 1. State, City and County Jurisdictions: Approximately 80% of total available funding will be awarded to all states and eligible cities and counties based on COVID-19 social and structural determinants, as defined by the COVID-19 Community Vulnerability Index (CCVI).
- 2. Rural Jurisdictions: Approximately 19% of total available funding will be awarded to states with rural populations, as defined by the Health Resources and Services Administration (HRSA) Federal Office of Rural Health Policy (FORHP) definition of rural. All state recipients will receive a portion of the rural funding available. Each recipient's share will be based on the size of the rural population within the recipient's jurisdiction. These funds will be distributed to state recipients in combination with the first Component (i.e., the CCVI allotment, in a single award.)
- 3. US Territorial and Freely Associated State Jurisdictions: Approximately 1% of total available funds will be awarded to US territories and freely associated states. Each US territorial and freely associated state recipient will receive base funding (\$500,000), plus a population-based allotment that has been adjusted for COVID-19 burden. The COVID-19 burden adjustment will be based on the cumulative number of cases and deaths (per 100,000) for each US territory and freely associated state.

Please see Attachment A: OT21-2103 List of Eligible Applicants for a complete list of eligible applicants.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Performance measures will be finalized and provided to recipients within approximately 45 days of award.

CDC will use recipients' financial and progress reporting data to address evaluation questions relating to use of funds and results associated with the grant. CDC will collect this information quarterly through the end of the period of performance utilizing standardize templates. Quarterly expenditure and progress reports will be submitted via the Research Electronic Data Capture, or otherwise known as REDCap. CDC will provide training and technical assistance for recipients on REDCap post-award.

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Given the flexible nature of this grant and diversity of allowable activities, a Data Management Plan (DMP) is not required unless a recipient chooses to allocate funding to a COVID-19 activity that involves the collection, generation, or analysis of data. The DMP may be submitted as a checklist, paragraph, or other format. To help guide applicants in developing a DMP, a sample plan is provided via the following link: http://www.icpsr.umich.edu/icpsrweb/content/datamanagement/dmp/plan.html

As a result of the declared public health emergency (PHE), COVID-19, CDC's COVID-19 related data collections currently fall under a PHE Paperwork Reduction Act (PRA) Waiver as part of the 21st Century Cures Act. PRA requirements for most information collection activities that support the investigation of, and response to the COVID-19 pandemic, that would normally require submission of a PRA package, can be waived. If information collection activities continue beyond the period of the declared public health emergency or beyond the termination PHE PRA Waiver, all collections will become subject to requirements of the PRA. Awardees will receive additional guidance from CDC on how to address these PRA requirements.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

Due to the nature of this grant and public health crisis, applicants are not required to provide an Evaluation and Performance Measurement plan with their application. Recipients are strongly encouraged to use evaluation and performance measurement data at the local level to monitor, evaluate, and continuously improve program performance. CDC will finalize and provide performance measures within approximately 45 days of award. Recipients will be required to report quarterly on CDC defined performance measures and participate in CDC evaluation and performance management activities. Evaluation reports will be made available to the public.

c. Organizational Capacity of Recipients to Implement the Approach

Applicants must demonstrate the organizational capacity needed to carry out and coordinate strategies to advance health equity and address COVID-19-related health disparities for populations at higher risk and that are underserved, including racial and ethnic minority groups and people living in rural communities.

Applicants must also demonstrate the capacity to collaborate with their State Offices of Rural Health (SORH) or equivalent, if applicable, and with key partners with community or social service delivery programs for African American, Hispanic, Asian American, Pacific Islander, Native American or other racial and ethnic minority groups or people living in rural communities. Please refer to Approach section of NOFO for a list of recommended key partners.

Acceptable documentation includes, but is not limited to, a signed letter by the health department leader or their designees on organization letterhead explaining the existing capacity and capability; departmental organizational charts; an incident management structure organizational chart; and resumes or CVs for key personnel positions that are currently filled (include position descriptions for vacant positions). Applicant must name this file "Organizational Capacity" and upload it as a PDF to www.grants.gov.

d. Work Plan

Applicants must develop and submit a high-level work plan for the 2-year period of performance. The work plan must align with the strategies and activities outlined in the NOFO. Specifically, activities must align to one or more of the following strategies:

• Strategy 1:Expand existing and/or develop new mitigation and prevention resources and services to reduce COVID-19 related disparities among populations at higher risk and that are underserved

- Strategy 2: Increase/improve data collection and reporting for populations experiencing a disproportionate burden of COVID-19 infection, severe illness, and death to guide the response to the COVID-19 pandemic
- Strategy 3: Build, leverage, and expand infrastructure support for COVID-19 prevention and control among populations that are at higher risk and underserved
- Strategy 4: Mobilize partners and collaborators to advance health equity and address social determinants of health as they relate to COVID-19 health disparities among populations at higher risk and that are underserved

Applicants are not required to implement all four strategies, but rather they should select the strategies and activities that best address their jurisdiction's respective priorities and needs. Strategies should engage representatives of populations and communities to be served by this NOFO. CDC will also allow applicants to propose additional strategies and activities beyond those included in the NOFO to best achieve local outcomes. Any proposed new strategy or activity should include the rationale for the approach or a brief justification with evidence showing why it should be included. Applicants should not propose to allocate all funding to one activity (e.g. all funding will be used for one vaccination or testing event only).

Applicants must use the template provided as Attachment B: CDC-RFA-OT21-2103 Work Plan Template. Applicant must name this file "[Name of Jurisdiction] Work Plan" and upload it as an attachment to www.grants.gov.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

CDC will collect recipient financial and progress reporting data quarterly through the end of the period of performance.

CDC will also conduct a virtual compliance visit after six months, but before the end of the first year, from date of the award. The virtual compliance visit will be a telephone call and/or video conference to ensure the recipient's compliance with using the funding for the approved activities and to identify technical assistance needs. CDC may conduct additional in-person site or virtual visits as needed to best facilitate grants management and oversight duties.

B. Award Information

1. Funding Instrument Type:

G (Grant)

2. Award Mechanism:

CDC-RFA-OT21-2103

3. Fiscal Year:

2021

4. Approximate Total Fiscal Year Funding:

\$ 2,250,000,000

5. Total Period of Performance Funding:

\$ 2,250,000,000

This amount is subject to the availability of funds.

All funding will be disbursed during year one with a total performance period of two years.

Estimated Total Funding:

\$ 2,250,000,000

6. Total Period of Performance Length:

2

year(s)

7. Expected Number of Awards:

8. Approximate Average Award:

\$ 0

Per Project Period

Funding will vary by jurisdiction category. Average one-year award amount by applicant type:

- State Health Department: \$32,000,000
- Local Health Departments Serving a County or City with a Population of ≥ 2 Million: \$26,000,000

- Local Health Departments Serving a City with a Population of 400,000 or more, but less than 2 Million: \$5,000,000
- US Territories and Freely Associated States: \$3,000,000

9. Award Ceiling:

\$ 50,000,000

Per Project Period

This amount is subject to the availability of funds.

Funding will vary by jurisdiction category. Award Ceiling by applicant type:

- State Health Department: \$50,000,000
- Local Health Departments Serving a County or City with a Population of ≥2 Million: \$35,000,000
- Local Health Departments Serving a City with a Population of 400,000 or more, but less than 2 Million: \$9,000,000
- US Territories and Freely Associated States: \$10,000,000

10. Award Floor:

\$ 500,000

Per Project Period

Funding will vary by jurisdiction category. Award Floor by applicant type:

- State Health Department: \$17,000,000
- Local Health Departments Serving a County or City with a Population of ≥2 Million: \$17,000,000
- Local Health Departments Serving a City with a Population of 400,000 or more, but less than 2 Million: \$2,000,000
- US Territories and Freely Associated States: \$500,000

11. Estimated Award Date:

June 01, 2021

12. Budget Period Length:

24 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

Direct Assistance (DA) is not available through this NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

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C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)

Local governments or their bona fide agents

Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau

2. Additional Information on Eligibility

Awards must be made to state, District of Columbia, local, US territorial, and/or freely associated state health departments (or their bona fide agents). Local (health departments) governments or their bona fide agents are eligible if they:

- Serve a county population of 2,000,000 or more; or serve a city population of 400,000 or more. Population for county and city jurisdictions are based on the following US Census 2019 resources:
 - City and Town Population Totals: 2010-2019 (census.gov) U.S. Census -- Annual Estimates of the Resident Population for Incorporated Places of 50,000 or More, Ranked by July 1, 2019 Population: April 1, 2010 to July 1, 2019
 - County Population Totals: 2010-2019 (census.gov)- US Census Annual Estimates for 2019

Bona fide agents are eligible to apply. For more information about bona fide agents, please see the CDC webpage on Expediting the Federal Grant Process with an Administrative Partner located at https://www.cdc.gov/publichealthgateway/grantsfunding/expediting.html#Q2

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http://fedgov.dnb.com/webform/displayHomePage.do. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at https://www.sam.gov/SAM/.

c. Grants.gov:

The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration

process as early as possible.

Step	System	Requirements	Duration	Follow Up
1		1. Click on http://fedgov.dnb.com/webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http://fedgov.dnb.com/webform) or call 1-866-705-5711
2	Management (SAM) formerly Central Contractor	1. Retrieve organizations DUNS number 2. Go to https://www.sam.gov/SAM/ and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fs d.gov/fsd-gov/ home.do Calls: 86 6-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account	Register early! Log into grants.gov and check AOR status

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at www.grants.gov.

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4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed or postmarked by)

Due Date for Letter Of Intent 03/26/2021

03/26/2021

b. Application Deadline

05/03/2021

11:59 pm U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Due Date for Information Conference Call

CDC will host *two* informational conference calls for potential applicants:

Date: 03/30/2021

Times: 3:00pm to 4:00pm Eastern Standard Time

6:00pm to 7:00pm Eastern Standard Time

Meeting Details:

Join ZoomGov Meeting

https://cdc.zoomgov.com/j/16040976381?pwd=NmNjdFcrQlFVSjVPZ25nR0dHay9zdz09

Meeting ID: 160 4097 6381 Passcode: OT21-2103

One tap mobile

+16692545252,,16040976381#,,,,,0#,,708148093# US (San Jose)

+16468287666, 16040976381#,,,,,0#,,708148093# US (New York)

Dial by your location

+1 669 254 5252 US (San Jose)

+1 646 828 7666 US (New York)

+1 669 216 1590 US (San Jose)

+1 551 285 1373 US

Meeting ID: 160 4097 6381

Passcode: 708148093

Find your local number: https://cdc.zoomgov.com/u/advmPjIAqk

Join by SIP

16040976381@sip.zoomgov.com

Join by H.323 161.199.138.10 (US West) 161.199.136.10 (US East) Meeting ID: 160 4097 6381 Passcode: 708148093

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjjmaa)))
/Homepage.aspx.

Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/grantassurances/
 (S(mj444mxct51lnrv1hljjjmaa))/ Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with

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supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

Letters of Intent (LOI) are not required but are requested as part of the application for this NOFO. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

Letters of Intent should be submitted via email to OT21-2103Support@cdc.gov no later than March 26, 2021.

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov. The Project Narrative must include all of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see http://www.hhs.gov/ocio/policy/collection/.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

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- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- **Supplies**
- Travel
- Other categories
- Contractual costs
- **Total Direct costs**
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub

accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

15. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS

identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

16. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See <u>Additional Requirement (AR) 12</u> for detailed guidance on this prohibition and <u>additional guidance on lobbying for CDC recipients</u>.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

Coronavirus Disease 2019 (COVID-19) Funds:

• A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139); and/or H.R. 133 - Consolidated Appropriations Act, 2021, Division M – Coronavirus Response and Relief Supplemental Appropriations Act, 2021, agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health

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measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

- In addition, to the extent applicable, Recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS—CoV—2 or to diagnose a possible case of COVID—19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC. HHS laboratory reporting guidance is posted at: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.
- Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected and evaluations conducted with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.
- To achieve the public health objectives of ensuring the health, safety, and welfare of all Americans, Recipient must distribute or administer vaccine without discriminating on non-public-health grounds within a prioritized group.

18. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:

https://www.cdc.gov/grants/additionalrequirements/ar-25.html

18. Other Submission Requirements

a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Nonvalidated applications will not be accepted after the published application deadline date.

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If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the email message generated at the time of application submission or the Grants.gov Online User Guide.

https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t= Get Started%2FGet Started. htm

- d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.
- e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

- 1. Include the www.grants.gov case number assigned to the inquiry
- 2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
- 3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below

- i. Approach
- ii. Evaluation and Performance Measurement
- iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements

i. Approach	Maximum Points: 0
ii. Evaluation and Performance Measurement	Maximum Points: 0
iii. Applicant's Organizational Capacity to Implement the Approach	Maximum Points: 0
Budget	Maximum Points: 0
i. Approach	Maximum Points: 0
ii. Evaluation and Performance Measurement	Maximum Points: 0
iii. Applicant's Organizational Capacity to Implement the Approach	Maximum Points: 0
Budget	Maximum Points: 0

c. Phase III Review

This is a noncompetitive NOFO. Applications will be reviewed for technical merit without scoring.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold,

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defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- (1) Financial stability;
- (2) Quality of management systems and ability to meet the management standards prescribed in this part;
- (3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards:
- (4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
- (5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

The anticipated posting date is March 17, 2021, on www.grants.gov. Applicants will have up to 45 days, or May 3, 2021, to respond. Applicants are encouraged to apply early. The anticipated award date is approximately 30 calendar days after the end of the application period, or June 1, 2021.

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

The following Administrative Requirements (AR) apply to this NOFO:

- AR-7: Executive Order 12372 Review
- AR-8: Public Health System Reporting Requirements
- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- *AR-11: Healthy People 2030*
- AR-12: Lobbying Restrictions
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-8: Public Health System Reporting Requirements
- AR-15: Proof of Non-profit Status
- AR-23: Compliance with 45 CFR Part 87
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act Requirements
- *AR-25: Data Management and Access*
- AR-26: National Historic Preservation Act of 1966
- AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
- <u>AR-30: Information Letter 10-006, Compliance with Section 508 of the Rehabilitation Act of 1973</u>
- AR-32: Enacted General Provisions
- AR-34: Language Access for Persons with Limited English Proficiency
- AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

Recipients are also expected to adhere to administrative requirements relating to nondiscrimination contained in Standard Form 424B (Rev. 7-97): Assurances - Non-Construction Programs, prescribed by OMB Circular A-102.

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

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- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report Type	When?	Required?
Expenditure Reporting	Quarterly expenditure reports are due 60 days into the award and at the end of each fiscal quarter thereafter through the period of performance.	Yes
Payment Management System (PMS) Reporting	Quarterly reports are due 60 days into the award and at the end of each fiscal quarter thereafter through the period of performance.	Yes
Progress Reporting	Quarterly progress reports are due 60 days into the award and at the end of each fiscal quarter thereafter through the period of performance.	Yes
Federal Financial Reporting Forms	Due 90 days after the end of the budget period	Yes
Final Performance and Financial Report	Due 90 days after end of period of performance	Yes

There may be flexibility in reporting deadlines. CDC will communicate updates or revisions to reporting requirements as appropriate.

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Quarterly expenditure and progress reports will be submitted via the Research Electronic Data Capture, or otherwise known as REDCap. CDC will provide training and technical assistance for recipients on REDCap post-award.

a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

Evaluation

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publically available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- Evaluation Results: Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- Work Plan: Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.

Successes

- Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
- Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
- o Recipients must describe success stories.

Challenges

- Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
- o Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

• CDC Program Support to Recipients

 Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

• Administrative Reporting (No page limit)

- o SF-424A Budget Information-Non-Construction Programs.
- Budget Narrative Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

The recipients must submit the Annual Performance Report via <u>www.Grantsolutions.gov</u> no later than 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www.fsrs.gov/documents/ffata legislation 110 252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

- A. Valued Added Tax (VAT) and Customs Duties Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.
- B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:
- 1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]
- 2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each guarter: April 15, July 15, October 15 and January 15.
- 3) Terms: For purposes of this clause:
- "Commodity" means any material, article, supplies, goods, or equipment;
- "Foreign government" includes any foreign government entity;
- "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
- 4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
- 5) Contents of Reports: The reports must contain:

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- a. recipient name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.
- 6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

- (1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;
- (2) By the HHS awarding agency or pass-through entity for cause;
- (3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- (4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

First Name:

Stacey

Last Name:

Mattison Jenkins

Project Officer

Department of Health and Human Services

Centers for Disease Control and Prevention

Address:

Department of Health and Human Services Centers for Disease Control and Prevention Center for State, Tribal, Local, and Territorial Support Division of Program and Partnership Services 1825 Century Center Blvd., Mailstop V18-1 Atlanta, GA 30345

Telephone:

Email:

OT21-2103Support@cdc.gov

Grants Staff Contact

For financial, awards management, or budget assistance, contact:

First Name:

Shirley

Last Name:

Byrd

Grants Management Specialist

Department of Health and Human Services

Office of Grants Services

Address:

Department of Health and Human Services Centers for Disease Control and Prevention Office of Grants Services 2939 Flowers Road Atlanta, GA 30341

Telephone:

(770) 488-2591

Email:

yuo6@cdc.gov

For assistance with **submission difficulties related to** <u>www.grants.gov</u>, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative

- Budget Narrative
- CDC Assurances and Certifications
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

References

- [1] Michener L, Aguilar-Gaxiola S, Alberti PM, Castaneda MJ, Castrucci BC, Harrison LM, et al. Engaging With Communities Lessons (Re)Learned From COVID-19. Prev Chronic Dis 2020;17:200250. https://www.cdc.gov/pcd/issues/2020/20 0250.htm
- 2] US Centers for Disease Control and Prevention. COVID-19 cases, data, and surveillance: hospitalization and death by race/ethnicity. Accessed October 12, 2020. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html
- [3] Rubin-Miller L, Alban C, Artiga S, Sullivan S. COVID-19 racial disparities in testing, infection, hospitalization, and death: analysis of Epic data. Published September 16, 2020. Accessed October 12, 2020. https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-racial-disparities-testing-infection-hospitalization-death-analysis-epic-patient-data/
- [4] Paul R, Arif A, Pokhrel K, Ghosh S. The association of social determinants of health with COVID-19

mortality in rural and urban counties. Journal of Rural Health. 2021;1-9. https://doi.org/10.1111/jrh.12557

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements

(ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additional requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

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Assistance Listings: A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

Assistance Listings Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http://www.cdc.gov/grants /additionalrequirements /index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/webform/displayHomePage.do.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These

activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

Healthy People 2030: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-SPOC_01_2018_OFFM.pdf.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

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Memorandum of Understanding (MOU) or Memorandum of Agreement

(MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of performance – formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

#: 5043

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and qualityof-life outcomes and risks.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

NOFO-specific Glossary and Acronyms

Health equity (2) is achieved when every person has the opportunity to "attain his or her full health potential" and no one is "disadvantaged from achieving this potential because of social position or other socially determined circumstances."

Underserved communities refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. Populations can include but are not limited to: African American, Latino, and Indigenous and Native American persons, Asian Americans and Pacific

Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural communities; and persons otherwise adversely impacted by persistent poverty or inequality (Definition modified from the Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, January 20, 2021).

Exhibit B



Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH **PROMOTION**

Community Health Workers for COVID Response and Resilient Communities (CCR)

CDC-RFA-DP21-2109

05/24/2021

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Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-DP21-2109. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Notice of Funding Opportunity (NOFO) Title:

Community Health Workers for COVID Response and Resilient Communities (CCR)

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-DP21-2109

E. Assistance Listings Number:

93.495

F. Dates:

1. Due Date for Letter of Intent (LOI):

03/25/2021

Not Applicable

LOI is not required or requested.

2. Due Date for Applications:

05/24/2021

11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call:

Date: March 31, 2021

Time: 3:30 pm - 4:30 pm U.S. Eastern Standard Time

Conference Number: 800-369-3192

Participant Code: 5479788

Join via Computer: https://adobeconnect.cdc.gov/r0er4qejjemc/

Potential applicants may also submit questions via email at: nccdphp chw@cdc.gov

The following website will contain pre-and post-conference call information, including questions and answers submitted by potential applicants: Community Health Workers for Covid Response and Resilient Communities | CDC

F. Executive Summary:

Summary Paragraph

The Coronavirus Aid, Relief, and Economic Security ("CARES") Act of 2020 allocated funds to the Centers for Disease Control and Prevention (CDC) to states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes. CDC announces the availability of funds to achieve the goal of the CARES Act in preventing COVID-19 and protecting the American people from related public health impacts. This Notice of Funding Opportunity (NOFO) supports this work through training and deployment of community health workers (CHWs) to response efforts and by building and strengthening community resilience to fight COVID-19 through addressing existing health disparities.

Program strategies include integrating CHWs into organizations and care teams and strengthening relevant CHW knowledge, roles, and skills to prepare them to successfully engage with existing state and/or local public health-led actions to manage COVID-19 among priority populations. Priority populations are those with increased prevalence of COVID-19 and are disproportionately impacted by long-standing health disparities related to sociodemographic characteristics, geographic regions, and economic strata. Examples include, racial and ethnic minority groups, persons who are economically disadvantaged, justice-involved, experiencing homelessness, or have certain underlying medical conditions that increase COVID-19 risk.

a. Eligible Applicants:

Open Competition

b. NOFO Type:

G (Grant)

c. Approximate Number of Awards

70

d. Total Period of Performance Funding:

\$ 300,000,000

e. Average One Year Award Amount:

\$ 1,000,000

Over a three-year period of performance, CDC will award approximately \$100 million each budget year for three years with the average award varying. These grants will range approximately from \$350,000 - \$3 million per year depending on the size and scope of activity. The range of funds is broad to accommodate a varied number of organizations based on capacity and a range of catchment areas whose resource needs will vary. Approximate average one-year award amounts for each component are:

Component A (Capacity Building): \$600K Component B (Implementation Ready): \$2M

Component C (Innovation – demonstration projects): \$2M

f. Total Period of Performance Length:

3

g. Estimated Award Date:

August 01, 2021

h. Cost Sharing and / or Matching Requirements:

No

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

The novel Coronavirus Disease 2019 (COVID-19) has impacted communities nation-wide, including all states, localities, and territorial jurisdictions. Public health crises, such as COVID-19, exacerbate existing health disparities and inequities in the social determinants of health (SDOH), conditions in which people are born, live, learn, work, play, worship, and age. Black/African Americans, Hispanics/Latinos, and American Indian/Alaska Native populations have higher rates of unemployment; are more likely to work in essential, low-income positions that do not allow telework; live in communities with higher rates of environmental hazards; and do not have health insurance or paid sick leave through employers. Racial and ethnic minority groups, economically disadvantaged persons, justice-involved, people experiencing homelessness, and people who use drugs and/or have certain underlying medical conditions are also at risk. All of these factors increase risk of exposure to COVID-19, while limiting ability to stay home or access care when sick. Racial and ethnic minority groups also experience higher incidence of severe heart disease, diabetes, obesity, and smoking, all shown to increase the risk of severe illness from COVID-19. Furthermore, distrust of medical and governmental entities and longstanding disparities in vaccine coverage may impact achievement of high COVID-19 vaccination rates, once vaccines are widely available in these population groups.

Along with CDC's strategies for ending the COVID-19 pandemic, focused investments are

needed to decrease disparities among the populations outlined above. Initiatives that promote health equity in all policies and reduce inequities should be pursued and evaluated for effective and targeted systems' changes across relevant sectors. Overwhelming evidence demonstrates that health is highly influenced by SDOHs such as intergenerational wealth, high quality education, stable and fulfilling employment opportunities, affordable housing, access to healthful foods, commercial tobacco-free policies, and safe green spaces for physical activity. Through partnerships around community health assessment and planning efforts, federal, state, local, tribal, and territorial governments have invested in long-range policy and environmental change plans to improve SDOHs in communities with the poorest health outcomes.

CHWs are well-positioned to reach communities, especially those disproportionately impacted by COVID-19. CHW interventions can improve uptake and access to health care services, improve communication between community members and health providers, reduce the need for emergency and specialty services, and improve adherence to health recommendations. While CHW administered interventions have a demonstrated impact, barriers to increased intervention implementation exist (e.g. insufficient numbers of trained individuals to meet existing needs; lack of funding/reimbursement; poor integration of CHWs in multidisciplinary care teams, in the health care delivery system, or in community organizations addressing the social determinants of health; and limited communication technology).

CHWs can improve access to COVID-19 related services (e.g. testing, contact tracing, health behavior education) and management of other underlying medical conditions that increase risk of severe COVID-19 illness and adverse outcomes. Through this initiative, CDC can highlight the integral role of CHWs in increasing resiliency, and response efforts in the hardest hit communities across the nation, especially during emergency crises by supporting three components in this NOFO: Component A focuses on building capacity for CHW efforts; Component B focuses on enhancing and expanding existing CHW efforts; and Component C focuses on developing innovative approaches to strengthening the use of CHWs.

b. Statutory Authorities

This program is authorized under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), Public Law 116-136 and under the Public Health Service Act 42 U.S.C. 301(a).

c. Healthy People 2030

This funding opportunity focuses on COVID-19 response and community resilience addressing Healthy People 2030 goals including emergency preparedness: https://health.gov/healthypeople/objectives-and-data/browseobjectives/emergency-preparedness and vaccination: https://health.gov/healthypeople/objectivesand-data/browse-objectives/vaccnation.

For further information, please see https://health.gov/healthypeople/objectives-and-data/browseobjectives.

d. Other National Public Health Priorities and Strategies

The COVID-19 pandemic requires a coordinated public health response; recipients should consider the following in their proposed work:

- Topics (e.g. social determinants of health) related to health conditions associated with increased risk of COVID-19 illness and poorer outcomes.
 https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
- Centers for Disease Control and Prevention (2020). Community Preventive Services Task Force. The Community Guide. Retrieved from The Community Guide).
- Health Resources and Services Administration (2020). Coronavirus-Related Supplemental Funding Allowable Uses Technical Assistance Resource. https://bphc.hrsa.gov/emergency-response/coronavirus-info/supplemental-funding-uses

e. Relevant Work

This NOFO will leverage previous work funded by the CDC with various public and private partners to implement and evaluate the effectiveness of different approaches for building the public health infrastructure to respond to COVID-19, particularly:

- Centers for Disease Control and Prevention (2020). Public Health Crisis Response NOFO. https://www.cdc.gov/cpr/readiness/funding-covid.htm
- Centers for Disease Control and Prevention (2020). CDC COVID-19 Funding for Tribes. https://www.cdc.gov/tribal/cooperative-agreements/covid-19.html?deliveryName=USCDC_289-DM25904
- Centers for Disease Control and Prevention (2020). COVID-19 Financial Resources. Retrieved from Financial Resources | CDC.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

CDC-RFA-DP21-2109: Community Health Workers for COVID Response and Resilient Communities (CCR) NOFO Logic Model

Scale up Community Health Worker (CHW) actions across the nation to support COVID-19 response efforts in those communities hit hardest by COVID-19 and among populations that are at high risk for COVID-19 exposure, infection, and outcomes (priority populations).

CDC-RFA-DP21-2109: Community Health Workers for COVID Response and Resilient Communities (CCR) NOFO Logic Model

		communities (cert) it	of o Logic Model	
Proposed Hig Strategies	gh Level	Proposed Outcomes		
		Short Term Outcomes: Year 1	Intermediate Outcomes: Year 2	Long Term:>Year 3
_				

Train Community Health Workers to ensure comprehensive acquisition and reinforcement of relevant knowledge, roles, and skills to support the COVID-19 public health response to manage outbreaks and community spread.

Increased skills/capacity/roles of CHWs to provide services and support for **COVID-19** public health response efforts among priority populations within communities.

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Increased reach of CHWinfluenced mitigation efforts among priority populations within communities.

Decreased impact of COVID-19 on those at risk (priority populations) and settings.

Increased community resilience to respond to COVID-19 and future public health emergencies.

Deploy Community Health to Support the COVID-19 **Public Health** Response to manage outbreaks and spread of COVID-19 among priority populations within communities.

Increased workforce of **CHWs delivering** services to manage the spread of COVID-19.

Continued promotion and integration of CHWs into existing workforce among priority populations within communities.

IMPACT

Decreased health disparities

 \downarrow

Increased health equity

Engage Community Health Workers to Help Build and Strengthen **Community** Resilience to mitigate the impact of COVID-19 by improving the overall health of priority populations within communities.

Increased utilization of community resources and clinical services for those at highest risk for poor health outcomes among priority populations within communities.

Increased provision of community resources and clinical services to those at highest risk for poor health outcomes among priority populations within communities.

i. Purpose

This new grant will address 1) disparities in access to COVID-19 related services, e.g., testing, contact tracing, immunization services etc., and 2) health outcomes and factors that increase risk of severe COVID-19 illness (e.g., chronic diseases, smoking, pregnancy) and poorer outcomes (e.g. health and mental health care access, access to healthy food, health insurance, etc.) which have been exacerbated by COVID-19 by scaling up and sustaining a nation-wide program of CHWs who will support COVID-19 response and prevention in populations at high risk and communities hit hardest by COVID-19.

#: 5053

ii. Outcomes

Applicants are expected to focus on those outcomes that align with the three high-level strategy categories, i.e. Train, Deploy, and Engage.

Short term outcomes:

- TRAIN: Increased skills/capacity/roles of CHWs to provide services and support for COVID-19 public health response efforts among priority populations within communities.
- **DEPLOY:** Increased workforce of CHWs delivering services to manage the spread of COVID-19.
- ENGAGE: Increased utilization of community resources and clinical services for those at highest risk for poor health outcomes among priority populations within communities.

iii. Strategies and Activities

COMPONENT A: CAPACITY BUILDING

Applicants applying for Component A funding must address the four required strategies identified in bold and also select one additional strategy from the menu of strategies targeting Capacity Building efforts.

TRAIN:

• Strategy CB1 (Required): Identify and collaborate with community-wide efforts to ensure comprehensive acquisition of relevant knowledge, roles, and skills by CHWs so they are prepared to successfully engage with existing state and/or local public

health-led actions to manage COVID-19 among priority populations within communities.

Strategy CB2: Align training opportunities for CHWs with the primary actions of state and/or local public health led efforts to address the underlying conditions and/or environments that increase the risk and severity of COVID-19 infections among priority populations within communities.

DEPLOY:

- Strategy CB3 (Required): Integrate CHWs into organizations and care teams to support the public health response to COVID-19 among priority populations within communities.
- Strategy CB4: Develop and disseminate messaging that educates organizations and care teams on the critical role CHWs play in delivering services and managing the spread of COVID-19 among priority populations within communities.

ENGAGE:

- Strategy CB5 (Required): Coordinate and/or promote opportunities, such as messaging/education, within communities and clinical settings to facilitate the engagement of CHWs in addressing the needs of those at highest risk for poor health outcomes, including those resulting from COVID-19.
- Strategy CB6 (Required) Year 1: Initiate and develop and/or utilize systems to document engagement of CHWs in the care, support, and follow-up across clinical and community settings of priority populations at highest risk for poor health outcomes, including those resulting from COVID-19. (Required) Year 2: Facilitate engagement of CHWs in the care, support, and follow-up across clinical and community settings of priority populations at highest risk for poor health outcomes, including those resulting from COVID-19.
- Strategy CB7: Establish and strengthen partnerships between CHWs and State Medicaid agencies, relevant state or local coalitions, initiatives, professional organizations, providers, and health systems that provide resources and support for deploying CHWs to engage with priority populations at highest risk for poor health outcomes, including those resulting from COVID-19 by addressing social determinants of health (e.g. those with underlying health conditions, with decreased access to care or lacking access to routine and usual care, challenges with having social needs met, food insecurity, housing insecurity and homelessness, etc.)

COMPONENT B: IMPLEMENTATION READY

Applicants applying for Component B funding must address the four required strategies identified in bold and also select two additional strategies from the menu of strategies targeting Implementation Ready efforts.

TRAIN:

- Strategy IR1 (Required): Identify and collaborate with community-wide efforts to ensure comprehensive acquisition of relevant knowledge, roles, and skills by CHWs so they are prepared to successfully engage with existing state and/or local public health-led actions to manage COVID-19 among priority populations within communities.
- Strategy IR2: Ensure appropriate training opportunities to disseminate messaging for CHWs focused on reaching those with underlying conditions and/or environments that increase the risk and severity of COVID-19 infections among priority populations in order to strengthen infrastructure critical to identification of infection, appropriate followup, including contact tracing, and treatment among priority populations within communities.
- Strategy IR3: Align training opportunities for CHWs with the primary actions of state and/or local public health led efforts to address the underlying conditions and/or environments that increase the risk and severity of COVID-19 infections among priority populations within communities.

DEPLOY:

- Strategy IR4 (Required): Integrate CHWs into organizations and care teams to support the public health response to COVID-19 among priority populations within communities.
- Strategy IR5: Integrate CHWs into public health emergency preparedness and vaccine deployment planning, e.g. inclusion in planning and coordination with Immunization and Public Health Preparedness Programs; existing vaccine infrastructure; and vaccine providers in the community to increase access to new and existing vaccination programs in priority populations within communities.

ENGAGE:

- Strategy IR6 (Required): Coordinate and/or promote opportunities, such as messaging/education within communities and clinical settings to facilitate the engagement of CHWs in addressing the needs of those at highest risk for poor health outcomes, including those resulting from COVID-19.
- Strategy IR7 (Required): Facilitate engagement of CHWs in the care, support, and follow-up across clinical and community settings of priority populations at highest risk for poor health outcomes, including those resulting from COVID-19.

COMPONENT C: INNOVATION - DEMONSTRATION PROJECTS

The demonstration project should identify an approach that employs policy, systems or environmental changes, is innovative and will train, deploy, and engage CHWs to further address health disparities and social inequities exacerbated by COVID-19 within the catchment area identified in the recipient's Component B application. The demonstration projects should each uniquely focus on improving selected conditions of the socioecological environment (e.g., community interventions intending to reduce toxic and chronic stress,

strategies that enhance community resilience; strategies that address reimbursement or other sustainable funding; strategies that increase income, housing and/or food security and support recovery from other unintended negative consequences of COVID-19 mitigation strategies; engaging employers in identifying and adopting policies that protect worker health and safety; engaging owners/overseers of multi-unit housing to identify and adopt policies that protect worker and tenant health from COVID-19 and conditions that increase COVID-19 risk). This is an opportunity to demonstrate how CHWs can incorporate interventions addressing social determinants of health, and be an integral part of innovative approaches, such as technology, payment models, communication campaigns, new ways to link to social services and/or provide "wrap-around" services, or other services that will improve health outcomes among those at greatest risk for severe COVID-19 disease.

Requirements for the demonstration project include the following:

- The demonstration project must address at least 1 of the 3 overarching strategies of the NOFO: train, deploy, and/or engage;
 - o This proposed project must be distinctly different from what the applicants is proposing in Component B; it is not meant to be an expansion of a Component B effort. It is an opportunity to test an innovative approach that accelerates impact to ameliorate effects of COVID-19 through the use of CHWs and builds more resilient communities.
- CHWs must be an integral part of the demonstration project;
- The project must be implemented in communities or populations at risk for poor health outcomes as a result of COVID-19 that the applicant has identified for Component B.
- The demonstration project must be aligned with the outcome(s) as described in the logic model.
- The demonstration project must include a rigorous evaluation to assess the project's impact, outcomes, and effectiveness and develop recommendations for sustainability. The applicant should plan to initiate evaluation in Year 1, continue data collection in Year 2, and complete and submit all data to CDC immediately upon completion of Year 3.

Performance measures related to Train, Deploy, and Engagement efforts for Component C and the impact on COVID-19 may be proposed by recipients based on activities conducted and finalized in collaboration with CDC and Evaluation/Technical Assistance partners, awarded through a separate NOFO. Performance measures will be reported annually, and CDC and Evaluation/Technical Assistance partners will manage and analyze the data to identify recipient program improvements, respond to broader technical assistance needs, and report to stakeholders.

1. Collaborations

a. With other CDC programs and CDC-funded organizations: **Required Collaborations:**

Recipients are required to collaborate with other CDC-funded programs that are currently implementing activities to mitigate the spread of COVID-19 infection in their respective communities and address certain underlying medical conditions that increase risk of exposure to #: 5057

COVID-19. These collaborations are especially essential for implementing both the training and deployment strategies of this NOFO; applicants must include letters of support to document these collaborations. Letters must be dated within 45 days of the application due date. These letters must state the role of organizations and specify how they will help the applicant achieve the goals and outcomes of the NOFO. Applicants must file the letter of support, as appropriate. name the file "CHW LOS Applicant Name", and upload it as a PDF file at www.grants.gov. This will ensure that proposed activities are complementary with other CDC funded programs operating in the same area and avoid duplication of efforts. State- and/or locallevel CDC funded programs to advance efforts to mitigate the spread of COVID-19 infection include:

- Epidemiology and Laboratory Capacity Program: https://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html
- State (and jurisdictional) Immunization Program: https://www.cdc.gov/vaccines/imz- managers/awardee-imz-websites.html
- Supporting Tribal Public Health Capacity in Coronavirus Preparedness and Response Program: https://www.cdc.gov/tribal/documents/cooperative-agreements/COVID-19-Funding-for-Tribes-Grant-Recipients-OT20-2004-508.pdf
- Tribal Public Health Capacity Building and Quality Improvement Program: https://www.cdc.gov/tribal/cooperative-agreements/tribal-capacity-building-OT18-1803.html
- Cooperative Agreement for Emergency Response: Public Health Crisis Response and COVID-19 Crisis Response Cooperative Agreement Components A and B Supplemental Funding Program: https://www.cdc.gov/cpr/readiness/funding-covid.htm
- Racial and Ethnic Approaches to Community Health (REACH) Flu Vaccine Supplement. DP18-1813. https://www.cdc.gov/nccdphp/dnpao/state-localprograms/reach/current programs/index.html.

Encouraged Collaborations:

Recipients are also highly encouraged to collaborate with other CDC-funded programs that focus on population health approaches to reduce health disparities and address the social determinants of health that contribute to them such as injury prevention, mental health promotion, sexually transmitted disease and chronic disease prevention. These collaborations are especially essential for implementing the strengthening community resilience strategies of this NOFO. This will ensure proposed activities are complementary with other CDC-funded programs operating in the same area and avoid duplication of efforts.

b. With organizations not funded by CDC: **Required Collaborations:**

- Recipients are required to appropriately align their work with other national, state or nongovernmental programs that support CHWs to promote healthy communities including State Medicaid agencies.
- Recipients are also required to collaborate, through formalized partnerships, supported by detail specific service agreements, with medical (e.g., Community Health Centers (CHCs), private providers, health insurers and health systems) and essential support service providers to maximize reach, increase coordination and collaboration, and support

the provision of essential services in respective communities. These collaborations are essential for the successful implementation of all three NOFO strategies.

• Letters of support with a firm commitment from partners should be included in the application. Applicants should submit letters of support from organizations that will have a role in helping to achieve the NOFO activities and outcomes. Letters must be dated within 45 days of the application due date. These letters must state the role of organizations and specify how they will help the applicant achieve the goals and outcomes of the NOFO. Applicants must file the letter of support, as appropriate, name the file "CHW LOS Applicant Name", and upload it as a PDF file at www.grants.gov.

Community Coalition

The recipients are required to either establish a new or expand an existing community coalition to serve as a formal arrangement for cooperation and collaboration among stakeholder groups to work together to achieve the short-term, intermediate, and long-term outcomes of this NOFO. Applicants should describe the proposed or existing coalition within the project narrative. Recipients will collaborate with the coalition to develop and carry out the program action plan to train and deploy CHWs to support the COVID-19 public health response as well as to build and strengthen resilience to mitigate the impact of COVID-19 by improving the overall health of priority populations in key communities.

The community coalition proposed by the recipient should have diverse and multi-sector representation and, at a minimum, should include the:

- Recipient
- Community Health Worker Network Representation
- Healthcare organization representative (who provides services for the priority population)
- Local public health department representation
- Community representation

The community coalition should:

- Demonstrate ability to leverage partnerships across settings and sectors to address key contributors to health disparities within their community (e.g., social determinants of health)
- Meaningfully engage and incorporate input from those who represent the proposed priority population(s)
- Use Community Based Participatory Approaches (http://ctb.ku.edu/en/table-of-contents /analyze/where-to-start/participatory-approaches/main) in their planning approach
- Reflect the composition of the proposed priority population
- Demonstrate a history of success in working together with partners on issues relating to health or other disparities.
- Demonstrate effectiveness and progress in mobilizing partners to assist in implementation of local evidence-based or practice-based improvements that are culturally tailored to the priority population(s)

Encouraged Collaborations:

Recipients are also encouraged to establish strategic partnerships with the following types of organizations: state- and jurisdictional-recipients of other relevant Federal programs (e.g., the Health Resources and Services Administration's State Office of Rural Health programs or Maternal and Child Health Bureau, the Centers for Medicare and Medicaid Services, and State-Medicaid Offices) and their recipients; local public health departments (for state recipients); local health insurers; American Indian/Alaska Native tribal governments and/or tribally designated organizations; non-CDC funded Community Based Organizations; faith-based organizations; local chambers of commerce or large employers, community advocates and other stakeholders with vested interests in reducing health disparities and the social determinants of health that contribute to them.

2. Target Populations

Applicants must identify and focus on populations with increased risk for or prevalence of COVID-19 or who are at increased risk for poor health outcomes from COVID-19 because they are also disproportionately impacted by long-standing health disparities as described in the Executive Summary and Background sections of this announcement. Applicants must demonstrate that the proposed catchment area(s) reflect a) the burden of COVID-19 infection rates and/or COVID-19 mortality rates and b) populations disproportionally affected by COVID-19 infections; particularly those affected by poverty. Catchment areas are defined in this NOFO as a county, metropolitan statistical area(s) or a group of contiguous counties. These catchment areas must have significant COVID-19 disease burden, evidence of disproportionate health disparities as evidenced by poverty rates, and sufficient combined populations to allow the strategies supported by this NOFO to reach significant numbers of people (see components below for information on population size). Applicants must describe the population selected, including relevant health disparities, and how the selected interventions will improve health and contribute to a more resilient community better able to address threats such as COVID-19.

Applicants must use the following two resources to document a) poverty rates and b) COVID-19 cases and/or mortality rates:

- Poverty rates may be found at https://www.census.gov/library/visualizations/interactive/2014-2018-poverty-rate-by-county.html.
- COVID-19 cases and/or deaths (county level) can be found at https://covid.cdc.gov/covid-data-tracker/#county-view. The two COVID-related data points that can be used are:
 - o 7 Day total reported cases per 100,000 population
 - o 7 Day total reported deaths per 100,000 population

Applicants should include the time period for the 7 day total for cases and/or deaths from the CDC COVID Data Tracker. Additional guidance on the two COVID-related data points can be found at: Community Health Workers for Covid Response and Resilient Communities | CDC

Applicants addressing racial and ethnic populations should address the inclusion of subpopulations within the identified target population that can benefit from the program strategies listed in this announcement. These subpopulations can include groups such as older

people, people with low socioeconomic status, ethnic minorities, economically disadvantaged persons, justice-involved, people experiencing homelessness, or those who traditionally do not access health care on a routine basis such as people with mental health or substance abuse disorders, non-English speaking populations, Lesbian, Gay, Bisexual, and Transgender (LGBT) populations, persons with disabilities, or other populations who may otherwise be missed by the program. In addition, applicants will be expected to provide specific activities to address the underlying health and social inequities that put many of these subpopulations at increased risk of getting sick, having more severe illness and dying from COVID-19 and other communicable and non-communicable conditions.

#: 5060

a. Health Disparities

CDC recognizes that social and economic opportunities, health behavior, and the physical environment in which people live greatly impact health outcomes. Health disparities represent preventable differences in the burden of disease, disability, injury or violence, or in opportunities to achieve optimal health. Applicants must describe the population(s) selected, including relevant health disparities, and how selected interventions will improve health and reduce or eliminate one or more identified health disparities. This announcement provides the opportunity to incorporate interventions to address health-related social needs, (e.g., housing instability and poor quality, food insecurity, insufficient utility resources, interpersonal violence, insufficient transportation, and inadequate educational resources) for the priority populations described in the background section. This is an opportunity to demonstrate how increased awareness of available community services, navigation assistance to access services, and partner alignment to ensure that available services support community needs can positively impact health in these communities; which should all be addressed in the proposed activities.

iv. Funding Strategy

Applicants must demonstrate that the proposed catchment area(s) reflect a) the disproportionate burden of COVID-19 infection rates/COVID-19 mortality rates and b) populations disproportionally affected by COVID-19 infections; particularly those affected by poverty. Catchment areas are defined in this NOFO as a county, metropolitan statistical area(s), or a group of contiguous counties. These catchment areas must have significant COVID-19 disease burden, evidence of disproportionate health disparities as evidenced by poverty rates, and sufficient combined populations to allow the strategies supported by this NOFO to reach significant numbers of people.

Applicants must use the following two resources to document a) poverty rates and b) COVID-19 cases and/or mortality rates:

- Poverty rates may be found at https://www.census.gov/library/visualizations/interactive/2014-2018-poverty-rate-bycounty.html.
- COVID-19 cases and/or deaths (county level) can be found at https://covid.cdc.gov/covid-data-tracker/#county-view. The two COVID-related data points that can be used are:
 - o 7 Day total reported cases per 100,000 population
 - o 7 Day total reported deaths per 100,000 population

Applicants should include the time period for the 7 day total for cases and/or deaths from the CDC COVID Data Tracker. Additional guidance on the two COVID-related data points can be found at: Community Health Workers for Covid Response and Resilient Communities | CDC

Component A focuses on organizations that have some experience with CHWs and want to build capacity by expanding training and oversight plans that will lead to the increased deployment of CHWs which will result in improved health outcomes. These organizations must have approximately one year of experience in implementing a CHW program in their catchment area. The experiences of this program may have been limited in scope, i.e., focusing on a single or a few disease concerns, providing advice and guidance to direct community members to appropriate clinical services. We expect to fund approximately 35 applicants. Applications for this component will reflect services addressing a catchment area, as defined in this NOFO, as a county, metropolitan statistical area(s), or a group of counties:

- up to 50,000 population, applicants may apply for up to \$350K.
- For 50,000 to 200,000 population, applicants may apply for up to \$600K.
- For 200,000+ population, applicants may apply for up to \$1M.

Component B focuses on expanding deployment of CHWs in organizations with substantial (approximately 3 years) experience currently utilizing CHWs that want to amplify activities to address COVID-19 within communities resulting in improved health outcomes; we expect to fund approximately 35 applicants. Applications for this component will reflect services addressing a catchment area, as defined in this NOFO, as a county, metropolitan statistical area(s), or a group of counties:

- up to 200,000 population, applicants may apply for up to \$1M.
- For 200,000 to 600,000 population, applicants may apply for up to \$2M
- For 600,000+ population, applicants may apply for up to \$3M.

Component C focuses on policy, systems or environmental changes, is innovative and will train, deploy, and engage CHWs to further address health disparities and social inequities exacerbated by COVID-19 within the catchment area identified in the recipient's Component B application. Only applicants that are approved and funded for Component B will be considered for Component C funding. We expect to fund approximately 5 recipients for Component C for up to \$2M each.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Evaluation and performance measurement help demonstrate program accomplishments and strengthen the evidence for strategy implementation. CDC, in collaboration with identified Evaluation and Technical Assistance (TA) partners, will work individually and collectively with recipients to track the implementation of recipient strategies and activities and assess progress in achieving NOFO outcomes within the three-year period of performance. Both process and outcome evaluation will seek to answer the following questions:

Approach:

1. To what extent has the recipient's implementation approach resulted in achieving the desired outcomes?

Effectiveness:

- 1. To what extent has the recipient increased the reach of Component A and B strategies to prevent and control COVID-19 infections and strengthen community resilience?
- 2. To what extent has implementation of Category A and B strategies led to improved health outcomes among the identified priority population(s)?

Recipients must collaborate with CDC and Evaluation/Technical Assistance partners and are strongly encouraged to submit at least two success stories per year with impacts using the NCCDPHP Success Stories Application. Information on this application is located in the Resources section of this document. CDC and Evaluation/Technical Assistance (TA) partners will implement an evaluation approach that consists of (1) ongoing monitoring and evaluation of progress through the collection and reporting of performance measures by recipients, (2) a CDC-and Evaluation/TA partner-led comprehensive evaluation, and (3) recipient-led evaluations, with support from CDC and Evaluation/TA partners, as appropriate.

Performance measures developed for this NOFO correspond to the high-level broad strategy categories and outcomes described in the logic model. All measures are broadly stated and may be refined with recipients, CDC, and Evaluation/TA partners, based on activities proposed and recipient needs. CDC and the Evaluation/TA partners, as appropriate, will work with recipients on operationalizing and further defining each performance measure and guidance will be provided prior to the first year of expected recipient reporting.

Performance measures will be reported semi-annually by all recipients to CDC and the Evaluation/TA partners, who will also manage and analyze the data to identify recipient program improvements, respond to broader technical assistance needs, and to report to stakeholders. CDC and the Evaluation/TA partners will analyze recipient submitted performance measure data and develop aggregate performance measure reports to be disseminated to recipients and other key stakeholders, including federal partners, non-funded partners, and policy makers, as appropriate. These aggregate findings may also be presented during site visits and recipient meetings. In addition to performance measures reported by recipients, CDC will track all outcome measures (not listed in required recipient table for reporting) that are relevant to the program through national data sets or the comprehensive evaluation activities. As part of the comprehensive evaluation activities, a subset of NOFO recipients will be selected who will be required to work collaboratively with CDC and the Evaluation/TA partners to report more in-depth narratives of activities over the course of the NOFO.

For the CDC- and Evaluation/TA partner-led comprehensive evaluation activities, CDC will lead the design, data collection, analysis, and reporting. Recipients will be expected to participate in evaluation activities such as surveys, interviews, case studies, and other data collection efforts to ensure there is a robust evaluation of the evidence-driven, community tailored/adapted efforts of the role CHWs play in leading, supporting, and collaborating with a wide variety of stakeholders

to improve the health of the community. An appropriate level of guidance and support, including one on one outreach, small peer-to-peer learning and sharing opportunities, webinars, learning collaboratives, electronic resources, and virtual engagements to showcase successes and brainstorm the resolution of potential challenges will be provided to the recipients. These connections among recipients, CDC and the Evaluation/TA partners are critical to the programmatic success and effective and meaningful evaluation of this grant. CDC and the Evaluation/TA partners will use finding from these evaluation efforts to refine technical assistance and, in turn, maximize and sustain program outcomes.

For recipient-led evaluations, CDC and Evaluation/TA partners will be available to work closely, where appropriate, with recipients to develop, refine, and implement evaluation plans that they can use to make program improvements and demonstrate the outcomes and impact of their programs.

CDC, Evaluation/TA partners, and recipients will only collect data that will be analyzed and used. CDC will provide recipients with performance measure reporting templates, and potentially evaluation plan and reporting templates. CDC and Evaluation/TA partners will provide ongoing TA on program implementation efforts, recipient-led evaluation, and recipient performance measure reporting. Evaluation TA will be provided using a customized approach to ensure that the tools and services provided best meet the needs of the recipients. All evaluation findings produced by CDC, the Evaluation TA providers, and recipients will contribute to: (1) program and quality improvement of program efforts; (2) practice-based evidence; (3) documentation and sharing of lessons learned to support replication and scaling up of these program strategies and/or (4) future funding opportunities to expand upon these successes.

The data CDC collects for performance measurement and evaluation are directly related to the implementation of the strategy and/or the desired outcome indicated in the logic model. Data being collected are strictly related to the implementation of the NOFO strategies and shall be used for assessing and reporting progress and for other pertinent implementation improvement actions. All performance measure data will be collected via secure data systems. Recipients will report their performance measure data semi-annually via the data system and will have access to their data only. Over the 3-year performance period, data will be secured with limited access to authorized CDC program and evaluation staff. CDC will publish summative reports on individual and aggregate performance measure data.

Applications involving public health data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for the applicant's assurance of the quality of the public health data through the data's lifecycle and any plans to deposit data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

Short-term measures reported by recipients are described in the table below. Recipients will report one level of measures:

• short-term outcomes measures for each required strategy and for each additional strategy selected

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The tables below align with the logic model and shows the alignment among the overarching high level strategy categories, i.e. TRAIN, DEPLOY, and ENGAGE, along with the specific strategies, outcomes, and performance measures for Component A and Component B.

Table 1. Component A: Capacity Building -- Strategies, Outcomes, and Performance Measures

Community Health Workers for COVID-1 Table 1. Component A: Capacity Buildin Me	•	,
Strategies (Component A Applicants are required to address the four strategies indicated in BOLD and must also select <u>one</u> additional strategy from any of the two areas (train/deploy) in the menu of strategies targeting capacity building (CB) efforts within this table.	Short-term Outcomes	Short-term Measures (Recipients will report short-term measures aligned with all required strategies in BOLD and the one additional strategy selected.) Note: All measures are broadly stated and will be refined with recipients and CDC based on activities proposed.
T	RAIN	
Strategy CB1 (Required): Identify and collaborate with community-wide efforts to ensure comprehensive acquisition of relevant knowledge, roles, and skills by CHWs so they are prepared to successfully engage with existing state and/or local public health-led actions to manage COVID-19 among priority populations* within communities.	Increased skills/capacity/roles of CHWs to provide services and support for COVID-19 public health response efforts among priority populations* within communities.	Measure (Required): # of CHWs successfully completing state/local public health-led COVID-19 response training efforts as determined by relevant public health-led entities, e.g., skills related to contact tracing, appropriate use and care of PPE, and sufficient documentation of relevant data collection efforts.

Strategy CB2: Align training opportunities for CHWs with the primary actions of state and/or local public health led efforts to address the underlying conditions and/or environments that increase the risk and severity of COVID-19 infections among priority populations* within communities.	Increased skills/capacity/roles of CHWs to provide services and support for COVID-19 public health response efforts among priority populations* within communities.	Measure: # and type of health conditions and/or social service needs for which CHWs are provided training and/or certification to deliver among priority populations* within communities, e.g. Lifestyle interventions and strategies, hypertension management, diabetes management, arthritis management, improving physical activity, improving healthy eating, tracking, referral, and connection of individuals to available social services to address identified needs.		
DE	PLOY			
Strategy CB3 (Required): Integrate CHWs into organizations and care teams to support the public health response to COVID19 among priority populations* within communities.	Increased workforce of CHWs delivering services to manage the spread of COVID-19.	Measure (Required): # and type of organizations/entities that are integrating CHWs to support state/local public health- led COVID-19 response efforts.		
Strategy CB4: Develop and disseminate messaging that educates organizations and care teams on the critical role CHWs play in delivering services and managing the spread of COVID-19 among priority populations* within communities.	Increased workforce of CHWs delivering services to manage the spread of COVID-19.	Measure: # and type of messages developed and disseminated		
ENGAGE				
Strategy CB5 (Required): Coordinate and/or promote opportunities, such as messaging/education, within communities	Increased utilization of community	Measure (Required): # of individuals within communities and/or		

and clinical settings to facilitate the engagement of CHWs in addressing the needs of those at highest risk for poor health outcomes, including those resulting from COVID-19.	those at highest	clinical settings reached through messaging and education, including those at highest risk for poor health outcomes, including those resulting from COVID-19, among priority populations* within communities.
Strategy CB6 (Required): Year 1: Initiate and develop and/or utilize systems to document engagement of CHWs in the care, support, and follow-up across clinical and community settings of priority populations* at highest risk for poor health outcomes, including those resulting from COVID19. Year 2: (Required): Facilitate engagement of CHWs in the care, support, and follow-up across clinical and community settings of priority populations* at highest risk for poor health outcomes, including those resulting from COVID-19.	Increased utilization of community resources and clinical services for those at highest risk for poor health outcomes among	Measure (required): # of patients referred for individual, specific named health and social conditions that increase the risk for COVID-19 for patients at highest risk for poor health outcomes, within clinical and/or community settings. Document referrals for any of the following specific named conditions: housing and shelter; food; healthcare; mental health and addictions; employment and income; clothing and household; childcare and parenting; government and legal.
Strategy CB7: Establish and strengthen partnerships between CHWs and State Medicaid agencies, relevant state or local coalitions, initiatives, professional organizations, providers, and health systems that provide resources and support for deploying CHWs to engage with priority populations* at highest risk for poor health outcomes, including those resulting from COVID-19 by addressing social determinants of health (e.g. those with underlying health conditions, with decreased access to care or lacking access to routine and usual care, challenges with having social needs met, food insecurity, housing	of community resources and clinical services for those at highest risk for poor health outcomes among priority populations* within communities.	Measure: # and type of partnerships established with traditional and nontraditional partners, such as, faith-based organizations, businesses, hospital systems, housing

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insecurity, and homelessness, etc).	populations* within	
	communities.	

^{*} Priority populations are those with increased prevalence of COVID-19 and are disproportionately impacted by long-standing health disparities related to sociodemographic characteristics, geographic regions, and economic strata. Examples include, racial and ethnic minorities, persons who are economically disadvantaged, justice-involved, experiencing homelessness, and/or have certain underlying medical conditions that increase COVID-19 risk

Table 2. Component B: Implementation Ready -- Strategies, Outcomes, and Performance Measures

Community Health Workers for COVID-19 Response and Resilient Communities (CCR)

Table 2. Component B: Implementation Ready--Strategies, Outcomes, and Performance Measures

Strategies (Component B Applicants | Short-term are required to address the four strategies indicated in **BOLD** and must also select two additional strategies from any of the two areas (train/deploy) in the menu of strategies targeting Implementation Ready (IR) efforts within this table).

Outcomes

Short-term Measures (Recipients will report short-term measures aligned with all required strategies in **BOLD** and the two additional strategies selected).

Note: All measures are broadly stated and will be refined with recipients and CDC based on activities proposed.

TRAIN

Strategy IR1 (Required): Identify and collaborate with communitywide efforts to ensure comprehensive acquisition of relevant knowledge, roles, and skills by CHWs so they are prepared to successfully engage with existing state and/or local public health-led actions to manage COVID-19 among priority populations* within communities.

Increased community resources and clinical services for those at highest risk for poor health outcomes among priority populations* within communities.

Measure (Required): # of CHWs utilization of successfully completing state/local public health-led COVID19 response training efforts as determined by relevant public health-led entities, e.g. skills related to contact tracing, appropriate use and care of PPE, and sufficient documentation of relevant data collection efforts.

Strategy IR2: Ensure appropriate training opportunities to disseminate messaging for CHWs focused on reaching those with underlying conditions and/or environments that increase the risk and severity of COVID-19 infections among priority populations in order to strengthen infrastructure critical to identification of infection, appropriate follow-up, including contact tracing, and treatment among priority populations* within communities.	for poor	Measure: # of individuals within specific media distribution areas, inside stated catchment areas that have been reached by critical messaging, as determined by relevant public health-led entities, to identification of infection, appropriate follow-up, including contact tracing, and treatment.			
Strategy IR3: Align training opportunities for CHWs with the primary actions of state and/or local public health led efforts to address the underlying conditions and/or environments that increase the risk and severity of COVID-19 infections among priority populations* within communities.	Increased utilization of community resources and clinical services for those at highest risk for poor health outcomes among priority populations* within communities.	Measure: # and type of health conditions and/or social service needs for which CHWs are provided training and/or certification to deliver among priority populations* within communities, e.g. Lifestyle interventions and strategies, hypertension management, diabetes management, arthritis management, improving physical activity, improving healthy eating, tracking, referral, and connection of individuals to available social services to address identified needs.			
DEPLOY					
Strategy IR4 (Required): Integrate CHWs into Organizations and Care Teams to support the public health response to COVID-19 among priority populations* within communities.	CHWs delivering services to manage the spread of COVID-19.	Measure (Required): # and type of organizations/entities that are integrating CHWs to support state/local public health-led COVID-19 response efforts.			
Strategy IR5: Integrate CHWs into public health emergency	Increased workforce of	Measure: # and types of vaccine deployment plans in which CHWs are			

preparedness and vaccine
deployment planning, e.g. inclusion
in planning and coordination with
Immunization and Public Health
Preparedness Programs; existing
vaccine infrastructure; and vaccine
providers in the community to
increase access to new and existing
vaccination programs in priority
populations* within communities.

CHWs delivering services to manage the spread of COVID-19.

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included in the planning and design; deployment of plan components; ethical distribution of initial COVID-19 vaccine supplies to vaccine providers in accordance with state, local, and federal regulations; and/or dissemination to identified individuals/populations.

ENGAGE

Strategy IR6 (Required): Coordinate and/or promote opportunities, such as messaging/education, within communities and clinical settings to facilitate the engagement of CHWs in addressing the needs of those at highest risk for poor health outcomes, including those resulting from COVID-19.

Increased community resources and clinical services for those at highest risk for poor health outcomes among priority populations* within

communities.

Measure (Required): # of individuals utilization of within communities and/or clinical settings reached through messaging and education, including those at highest risk for poor health outcomes, including those resulting from COVID-19, among priority populations* within communities.

Strategy IR7. (Required): Facilitate engagement of CHWs in the care, support, and follow-up across clinical and community settings of priority populations* at highest risk for poor health outcomes, including those resulting from COVID-19.

Increased community resources and clinical services for those at highest risk for poor health outcomes among priority populations*

Measure (required): # of patients utilization of referred for individual, specific named health and social conditions that increase the risk for COVID-19 for patients at highest risk for poor health outcomes, within clinical and/or community settings. Document referrals for any of the following specific named conditions: housing and shelter; food; healthcare; mental health and addictions; employment and income; clothing and household; childcare and parenting; government and legal.

within communities.

* Priority populations are those with increased prevalence of COVID-19 and are disproportionately impacted by long-standing health disparities related to sociodemographic characteristics, geographic regions, and economic strata. Examples include, racial and ethnic minorities, persons who are economically disadvantaged, justice-involved, experiencing homelessness, and/or have certain underlying medical conditions that increase COVID-19 risk.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

With support from CDC, recipients will be required to submit a more detailed Evaluation and Performance Measurement Plan, including a Data Management Plan (DMP), within the first 6 months of receiving the award, as described in the Reporting Section of this NOFO. CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement and for compliance with the monitoring and evaluation guidance established by CDC or other guidance otherwise applicable to this cooperative agreement. CDC recommends that at least 10% of total annual funds be allocated for evaluation, per Best Practices for Comprehensive Tobacco Control Programs.

Applicants are required to submit a plan for Performance Measurement Data Collection and Use. A detailed plan for Performance Measurement Data Collection and Use will be due within 6 months of receiving the award. CDC will provide additional templates and guidance for developing the Performance Measurement Data Collection and Use plan. Any anticipated issue with data collection should be highlighted in the plan, along with options to remedy it. Additionally, the plan should address how the information generated by the performance measures will be used for program improvement by the recipient.

c. Organizational Capacity of Recipients to Implement the Approach **Core Capacity for All Applicants**

Upon receipt of award all recipients must be able to implement this program in the state, locality, territory or tribal area in which they operate and are located. To ensure that recipients are able to execute CDC program requirements and meet period of performance outcomes, applicants must: describe relevant experience to implement the activities and achieve the project outcomes. describe experience and capacity to implement the evaluation plan, provide a staffing plan with clearly defined staff roles (including contractual staff if applicable) and resumes of key staff, and ensure a project management structure sufficient to achieve the project outcomes. This information must be described in the project narrative. Applicants must name the staffing plan file "Component [A, B or C] Staffing Plan" and upload to www.grants.gov. Applicants must name the resumes "Component [A, B or C] Resumes" and upload to www.grants.gov.

Key capacity requirements include:

- Leadership and management to plan and supervise the project and improve outcomes.
- Readiness and ability to begin implementation and data collection within 1 month of award.
- Budget management and administration capacity to establish financial procedures and track, monitor, and report expenditures.
- Contract management to manage the required procurement efforts, including the ability to write, award, and monitor contracts.
- Data management to design collection and evaluation strategies to produce useful data that demonstrate impact, program improvement, and sustainability
- Partnership development and coordination to leverage resources and maximize the reach and impact of CHW interventions within the state, locality, territory, or tribal area.
- Evaluation and performance monitoring to implement the evaluation plan and maintain programmatic quality, consistency, and fidelity.
- Knowledge and awareness of CDC-funded programs or other federally funded programs, that support the ongoing COVID-19 response in the jurisdiction they are proposing to serve and how they plan to work and align their activities with the program. These

programs, must include, at a minimum, the CDC Epidemiology, Lab and Capacity (ELC) cooperative agreement, the Public Health Emergency Preparedness (PHEP) cooperative agreement and the Emergency Response: Public Health Crisis Response cooperative agreement.

- Experience convening and/or supporting a community coalition to achieve program goals.
- For the engage community resilience to COVID-19 strategy, applicants must describe in the project narrative their expertise and credibility working with CDC or other federal programs supporting this work (e.g., National Diabetes Prevention Program, Prescription Drug Overdose Program, Wisewoman). The work proposed should align with these already funded projects.
- Applicants for *Component A* must have approximately one year of experience in implementing a CHW program in their catchment area. The experiences of this program may have been limited in scope, i.e., focusing on a single or few disease concerns, providing advice and guidance to direct community members to appropriate clinical services.

Components B: Enhanced Organizational Capacity Requirements for Implementation Ready (IR).

- Applicants for *Component B* must have approximately three years of experience in implementing a CHW program in their catchment area. The experiences of this program, however, have been broad in scope and provided appropriate education and assistance to community members from CHWs for a wide variety of concerns, including health and social services. Component B applicants must describe their history and experience in a) engaging CHWs to identify and enroll eligible community members in applicable health and social service programs, b) engaging CHWs to coordinate health care by providing appropriate referral and follow-up services, c) engaging CHWs to act as an advocate for those community members needing language assistance or support with health systems and d) working with health care payers in the public and private health systems to incorporate CHWs into teams of care professionals. Component B applicants must describe their quality assurance program, and the results of their ongoing evaluation or quality improvement efforts to identify priority needs and the actions they have taken to meet those needs, as well as evidence of documented improvement in the health status of the community served.
- Established expertise and credible working relationships with health care organizations/systems documented by letters of support, interagency agreements, or MOUs. These could include: federally qualified health centers, private health care provider systems, Accountable Care Organizations, hospitals. Applicants must name these files "Component [A, B or C] [Letters of Support, Interagency Agreements, MOUs]" and upload to www.grants.gov.
- Technical and technological infrastructure to support rapid recruitment, selection, hiring, training and deployment of CHWs for the work of this grant.

- Readiness and ability to begin implementation and data collection within 1 month of award.
- Description of having met any state, NGO or other CHW certification requirements as appropriate.
- Existing training infrastructure that is multimodal and includes virtual modules (instructional design expert, online learning platforms and tools).
- Accomplishments working with a community coalition of partnerships.
- Advanced infrastructure for leveraging existing partnerships.

Component C: Innovation - Demonstration Projects

- Readiness and ability to begin implementation of the demonstration project and data collection within 1 month of award.
- Describes their relationship(s) with existing partners that will be engaged to implement the demonstration project.
- Additional capacity to evaluate the impact and effectiveness of the demonstration project to build community resilience.

d. Work Plan

Applicants should provide a detailed work plan for the first year of the project and a high-level work plan for the subsequent years. The work plan should include evidence-based strategies and activities to achieve all outcomes listed in the logic model.

All applicants must propose a comprehensive work plan to include activities designed to achieve the short- and intermediate- term outcomes specified in this NOFO and that are aligned with the following three high-level strategy categories:

- *TRAIN* CHWs to ensure comprehensive acquisition and reinforcement of relevant knowledge, roles, and skills to support the COVID-19 public health response to manage outbreaks and community spread.
- **DEPLOY** CHWs to manage outbreaks and spread of COVID-19 among priority populations within communities.
- *ENGAGE* CHWs to help build and strengthen community resilience to mitigate the impact of COVID-19 by improving the overall health of priority populations within communities.

CDC will provide feedback and technical assistance to recipients to finalize the work plan post-award.

Applicants must name this file "Component ___[A, B or C] Work Plan" and upload to www.grants.gov.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting).

Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

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- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

Failure to participate in the monitoring and reporting activities could result in the restriction of funds.

Satisfactory progress for this NOFO would include: (a) meeting all deadlines for reporting performance measures, (b) working with recipients of DP21-2110 to evaluate impact, and (c) appropriate and timely response to requests from CDC staff supporting this NOFO.

f. CDC Program Support to Recipients

N/A

B. Award Information

1. Funding Instrument Type:

G (Grant)

2. Award Mechanism:

Activity Code: U58

3. Fiscal Year:

2021

Estimated Total Funding:

\$ 300,000,000

4. Approximate Total Fiscal Year Funding:

\$ 100,000,000

This amount is subject to the availability of funds.

5. Approximate Period of Performance Funding:

\$ 300,000,000

This amount represents approximate funding provided through the CARES Act over a three-year period of performance (\$100 million per budget period for three budget periods) for formulabased awards. This amount could increase during the period of performance.

6. Total Period of Performance Length:

year(s)

7. Expected Number of Awards:

8. Approximate Average Award:

\$ 1,000,000

Per Budget Period

Over a three-year period of performance, CDC will award approximately \$100 million each budget year for three years with the average award varying. These grants will range approximately from \$350,000 - \$3 million per year depending on the size and scope of activity. The range of funds is broad to accommodate a varied number of organizations based on capacity and a range of catchment areas whose resource needs will vary. Approximate average one-year award amounts for each component are:

Component A (Capacity Building): \$600K Component B (Implementation Ready): \$2M

Component C (Innovation – demonstration projects): \$2M

9. Award Ceiling:

\$ 5,000,000

Per Budget Period

The ceiling may increase based on availability of funds.

10. Award Floor:

\$ 350,000

Per Budget Period

11. Estimated Award Date:

August 01, 2021

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal

government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

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12. Budget Period Length:

12 month(s)

13. Direct Assistance

Direct Assistance (DA) is not available through this NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

00 (State governments)

01 (County governments)

07 (Native American tribal governments (Federally recognized))

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

11 (Native American tribal organizations (other than Federally recognized tribal governments))

Additional Eligibility Category:

Government Organizations:

State (includes the District of Columbia)

Local governments or their bona fide agents

Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau

American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

American Indian or Alaska native tribally designated organizations

2. Additional Information on Eligibility

As authorized by the Coronavirus Aid, Relief, and Economic Security Act ("CARES ACT"; <u>Public Law 116-136</u>), eligibility is limited to those listed above as well as those listed in Additional Information on Eligibility and include:

American Indian/Alaska Native Urban Indian Centers

Health Service Providers to tribes

Applicants may apply for Component A only, or Component B only, but not both.

If an applicant applies for both Component A AND Component B, CDC will determine the application to be non-responsive and it will not receive further review.

Only Component B applicants may also apply for Component C.

 Only applicants that are approved and funded for Component B will be considered for Component C funding. The Component C application must be submitted at the same time as the Component B application. No awards for Component C will be made to Component A applicants. If applying for Component C, three elements are required for submission: a) a separate proposal not to exceed four pages clearly describing the proposed innovation for the demonstration including rationale, approach, expected impact, and evaluation; b) a budget narrative; and c) a workplan.

A minimum of 3 eligible tribal entities (i.e., tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes) across Components A, B, and C will be funded.

For non-tribal applicants, we will fund at least one application in each of the 10 HHS regions with a maximum of 3 awards per state.

If a state applies and identifies a particular county(ies) as their catchment area, they must submit a letter from appropriate county-level government confirming the county's agreement with the application. A locality may apply separately or may join with other localities meeting COVID-19 and poverty requirements and submit an application for a single responsibility for all financial and reporting requirements. A locality joining with other localities for the application must submit a letter from appropriate county-level government confirming the county's agreement with the application. Applicants must file the letter, as appropriate, name the file "CHW County Agreement ApplicantName', and upload it as a PDF file at www.grants.gov.

APPLICANTS MUST CLEARLY STATE WHICH COMPONENT(S) THEY ARE APPLYING FOR IN THEIR PROJECT ABSTRACT.

3. Justification for Less than Maximum Competition

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

No

5. Maintenance of Effort

Maintenance of effort is not required for this program

D. Required Registrations

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System: All applicant organizations must obtain a Data

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Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http://fedgov.dnb. com/webform/displayHomePage.do. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those subrecipients must provide their DUNS numbers before accepting any funds.

- b. System for Award Management (SAM): The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at https://www.sam.gov/index.html.
- c. Grants.gov: The first step in submitting an application online is registering your organization atwww.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option atwww.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more

than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http://fedgov.dnb.com/webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http://fedgov.dnb.com/webform) or call 1-866-705-5711

2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to https://www.sam.gov/SAM/and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	to 2 weeks and must be	For SAM Customer Service Contact https://fsd.g ov/fsd-gov/ home.do Calls: 866- 606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

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2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed or postmarked by)

03/25/2021

LOI is not required or requested.

b. Application Deadline

Number Of Days from Publication 60

05/24/2021

11:59 pm U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension. then applications must be submitted by the first business day on which grants gov operations resume.

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Due Date for Information Conference Call

Date: March 31, 2021

Time: 3:30 pm - 4:30 pm U.S. Eastern Standard Time

Conference Number: 800-369-3192

Participant Code: 5479788

Join via Computer: https://adobeconnect.cdc.gov/r0er4gejjemc/

Potential applicants may also submit questions via email at: nccdphp chw@cdc.gov

The following website will contain pre-and post-conference call information, including questions and answers submitted by potential applicants: Community Health Workers for Covid Response and Resilient Communities | CDC

5. Pre-Award Assessments

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with

supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

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When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

Is a LOI:

Not Applicable

LOI is not requested or required as part of the application for this NOFO.

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file

"Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

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Applicants must clearly state which component(s) they are applying for in their Project Abstract.

10. Project Narrative

Multi-component NOFOs may have a maximum of 15 pages for the "base" (subsections of the Project Description that the components share with each other, which may include target population, inclusion, collaboration, etc.); and up to 4 additional pages per component for

Project Narrative subsections that are specific to each component.

Text should be single spaced, 12 point font, 1-inch margins, and number all pages. Page limits include work plan; content beyond specified limits may not be reviewed.

Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity Announcement. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

Component A applicants can submit a project narrative that is up to 20 pages long. The work plan and budget narrative are included in the 20 pages.

Component B applicants can submit a project narrative that is up to 20 pages long. The work plan and budget narrative are included in the 20 pages.

Applicants applying for both Component B and Component C can submit a project narrative for Component B that is up to 20 pages long (including the Component B work plan and budget narrative) and a separate Component C proposal, not to exceed 4 pages, clearly describing the proposed innovation for the demonstration project including rationale, approach, expected impact and evaluation, budget narrative, and work plan.

Pages in the narrative exceeding these limits may not be reviewed.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the period of performance. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

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iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidencebased strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the period of performance. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see https://www.cdc.gov/od/science/integrity/reducePublicBurden/.
- How key program partners will participate in the evaluation and performance measurement planning processes.

Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

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Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative,

applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- **Supplies**
- Travel
- Other categories
- Contractual costs
- **Total Direct costs**
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO. applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and upload it as a PDF file

at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

13. Pilot Program for Enhancement of Employee Whistleblowers Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations

(CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

13a. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded.

Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federallyfunded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

13b. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

13c. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

14. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

15. Other Submission Requirements

- a. Electronic Submission: Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity atwww.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.
- **b.** Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt whenwww.grants.gov receives the

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application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated bywww.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non- validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the email message generated at the time of application submission or the Grants.gov Online User Guide.

https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=GetStarted%2FGetStart ed.htm

- **d.** Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service atwww.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note thatwww.grants.gov is managed by HHS.
- e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call thewww.grants.gov Contact Center at 1-800-518-4726 or e-mail them

at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application.

Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

- 1. Include the www.grants.gov case number assigned to the inquiry
- 2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
- 3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by the Office of Grants Services. Complete applications will be reviewed for responsiveness by Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below

- i. Approach
- ii. Evaluation and Performance Measurement
- iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

i. Component A: Approach

Purpose and Outcomes (20 points) – The extent to which the applicant:

- 1. Describes the catchment area and provides quality information reflecting a) the burden of COVID-19 infection rates and/or COVID-19 mortality rates and b) poverty rates in the populations disproportionally affected by COVID-19 infections. (5 points)
- 2. Describes how they will work with CHWs to reach and serve the communities described in the catchment area. (5 points)
- 3. Provides a clear, concise statement of the community problem(s) and how CHWs are integral to the project. (5 points)
- 4. Provides a clear description of how they intend to train, deploy, and engage CHWs to support COVID-19 response and prevention in described catchment area. (5 points)

Strategies and Activities (25 points)- The extent to which the applicant:

- 5. Proposes activities that are aligned with existing COVID-19 response activities, including other CDC-funded programs, and ensures there is no duplication of effort. (5 points)
- 6. Proposes work that will be done in the required and optional strategy areas that are aligned with the outcomes presented in the logic model. (5 points)

7.	Describes how they will □ collaborate □ with other federally funded programs, community
	partners, and coalitions who are addressing COVID-19, to carry out the work of the
	grant. ☐ Letters of support are provided. ☐ If applicant identifies a particular county(ies)

Maximum Points: 45

Maximum Points: 25

Maximum Points: 30

- as their catchment area, or is a state intending to work in a specific county(ies), a letter(s) from appropriate county-level government confirming the county's agreement with the application is included. (5 points)
- 8. Provides a work plan that is aligned with the strategies and activities described in the NOFO and includes a description of specific tasks that are reasonable and feasible, with realistic completion dates, to accomplish the outcomes as stated in the NOFO. (10 points)

ii. Component A: Evaluation and Performance Measurement

The extent to which the applicant:

- 1. Dedicates at least 10% of funds to support evaluation (5 points)
- 2. Commits to work with the recipient(s) of the Evaluation TA NOFO to refine evaluation plans and performance measures and facilitate the national evaluation. (5 points)
- 3. Describes how CHWs and key partners will be engaged in the evaluation and performance measurement planning processes. (5 points)
- 4. Describes potentially available data sources for the performance measures. (5 points)
- 5. Describes plans to submit □ at least two success stories per year with impacts using the NCCDPHP Success Stories Application. (5 points)

iii. Component A: Applicant's Organizational Capacity to **Implement the Approach**

The extent to which the applicant:

- 1. Describes their relevant experience (approximately 1 year) working with CHWs and provides examples of CHW-related projects and accomplishments they've achieved. (10 points)
- 2. Describes □ a staffing plan that includes □ roles, responsibilities, and qualifications of all staff, including evaluation staff, who will have a role in implementing program strategies and achieving outcomes. ☐ Contractual staff and/or organizations should be included in the staffing plan, as applicable. Resumes for key staff, including key contractual staff, are included. \Box (5 points)
- 3. Describes day-to-day responsibility for key tasks including leadership of project, budget management, contract management, implementation of activities and tasks, monitoring progress, data collection and management, preparation of reports, partnership development and coordination, evaluation and performance monitoring, and communication with partners and CDC. Describes readiness and ability to begin implementation within 1 month of award. (10 points)

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4. Describes their relationship and accomplishments with existing coalition(s) and other CDC-funded programs with which they will partner to implement the activities outlined in their workplan and address COVID-19 response and prevention response efforts? (5 points)

Budget Maximum Points: 0

Though not scored, applicants must assure their proposed budget(s) align with the proposed work plan and adhere to CDC fiscal policy.

i. Approach **Maximum Points: 35**

Component B: Approach

Purpose and Outcomes (15 \square points) – The extent to which the applicant: \square

- 1. Describes the catchment area and provides quality information reflecting a) the burden of COVID-19 infection rates and/or COVID-19 mortality rates and b) poverty rates in the populations disproportionally affected by COVID-19 infections. (5 points)
- 2. Describes how they will work with CHWs to reach and serve the communities described in the catchment area. (5 points)
- 3. Provides a clear, concise statement of the community problem(s) and how CHWs are integral to the project. (2 points)
- 4. Provides a clear description of how they intend to train, deploy, and engage CHWs to support COVID-19 response and prevention in described catchment area. (3 points)

Strategies and Activities (20 points)- The extent to which the applicant:

- 5. Proposes activities that are aligned with existing COVID-19 response activities, including other CDC-funded programs, and ensures there is no duplication of effort. (5 points)
- 6. Proposes work that will be done in the required and optional strategy areas that are aligned with the outcomes presented in the logic model. (5 points)
- 7. Describes how they will \(\sigma \) collaborate \(\sigma \) with other federally funded programs, community partners, and coalitions who are addressing COVID-19, to carry out the work of the grant. ☐ Letters of support are provided. ☐ If applicant identifies a particular county(ies) as their catchment area, or is a state intending to work in specific county(ies), a letter(s) from appropriate county-level government confirming the county's agreement with the application is included. (5 points)
- 8. Provides a work plan that is aligned with the strategies and activities described in the NOFO and includes a description of specific tasks that are reasonable and feasible, with realistic completion dates, to accomplish the outcomes as stated in the NOFO. (5 points)

ii. Evaluation and Performance Measurement

Maximum Points: 25

Component B: Evaluation and Performance Measurement

The extent to which the applicant:

- 1. Dedicates at least 10% of funds to support evaluation (5 points)
- 2. Commits to work with the recipient(s) of the Evaluation TA NOFO to refine evaluation plans and performance measures and facilitate the national evaluation. (5 points)
- 3. Describes how CHWs and key partners will be engaged in the evaluation and performance measurement planning processes. (5 points)
- 4. Describes potentially available data sources for the performance measures. (5 points)
- 5. Describes plans to submit □ at least two success stories per year with impacts using the NCCDPHP Success Stories Application. (5 points)

iii. Applicant's Organizational Capacity to Implement the Approach Maximum Points: 40

Component B: Applicant's Organizational Capacity to Implement Approach

The extent to which the applicant:

- 1. Describes their relevant experience (approximately 3 years) working with CHWs and provides examples of CHW-related projects and accomplishments they've achieved. (10 points)
- 2. Describes \square a staffing plan that includes \square roles, responsibilities, and qualifications of all staff, including evaluation staff, who will have a role in implementing program strategies and achieving outcomes. \square Contractual staff and/or organizations should be included in the staffing plan, as applicable. Resumes for \square key staff, including key contractual staff, are included. \square (5 points)
- 3. Describes day-to-day responsibility for key tasks including leadership of project, budget management, contract management, implementation of activities and tasks, monitoring progress, data collection and management, preparation of reports, partnership development and coordination, evaluation and performance monitoring, and communication with partners and CDC. Describes readiness and ability to begin implementation within 1 month of award. (5 points)
- 4. Describes their relationship and accomplishments with existing coalition(s) and other CDC-funded programs with which they will partner to implement the activities outlined in their workplan and address COVID-19 response and prevention response efforts (10 points)
- 5. Describe their expertise and credible working relationships with health care organizations/systems documented by □letters of support/MOUs/MOAs. □These could include: □federally qualified health centers, private health care provider systems, Accountable Care Organizations, hospitals. □(5 points)
- 6. Demonstrates technical and technological infrastructure to support rapid recruitment, selection, hiring, training, and deployment of CHWs for the work of this grant. (5 points)

Budget Maximum Points: 0

Component B: Budget

Though not scored, applicants must assure their proposed budget(s) align with the proposed work plan and adhere to CDC fiscal policy.

Component C: Approach The extent to which the applicant:	Maximum Points: 40
1. Provides the rationale for the project through a clear, problem(s) and how □ the □ innovative approach(es) that are □ foundational in building community resilience. (10	□ they propose □ involving □ CHWs
2. Provides a proposal that clearly □ describes □ the □ app the demonstration project, □ how innovation can address will be employed □ to accomplish those □ expected outco achieved within 2 years. □ (10 □ points)	the issue, \(\precent{\precentage} \) tangible \(\precent{\precentage} \) activities \(\precent{\precentage} \) that
3. Clearly describes the □critical role □CHWs □ will play the demonstration □ project. □(5 points)	y□in□implementing□and evaluating
4. □Provides a clear description in their proposal of how CHWs to address□at least one of the high-level strategi deploy,□or□engage).□ (5 points)□	
5. Describes how they will work with □new and/or □exi and coalitions to carry out the □innovative strategies and demonstration project. □ Letters of support will strength	d activities proposed for the
6. Provides a work plan that is aligned with the □propos specific tasks that are reasonable □ and □ feasible □ to □ in and clearly identifies CHW role(s) □ and responsibilities demonstration project. □ □ (5 points)	nplement the demonstration project
Component C: Evaluation and Performance Measurement The extent to which the applicant:	ent Maximum Points: 35
1. Ensures □ at least 10% of funds are budgeted to suppo	ort evaluation. (5 points)
2. Provides a thorough evaluation plan that □ describes □ potential data sources □ to □ determine the impact and eff project □ on building community resilience. □ □ □ (10 □ potential)	fectiveness of the demonstration
3. Describes additional □ experienced □ staff (not identificated organization identified to □ lead evaluation of points) □	, ,
4. Commits to work with the recipient(s) of the Evaluation plans and performance measures, and ☐ finalize ☐ appropriate in the committee of the Evaluation	
5. Describe how CHWs and key partners will be engage measurement planning processes and how recommend efforts will be incorporated into the evaluation plan. (5)	ations for sustainability of such

6. Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementing, and reporting of project activities and outcomes and enable continuous program quality improvement and inform sustainability planning. □ (5 points)

Component C: Applicant's Organizational Capacity to **Implement Approach**

The extent to which the applicant:

- 1. Describes a staffing plan that is separate from Component B, inclusive of any contracts as applicable, for the demonstration project including roles and responsibilities and qualifications. □ Resumes for □ key staff, including contract staff if applicable, are included. $(5\square points)$
- 2. Describes day-to-day responsibility for key tasks including leadership of the demonstration project, budget management, contract management, Dimplementation of activities and tasks, monitoring progress, data collection and management, preparation of reports, partnership development and coordination, and evaluation and performance monitoring, and communication with partners and CDC. (5 points)
- 3. Demonstrates readiness and ability to begin implementation □ of the demonstration project within 1 month of award. (10 points)
- 4. Describes their relationship with existing partners that will be engaged to implement the demonstration project. \Box (5 points)

Component C: Budget

Maximum Points: 0

Maximum Points: 25

Though not scored, applicants must assure their proposed budget(s) align with the proposed work plan and adhere to CDC fiscal policy.

c. Phase III Review

- Applications for Components A and B will be funded separately. Only one application per organization will be considered for either Component A or Component B.
- CDC may fund out of rank order to ensure geographical representation in each of the 10 HHS regions, COVID-19 infection rates, and/or poverty rates are being addressed, as well as ensuring applicants are reaching larger numbers of the target population and that a minimum of 3 eligible tribal entities (i.e., tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes) across Components A, B, and C are funded.
- For Component C, CDC may fund out of rank order to ensure that innovative approaches are not duplicative and that demonstration projects are geographically dispersed.
- CDC will provide justification for any decision to fund out of rank order.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

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In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMBdesignated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold. defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- (1) Financial stability;
- (2) Quality of management systems and ability to meet the management standards prescribed in this part;
- (3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards:
- (4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
- (5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

Successful applicants can anticipate notice of funding by August 1, 2021.

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.

The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

A recipient of a grant or cooperative agreement awarded by the Department of Health and Human Services (HHS) with funds made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); the Coronavirus Aid, Relief, and Economic Security Act, 2020 (the "CARES Act") (P.L. 116-136); and/or the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139) agrees, as applicable to the award, to: 1) comply with existing and/or future directives and guidance from the Secretary regarding control of the spread of COVID-19; 2) in consultation and coordination with HHS, provide, commensurate with the condition of the individual, COVID-19 patient care regardless of the individual's home jurisdiction and/or appropriate public health measures (e.g., social distancing, home isolation); and 3) assist the United States Government in the implementation and enforcement of federal orders related to quarantine and isolation.

In addition, to the extent applicable, Recipient will comply with Section 18115 of the CARES Act, with respect to the reporting to the HHS Secretary of results of tests intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19. Such reporting shall be in accordance with guidance and direction from HHS and/or CDC.

Further, consistent with the full scope of applicable grant regulations (45 C.F.R. 75.322), the purpose of this award, and the underlying funding, the recipient is expected to provide to CDC copies of and/or access to COVID-19 data collected with these funds, including but not limited to data related to COVID-19 testing. CDC will specify in further guidance and directives what is encompassed by this requirement.

This award is contingent upon agreement by the recipient to comply with existing and future guidance from the HHS Secretary regarding control of the spread of COVID-19. In addition, recipient is expected to flow down these terms to any subaward, to the extent applicable to activities set out in such subaward

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/textidx?node=pt45.1.75

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	Semi-annually	Yes
Federal Financial Reporting Forms	90 days after the end of the budget period.	Yes
Final Performance and Financial Report	90 days after end of period of performance.	Yes

Payment Management System (PMS)	Quarterly reports due January 30;	Yes
Reporting	April 30; July 30; and October 30.	res

a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

Evaluation

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publically available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

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This report must include the following:

- Performance Measures: Recipients must report on performance measures for each budget period and update measures, if needed.
- Evaluation Results: Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- Work Plan: Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.

Successes

- Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
- o Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
- o Recipients must describe success stories.

Challenges

- o Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
- o Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

CDC Program Support to Recipients

o Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

Administrative Reporting (No page limit)

- o SF-424A Budget Information-Non-Construction Programs.
- o Budget Narrative Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

The recipient must submit the Annual Performance Report via https://www.grantsolutions.gov 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

Performance measures should be reported semi-annually. CDC and the Evaluation/TA partners will specify data fields and format at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the period of performance, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

No additional information is required, other than what is listed above.

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000.

#: 5101

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www.fsrs.gov/documents/ffata legislation 110 252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

- A. Valued Added Tax (VAT) and Customs Duties Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.
- B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:
- 1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]
- 2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.
- 3) Terms: For purposes of this clause:
- "Commodity" means any material, article, supplies, goods, or equipment;
- "Foreign government" includes any foreign government entity;
- "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
- 4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
- 5) Contents of Reports: The reports must contain:

- a. recipient name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.
- 6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

- (1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;
- (2) By the HHS awarding agency or pass-through entity for cause;
- (3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- (4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this NOFO.

Program Office Contact

For programmatic technical assistance, contact:

First Name:

Stacy

Last Name:

De Jesus

Project Officer

Department of Health and Human Services Centers for Disease Control and Prevention

Address:

Telephone:

Email:

NCCDPHP CHW@cdc.gov

Grants Management Office Information

For financial, awards management, or budget assistance, contact:

First Name:

Rhonda

Last Name:

Latimer

Grants Management Specialist

Department of Health and Human Services

Office of Grants Services

Address:

2939 Flowers Rd.

South KOGR Bldg, VANDE Rm 211, MS TV-2

Atlanta, GA 30341

Telephone:

Email:

ito1@cdc.gov

For assistance with submission difficulties related to www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments applicants can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

Bona Fide Agent status documentation, if applicable

Indirect Cost Rate, if applicable

Position descriptions

Letters of Support

Required Attachments:

- Resumes/CVs
- Letters of Support
- Staffing plan, can include position descriptions

Other Optional attachments

• County agreement letter

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements(**ARs**): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additional requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assistance Listings: A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

Assistance Listings Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency.

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the period of performance. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http://www.cdc.gov /grants/additionalrequirements /index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

#: 5106

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions. Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

Healthy People 2030: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount. Memorandum of Understanding (MOU) or Memorandum of Agreement(MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and

obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

#: 5108

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of performance – formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs. Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and qualityof-life outcomes and risks.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

#: 5109

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

Community Health Worker - A community health worker is a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery. [accessed from www.apha.org 12/14/2020]

Bona Fide Agent -□a bona fide agent is an agency/organization identified as eligible to submit an application in lieu of a state application. If applying as a bona fide agent, a legal, binding agreement from the state, tribal, territorial, or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via grants.gov.

Innovation - Novel combinations or uses of preexisting efforts [programs, tools, ideas, etc.] to enable or enhance the solution to a need

HHS Regions - The Department of Health and Human Services Office of Intergovernmental and External Affairs hosts 10 Regional Offices in various cities across the United States. These offices each oversee a geographic area, or region, across multiple states and are maintained to ensure that the Department is able to remain in close contact with state, local, or tribal partners and to ensure HHS programs and policies address the needs of individuals and communities across the country. For details on each region or Regional Office, visit Regional Offices HHS.gov

References/Resources

- 1. Centers for Disease Control and Prevention (2019). CHW Forum: Community Health Worker Forum: Engaging Community Health Workers in the Development of a Statewide Infrastructure for Sustainability. Retrieved fromhttps://www.cdc.gov/diabetes/programs/stateandlocal/resources/chwforum.html
- 2. Department of Health and Human Services (HHS, 2020. Healthy People 2030. Emergency Preparedness. Retrieved from https://health.gov/healthypeople/objectivesand-data/browse-objectives/emergency-preparedness

- 3. Department of Health and Human Services (HHS, 2020). <u>Compendium of Federal</u> Datasets Addressing Health Disparities
- 4. <u>HRSA 2019-2020 Health Equity Report: Special Feature on Housing and Health Inequalities.</u> Retrieved from https://www.hrsa.gov/sites/default/files/hrsa/health-equity/HRSA-health-equity-report.pdf
- 5. National Stakeholder Strategy for Achieving Health Equity. Retrieved from https://sph.umd.edu/sites/default/files/files/NSS Summary0405 1 .pdf
- 6. National Association of Community Health Workers (2020). See New report on sustainable financing for CHWs.
- 7. World Health Organization (2018). WHO launches new guideline on health policy and system support to optimize community health worker programmes. Retrieved from https://www.who.int/hrh/community/guideline-health-support-optimize-hw-programmes/en/
- 8. Centers for Disease Control and Prevention (2020). Resources for Community Health Workers, Community Health Representatives and Promotores de la Salud. Retrieved from Resources for Community Health Workers, Community Health Representatives, and Promotores de la Salud | CDC.
- 9. NCCDPHP Success Stories Application: This online application provides a step-by-step template for awardees as they develop their success stories. Awardees can use the application to create stories for their own needs or choose to submit the story to CDC for consideration in the online library. https://nccd.cdc.gov/NCCDSuccessStories/
- 10. The application is supported by the Success Stories Development Guide. This Word document guides users through the sections of the NCCDPHP Success Stories application and helps them prepare a story for submission: https://nccd.cdc.gov/NCCDSuccessStories/pdfs/Success_Stories_Development Guide.docx
- 11. Centers for Disease Control and Prevention (2020), National Center for Health Statistics. Health Disparities: Race and Hispanic Origin. Retrieved from COVID-19 Provisional Counts Health Disparities (cdc.gov).
- 12. People at Increased Risk and Other People Who Need to Take Extra Precautions: <u>Do I need to Take Extra Precautions Against COVID-19 | CDC</u>

Exhibit C

Emerging Issues (E) Project funding for adjusting community mitigation in response to COVID-19

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ELC CARES

EMERGING ISSUES (E) PROJECT

BACKGROUND

As part of the "Coronavirus Aid, Relief, and Economic Security Act" or the "CARES Act" of 2020, ELC is awarding a total of nearly \$631 million to our recipient base in a program-initiated component funding under the Emerging Issues (E) Project of CK19-1904, henceforth 'ELC CARES'. The intention of this funding is to rapidly establish and monitor key activities related to COVID-19 in the areas of epidemiology, laboratory, and informatics. Monitoring the indicators associated with these activities are intended to assist State, local, and territorial governments in making data-driven policy decisions regarding testing, mitigation, and prevention efforts.

PROCESS

This funding is intended to support ELC CARES activities and associated indicator reporting for Budget Period 1 under CK19-1904; however, recipients are reminded that expanded authority applies, and activities are likely to take 24 months for completion due to the nature of COVID-19. Within 30 days of receipt of the Notice of Award (NOA), the recipient is required to submit a workplan and budget describing their ELC CARES activities.

To facilitate recipients meeting the 30-day requirement:

- (1) Workplan entries will be completed in the 'ELC CARES' portal in REDCap; and
- (2) Revised budgets will be completed by using the template provided via GrantSolutions Grant Notes at time of NOA issuance.
 - a. Funds will be awarded under the 'Other' cost category;
 - b. Recipients will adjust the cost category allocations of awarded funds to reflect the areas where financial assistance is needed; and
 - c. Recipients will upload the revised budget into GrantSolutions in the form of a Grant Note, with a courtesy copy into REDCap 'ELC CARES' portal, by the 30-day post award deadline.

ACTIVITIES

- 1. Establish or enhance ability to aggressively identify cases, conduct contact tracing and follow up, as well as implement recommended containment measures.
 - a. Enhanced contact tracing including contact elicitation/identification, contact notification, and contact follow-up. Activities could include traditional contact tracing methods as well as healthcare-specific and other proximity/location-based methods.
- 2. Improve morbidity and mortality surveillance, including:
 - a. Establish or enhance community-based surveillance
 - i. Surveillance of populations and individuals without severe illness, travel to high-risk locations, or contacts to known cases.
 - b. Monitor and report daily incidence rate.
 - c. Track and send Emergency Department and outpatient visits for COVID-like illness, as well as other illnesses, to CDC. Send copies of all admit, discharge, and transfer (ADT) messages to CDC National Syndromic Surveillance Program (NSSP).
 - d. Monitor and utilize NHSN acute care, long-term care, and ambulatory care setting data for confirmed COVID-19 infection or for COVID-like illness.
 - e. Provide accurate accounting of COVID-19 associated deaths. Establish electronic death reporting to CDC.
 - f. Establish or enhance electronic case reporting from healthcare facilities to public health, including for COVID-19
- 3. Enhance laboratory testing and reporting capacity:
 - a. Establish or expand capacity to test all symptomatic individuals, and secondarily expand capacity to achieve community-based surveillance.
 - b. Screen for past infection (e.g., serology) for health care workers, employees of high-risk facilities, critical infrastructure workforce, and childcare providers.
 - c. Obtain all jurisdictional laboratory test data electronically, including from new, non-traditional testing settings, and using alternative file formats (e.g., .csv or .xls) to help automate. In addition to other reportable results, this should include all COVID-19 related testing data, including all tests to detect SAR-CoV-2 and serology testing.
 - d. Report all COVID-19 related line level testing data (negatives, positives, indeterminants, serology) daily to CDC.
- 4. Prevent and control COVID-19 in healthcare settings and protect other vulnerable or high-risk populations:
 - a. Assess and monitor infections in healthcare workers across the healthcare spectrum.
 - b. Perform preparedness assessment to ensure interventions are in place to protect high-risk populations
 - c. Monitor and help implement mitigation strategies for COVID-19 in all high-risk healthcare facilities (e.g., hospitals, dialysis clinics, cancer clinics, nursing homes, and other long-term care facilities, etc.).
 - d. Monitor and help implement mitigation strategies for other high-risk employment settings (e.g., meat processing facilities), and congregate living settings (e.g., prisons, youth homes, shelters).
- 5. Monitor and mitigate COVID-19 introductions from connected jurisdictions (i.e., neighboring cities, states; including air travel).
- 6. Work with healthcare system to manage and monitor system capacity.
 - a. Assess and monitor the number and availability of critical care staff, necessary PPE and potentially life-saving medical equipment, as well as access to testing services.
 - b. Utilize eCR data to enhance morbidity and mortality surveillance and to help monitor the health of the community and inform decisions for the delivery of public health services.
 - c. Leverage NHSN data to monitor healthcare worker staffing, testing, and treatment supplies.
- 7. Improve understanding of jurisdictional communities with respect to COVID-19 risk:

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- a. Build understanding of population density and high-risk population density (i.e. population of >65 yrs., proportion of population with underlying conditions, households with limited English fluency, healthcare seeking behavior, populations without insurance and below poverty level.
- b. Monitor compliance indicators (Number of Violations / complaints related to mandatory or recommended community mitigation).

See Appendix A for draft indicators to be reported to CDC; these will be finalized following the release of awards.

APPENDIX A: DRAFT INDICATORS

Public Health Capacity

Category	Indicator	Threshold
Capacity for case identification, follow up and containment	No barriers to SARS-CoV-2 testing in jurisdiction	Testing availability of 100% symptomatic individuals and exposed contacts
	Rapid identification of all newly identified COVID-19 cases by jurisdiction	Daily identification of all newly identified COVID-19 cases in the jurisdiction is achieved through active surveillance of labs and healthcare facilities.
	Rapid interviewing of new cases with full assessment of contacts	Interviews are rapidly attempted for every newly identified case, resulting in contacts being ascertained for >90% of newly identified illnesses.
	Rapid and complete follow up for identified contacts of newly identified cases	Rapid follow up (isolation, self- monitoring, and testing when indicated) initiated for >90% of identified contacts of newly identified cases.
Reduced disease burden	Consistent downward trajectory in newly identified COVID-19 cases	Consistent reductions in newly identified cases of COVID-19 over a 28-day period that represent a significant decline from peak.
	Incidence drops to a manageable level	Average daily incidence rate over the last 14 days reaches a level that does not overwhelm healthcare and public health capacity (determined locally based on resources available.)
Corroborate reductions in disease burden with other data	Reductions observed in case report data are also observed in other data	Sustained reductions also observed in one or more of the following: • ED and outpatient visits for COVID-like illness (fever, cough or shortness of breath] and absence of other cause) • Hospital admissions for confirmed COVID-19 infection or for COVID-like illness

		 Percent of SARS-CoV-2 positive tests (in the absence of major changes in how testing is being implemented locally) COVID-19 deaths
Demonstrate control in healthcare facilities and other high-risk settings	Infections rare in healthcare personnel	Daily number of newly identified infections in healthcare personnel is near zero for 15 days and HCP infections are not causing staffing shortages.
	Decline in COVID-19 activity in high risk healthcare facilities (e.g., nursing homes, dialysis centers, long term care facilities etc.) and congregate living settings (e.g. prisons, youth homes, shelters etc.)	Sustained decline in new COVID-19 illnesses acquired in healthcare facilities and congregate living settings over the past 30 days such that potential facility outbreaks are identified rapidly and mitigated.
Assess disease burden in connected jurisdictions	The risk of introduction of a significant number of new cases from neighboring jurisdictions or air travel is low	Disease burden and trajectory in "connected jurisdictions" is not significantly different than in the home jurisdiction

APPENDIX B: INFECTION PREVENTION AND CONTROL ASSESSMENT TOOL (TELE-ICAR)

Infection Prevention and Control Assessment Tool (Tele-ICAR)

MARCH 2020 - DRAFT

[contact HAIAR@CDC.gov for updates]

Attached is an infection prevention and control assessment tool (ICAR) that can be used to help nursing homes prepare for COVID-19. This tool may also contain content relevant for assisted living facilities. The items assessed support the key strategies of: keeping COVID-19 out of the facility, identifying infections as early as possible, preventing spread of COVID-19 in the facility, assessing and optimizing personal protective equipment (PPE) supplies, and identifying and managing severe illness in residents with COVID-19. The areas assessed include:

- Visitor restriction
- Education, monitoring, and screening of healthcare personnel (HCP)
- Education, monitoring, and screening of residents
- Ensuring availability of PPE and other supplies
- Ensuring adherence to recommended infection prevention and control (IPC) practices
- Communicating with the health department and other healthcare facilities

Findings from the assessment can be used to target specific IPC preparedness activities that nursing homes can immediately focus on while continuing to keep their residents and HCP safe.

Additional Information:

- The assessment includes a combination of staff interviews and direct observation of practices in the facility and can be conducted in-person or remotely (e.g., Tele-ICAR via phone or video conferencing). Provide a copy of the tool to the facility in advance of completing the Tele-ICAR and encourage them to take their own notes as you conduct the assessment.
- Background information in the grey boxes above each section being assessed provides context for the ICAR user. This information does not need to be read during the assessment process but can be referred to for additional information.
- Assessments can be conducted by state or local health department (HD) staff, or a designee (e.g., volunteer, student), even if they do not have an extensive IPC background. The goal is to convey key messages to nursing homes and identify COVID-19 specific preparedness needs. IPC questions and concerns can be noted and addressed after the ICAR is completed.
 - Individuals completing the assessment should be given a brief introduction to COVID-19
 and nursing homes as well as the use of the tool. Resources are available on the CDC
 website, including current guidance, a nursing home pre-recorded webinar, and
 additional tools
 - Engage State HD HAI/AR program leads for additional support and technical assistance is required for the facility
- Assessment activities provide an opportunity for dialogue and information sharing
 - Discuss the purpose of the assessment and emphasize that it is not a regulatory inspection and is designed to ensure the facility is prepared to quickly identify and prevent spread of COVID-19

- o Promote discussion by asking additional questions to prompt or probe. Use this opportunity to address concerns and offer available resources
- Be aware of applicable federal, state, county, or city rules, regulations (e.g., CMS requirements for nursing homes, life safety code) and governor proclamations that may impact implementation of recommended practices
- Provide feedback or a high-level summary immediately after the assessment including elements in place and areas for improvement
 - Consider scanning and providing a copy of your assessment tool or a brief summary with feedback, answers to the facility's questions, and recommended next steps directly to the facility within 2-3 days.
- Schedule a follow-up call with the facility (e.g., within the next week after the assessment findings are shared)

#: 5120

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Investigator:	Date:
	_ and I am calling from the Department of Health. May I fection prevention and control (IPC) at your facility?
control (IPC) preparedness activities combat COVID-19 while continuing twould like to go through an IPC asse	and I am calling to discuss infection prevention and that your facility can immediately put into place to o keep your residents and healthcare personnel safe. I ssment with you and your team if now is a good time to ling to do a video call)? If not when would work
ICARs (eye-cars), were developed by	trol assessment and response surveys, also referred to as CDC to assist health departments in assessing IPC ment activities. ICARs are particularly useful for stopping break experiences.
	ne and contact information. Is there another person at arry contact for the health department, if yes, can I get
Demographics:	
Facility POC Name:	
POC Phone:	
POC E-mail Address:	
 Number of beds in the facility: Total number of residents in the Total number of units: 	
or Subacute Rehab	apply). In verify tracin indicates in the contention of the content of t
or Subacute Rehab These units have residents at hi	gher risk for poor outcomes. Vent/trach units provide respiratory units are often secured, and limit resident movement to other

Ho	w many days supply does the facility have of the following PPE ar Facemasks:	nd alcohol-bas	ed hand sanitizer (ABHS)?
	N-95 or higher-level respirators:		
	Isolation gowns:		
	Eye protection:		
	Gloves:		
	ABHS:		
	itor restrictions: h CDC and CMS recommend restricting all visitors to nursing homes to pre	avant COVID 10	from ontoring the facility
	eptions for compassionate care, such as end of life situations, may be con	-	
	uld first have temperature and symptom screening (e.g., cough, shortness		•
	eguard residents. Ill visitors should not enter. Visitors who are granted acc	-	
wed	ar a facemask, and conduct their visit in a location designated by the facil	ity (e.g., residen	t's room). Additional best
•	ctices include designating a single entrance for visitors, posting signage a	t entrances to th	ne facility, and providing
	nmunication to residents and families.		
Ele	ments to be assessed	Assessment (Y/N)	Notes/Areas for Improvement
•	- 11		
	Facility restricts all visitation except for certain compassionate care situations, such as end of life situations.		
•	· · · · · · · · · · · · · · · · · · ·		
•	care situations, such as end of life situations.		
•	 care situations, such as end of life situations. Decisions about visitation are made on a case-by-case basis. Potential visitors are screened prior to entry for fever or respiratory symptoms. Those with symptoms are not 		
•	 care situations, such as end of life situations. Decisions about visitation are made on a case-by-case basis. Potential visitors are screened prior to entry for fever or respiratory symptoms. Those with symptoms are not permitted to enter the facility. 		
•	 care situations, such as end of life situations. Decisions about visitation are made on a case-by-case basis. Potential visitors are screened prior to entry for fever or respiratory symptoms. Those with symptoms are not permitted to enter the facility. Visitors that are permitted inside, must wear a facemask 		
•	 care situations, such as end of life situations. Decisions about visitation are made on a case-by-case basis. Potential visitors are screened prior to entry for fever or respiratory symptoms. Those with symptoms are not permitted to enter the facility. Visitors that are permitted inside, must wear a facemask while in the building and restrict their visit to the resident's 		
•	 care situations, such as end of life situations. Decisions about visitation are made on a case-by-case basis. Potential visitors are screened prior to entry for fever or respiratory symptoms. Those with symptoms are not permitted to enter the facility. Visitors that are permitted inside, must wear a facemask 		

Education, monitoring, and screening of healthcare personnel (HCP)

Facility has posted signs at entrances to the facility advising that

Facility has provided alternative methods for visitation (e.g.,

conferencing) will be facilitated by the facility.

video conferencing) for residents.

no visitors may enter the facility.

Facility has sent a <u>communication</u> (e.g., letter, email) to families advising them that no visitors will be allowed in the facility except for certain compassionate care situations, such as end of life, and that alternative methods for visitation (e.g., video

Education of HCP (including consultant personnel) should explain how the IPC measures protect residents, themselves, and their loved ones, with an emphasis on hand hygiene, PPE, and **monitoring** of their symptoms. Consultant personnel are individuals who provide specialized care or services (e.g. wound care, podiatry) to residents in the facility on a periodic basis. They often work at multiple facilities in the area and should be included in education and screening efforts as they can be exposed to or serve as a source of pathogen transmission. If HCP work while ill, they can serve as a source of pathogen transmission within the facility, which is why screening is so important. HCP should be reminded not to report to work when ill. All HCP should self-monitor when they are not at work and be **actively screened** upon entering the facility. Ideally, this would occur at the entrance to the facility, before they begin their shift. Screening includes

temperature check and asking about symptoms like subjective fever, new or worsening cough, difficulty breathing, sore throat, and muscle aches. If they have a fever of 100.0F or higher or symptoms, they should be masked and go home.

Ele	ments to be assessed	Assessment	Notes/Areas for
		(Y/N)	Improvement
•	 Facility has provided education and refresher training to HCP (including consultant personnel) about the following: COVID-19 (e.g., symptoms, how it is transmitted) Sick leave policies and importance of not reporting or remaining at work when ill Adherence to recommended IPC practices, including: Hand hygiene Selection and use of PPE; have HCP demonstrate competency with putting on and removing PPE Cleaning and disinfecting environmental surfaces and resident care equipment Any changes to usual policies/procedures in response to PPE or staffing shortages 		
•	Non-essential personnel including volunteers and non-medical service providers (e.g., salon, barbers) are restricted from entering the building.		
•	All HCP are reminded to practice social distancing when in break rooms or common areas.		
•	Facility screens all HCP (including ancillary staff (e.g. dietary and housekeeping) and consultant personnel) at the beginning of their shift for fever and symptoms of COVID-19 (actively records their temperature and documents absence of shortness of breath, new or change in cough, sore throat and muscle aches). If they are ill, they are instructed to put on a facemask and return home. Ill HCP should notify their supervisor at any facility that they work at.		
•	facility that they work at. Facility keeps a list of symptomatic HCP.		

Education, monitoring, and screening of residents

Education of residents and their loved ones should include an explanation of steps the facility is taking to protect them and how visitors can serve as a source of pathogen transmission. The facility should ask residents to report if they feel feverish or have respiratory symptoms. They should actively monitor all residents upon admission and at least daily for fever and symptoms of COVID-19 (shortness of breath, new or change in cough, sore throat, muscle aches). If they have a fever (temperature of 100.0F or higher) or symptoms they should be restricted to their room and put into appropriate Transmission-Based Precautions. Group activities (e.g., communal meals, religious gatherings, classes, field trips) should be stopped to promote social distancing (residents remaining at least 6 feet apart from one another).

Elements to be assessed	Assessment (Y/N)	Notes/Areas for Improvement
Facility has provided education to residents about the following:		
 COVID-19 (e.g., symptoms, how it is transmitted) 		

	Importance of immediately informing HCP if they feel	
	feverish or ill	
	Actions they can take to protect themselves (e.g., hand	
	hygiene, covering their cough, maintaining social	
	distancing)	
	Actions the facility is taking to keep them safe (e.g., visitor	
	restrictions, changes in PPE, canceling group activities and	
	communal dining)	
•	Facility assesses residents for fever and symptoms of COVID-19	
	(shortness of breath, new or change in cough, sore throat,	
	muscle aches) upon admission and at least daily throughout	
	their stay in the facility.	
	Residents with suspected respiratory infection are	
	immediately placed in appropriate Transmission-Based	
	Precautions.	
•	Note: Older adults with COVID-19 may not show typical	
	symptoms such as fever or respiratory symptoms. Atypical	
	symptoms may include: new or worsening malaise, new	
	dizziness, or diarrhea. Identification of these symptoms should	
	prompt isolation and further evaluation for COVID-19.	
•	Facility keeps a list of symptomatic residents (link to respiratory infection surveillance tool:	
	https://www.cdc.gov/longtermcare/pdfs/LTC-Resp-	
	OutbreakResources-P.pdf)	
•	Facility has stopped group activities inside the facility and field	
	trips outside of the facility.	
•	Facility has stopped communal dining.	
•	Facility has residents who must regularly leave the facility for	
•	medically necessary purposes (e.g., residents receiving	
	hemodialysis or chemotherapy) wear a facemask whenever	
	they leave their room, including for procedures outside of the	
	facility.	
	Consider having HCP wear all recommended PPE (gown,	
	gloves, eye protection, N95 respirator (or facemask if not	
	available)) for the care of these residents, regardless of	
	presence of symptoms (if PPE supply allows). Refer to	
	strategies for optimizing PPE supplies when shortages exist	
	(https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-	
	strategy/index.html).	
Ad	ditional actions when COVID-19 is identified in the facility or	
the	ere is sustained transmission in the community (some facilities	
ma	ay choose to implement these earlier)	
•	Residents are encouraged to remain in their room.	
	If there are cases in the facility, residents are restricted (to	
	the extent possible) to their rooms except for medically	
	necessary purposes.	

 If residents leave their room, they wear a facemask, perform hand hygiene, limit movement in the facility and perform social distancing. 		
Facility bundles resident care and treatment activities to		
minimize entries into resident room (e.g. having clinical staff clean and disinfect high-touch surfaces when in the room)		
 Consider implementing protocols for cohorting ill residents with dedicated HCP. 		
• The facility monitors ill residents at least 3 times daily including symptoms, vital signs, oxygen saturation via pulse oximetry,		
and respiratory exam to identify and quickly manage serious infection		

Availability of PPE and Other Supplies

Major distributors in the United States have reported shortages of PPE. Shortages alcohol-based hand sanitizers and refills, and certain disinfectants have also been reported. Facilities should assess their current supplies of PPE and other critical materials as soon as possible and begin implementing strategies to optimize their current supply of PPE (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html). Examples of strategies described in those documents include extended use of facemasks and eye protection, which allow the same facemask and eye protection to be worn for the care of more than one resident. Gowns could be prioritized for select activities such as activities where splashes and sprays are anticipated (including aerosol generating procedures) and high-contact resident care activities that provide opportunities for transfer of pathogens to hands and clothing of HCP. If a facility anticipates or has a shortage, they should engage their health department and healthcare coalition for assistance.

- Link to identifying your state HAI coordinator: https://www.cdc.gov/hai/state-based/index.html
- Link to healthcare coalition/preparedness: https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx

Disinfectants used at a facility should be EPA-registered, hospital-grade disinfectants with an emerging viral pathogens claim against SARS-CoV-2. List N on the EPA website lists products that meet EPA's criteria for use against SARS-CoV-2 (https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2)

Elements to be assessed	Assessment (Y/N)	Notes/Areas for Improvement
 Facility has assessed current supply of PPE and other critical materials (e.g., alcohol-based hand rub, EPA-registered disinfectants, tissues). (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html) If PPE shortages are identified or anticipated, facility has engaged their health department and/or healthcare coalition for assistance. 	(1714)	Improvement
 Facility has implemented measures to optimize current PPE supply (https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html) 		
 PPE is available in resident care areas (e.g., outside resident rooms). PPE includes: gloves, gowns, facemasks, N-95 or higher-level respirators (if facility has a respiratory protection 		

	program and HCP are fit-tested) and eye protection (face shield or goggles).	
•	EPA-registered, hospital-grade disinfectants with an emerging viral pathogens claim against SARS-CoV-2 are available to allow for frequent cleaning of high-touch surfaces and shared resident care equipment.	
•	Tissues and trash cans are available in common areas and resident rooms for respiratory hygiene and cough etiquette and source control.	

Infection Prevention and Control Practices

Alcohol-based hand sanitizer (ABHS) is the preferred method of hand hygiene; however, sinks should still be stocked with soap and paper towels. Hand hygiene should be performed in the following situations: before resident contact, even if PPE is worn; after contact with the resident; after contact with blood, body fluids or contaminated surfaces or equipment; before performing aseptic tasks; and after removing PPE.

Recommended PPE when caring for residents with suspected or confirmed COVID-19 includes: gloves, gown, N-95 or higher-level respirator (or facemask if respirators are not available or HCP are not fit-tested) and eye protection (face shield or goggles). PPE should be readily available outside of resident rooms, although the facility should consider assigning a staff member to shepherd supplies and encourage appropriate use.

All EPA-registered, hospital grade disinfectants have a contact time which is required to kill or inactivate pathogens. Environmental surfaces must remain wet with the product for the entire contact time duration to work appropriately. Contact times range from 30 seconds to 10 minutes. Keeping a surface wet for 10 minutes is seldom accomplished. It is important for facilities to know that their product is appropriate (List N as above) and is being used for the entire contact time. Also, it is helpful for the facility to assign responsibility for cleaning and disinfection of specific surfaces and equipment (who cleans what).

Elements to be assessed	Assessment	Notes/Areas for
	(Y/N)	Improvement
HCP perform hand hygiene in the following situations:		
Before resident contact, even if PPE is worn		
After contact with the resident		
 After contact with blood, body fluids or contaminated surfaces or equipment 		
Before performing an aseptic task		
After removing PPE		
HCP wear the following PPE when caring for residents with		
undiagnosed respiratory illness unless the suspected diagnosis		
required Airborne Precautions (e.g., tuberculosis):		
• Gloves		
Isolation gown		
 Facemask 		
Eye protection (e.g., goggles or face shield)		
If COVID-19 is suspected, an N-95 or higher-level respirator is		
preferred, if available and the facility has a respiratory protection		
program with fit-tested HCP; facemasks are an acceptable		
alternative.		

•	PPE are removed in a manner to prevent self-contamination,	
	hand hygiene is performed, and new PPE are put on after each	
	resident except as noted below.	
•	Hand hygiene supplies are available in all resident care areas.	
	Alcohol-based hand sanitizer* with 60-95% alcohol is	
	available in every resident room and other resident care	
	and common areas.	
	 Sinks are stocked with soap and paper towels. 	
•	*If there are shortages of ABHS, hand hygiene using soap and	
	water is still expected.	
•	Hand hygiene and PPE compliance are audited	
•	Non-dedicated, non-disposable resident care equipment is	
	cleaned and disinfected after each use.	
•	EPA-registered, hospital-grade disinfectants with an emerging	
	viral pathogens claim* against SARS-CoV-2 are available to	
	allow for frequent cleaning of high-touch surfaces and shared	
	resident care equipment.	
•	*See EPA List N: https://www.epa.gov/pesticide-	
	registration/list-n-disinfectants-use-against-sars-cov-2	
•	Name of EPA-registered disinfectant used in facility:	
•	Contact time for EPA-registered disinfectant:	
•	EPA-registered disinfectants are prepared and used in	
	accordance with label instructions.	
•	Facility is aware of the contact time for the EPA-registered	
	disinfectant and shares this information with HCP	
Ad	ditional actions when COVID-19 is identified in the community	
(so	me facilities may choose to implement these earlier)	
•	Facility has implemented universal use of facemasks for HCP	
	(for source control) while in the facility. If facemasks are in	
	short supply, they are prioritized for direct care personnel.	
•	All HCP are reminded to practice social distancing when in break	
	rooms or common areas.	
	ditional actions when COVID-19 is identified in the facility or	
	ere is sustained transmission in the community (some facilities	
ma	y choose to implement these earlier)	
	Consider having HCP wear all recommended PPE (gown,	
	gloves, eye protection, N95 respirator or, if not available, a	
	facemask) for the care of all residents, regardless of	
	presence of symptoms. This is done (if PPE supply allows)	
	when COVID-19 is identified in the facility. Refer to strategies for optimizing PPE when shortages exist. This	
	approach is recommended to account for residents who are	
	infected but not manifesting symptoms. Recent experience	
	suggests that a substantial proportion of long-term care	
	residents with COVID-19 do not demonstrate symptoms.	
Co	mmunication	
COI	illiulication	

Communicating is essential during an outbreak, with HCP, residents, families, the health department, transport personnel and receiving facilities. Facilities should notify the health department about any resident with severe respiratory infection, identification of residents or HCP with suspected or confirmed COVID-19, or if the facility identifies more than 2 cases of respiratory illness among residents and/or HCP in 72 hours. These situations should prompt further investigation and testing for SARS-CoV-2. Should a higher level of care be indicated for a resident with suspected or confirmed COVID-19, the facility should communicate this information with transport personnel, the receiving facility, and the health department.

Elements to be assessed	Assessment (Y/N)	Notes/Areas for Improvement
 Facility notifies the health department about any of the following: COVID-19 is suspected or confirmed in a resident or healthcare provider 		
 A resident has severe respiratory infection A cluster of new-onset respiratory symptoms among residents or HCP (e.g., ≥3 cases over 72 hours) 		
 Facility has process to notify residents, families and staff members about COVID-19 cases occurring in the facility. 		
 Facility communicates information about known or suspected COVID-19 residents to appropriate personnel (e.g., transport personnel, receiving facility) before transferring them to healthcare facilities (e.g. dialysis and acute care facilities). 		

Exhibit D



Services Administration

5600 Fishers Lane • Rockville, MD 20857 www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

March 11, 2021

Dear State Mental Health Commissioner:

In accordance with the Coronavirus Response and Relief Supplement Appropriations Act, 2021 [P.L. 116-260], the Substance Abuse and Mental Health Services Administration (SAMHSA) is releasing an additional \$825 million to states through the Community Mental Health Services Block Grant (MHBG) program to assist in response to the COVID-19 pandemic. The specific language in the Act states:

Provided further, That with respect to the amount appropriated under this heading in this Act the Substance Abuse and Mental Health Services Administration may waive requirements with respect to allowable activities, timelines, or reporting requirements for theCommunity Mental Health Services Block Grant as deemed necessary to facilitate a grantee's response to coronavirus: Provided further, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.

MHBG is designed to provide comprehensive community mental health services to adults with serious mental illness (SMI) or children with serious emotional disturbance (SED). States may use this supplemental COVID-19 Relief funding to prevent, prepare for, and respond to SMI and SED needs and gaps due to the on-going COVID-19 pandemic. The COVID-19 pandemic has significantly impacted people with mental illness. Public health recommendations, such as social distancing, are necessary to reduce the spread of COVID-19. However, these public health recommendations can at the same time negatively impact those with SMI/SED. The COVID-19 pandemic can increase stress, anxiety, feelings of isolation and loneliness, the use of alcohol or illicit substances, and other symptoms of underlying mental illness.

Too many people with SMI and SED cannot access the treatment and support that they need, and the pandemic has further disrupted access and care for even greater numbers. The Biden-Harris Administration is committed to advancing behavioral health and addressing the particular challenges the pandemic has brought to the forefront (e.g., concerning suicide and overdose rates). The MHBG is a critical source of funding to states to support a continuum of prevention, intervention, treatment, and recovery services. SAMHSA recommends that states use the COVID-19 Relief supplemental funds wherever possible to develop and support evidence-based crisis services development and to increase access to evidence-based treatment and coordinated recovery support for those with SMI and SED.

With this letter, SAMHSA is providing recommendations for potential funding use. In addition to meeting the standard goals and objectives of the MHBG to provide evidence-based services to individuals with SMI/SED, COVID-19 Relief supplemental funds can be used for:

- a. operation of an "access line," "crisis phone line," or "warm lines" to address any mental health issues for individuals;
- b. training of staff and equipment that supports enhanced mental health crisis response and services;
- c. Mental Health Awareness training for first responders and others.
- d. hire of outreach and peer support workers for regular check-ins for people with SMI/SED;
- e. prison and jail re-entry and enhanced discharge from inpatient settings in order to reduce risks of COVID-19 transmission; and
- f. COVID-19 related expenses for those with SMI/SED, including testing and administering COVID vaccines, COVID awareness education, and purchase of Personal Protective Equipment (PPE)

Further information about these initiatives is summarized below.

Through careful design, planning and coordination, states can increase access through crisis response system development. A fully realized crisis response system will have the capacity to respond, deescalate, and follow-through crises so that individuals in crisis not only land safely but also transition well onto a path of recovery. Services that include three elements are ideal: someone to talk with; someone to respond and/or a place to go for rapid treatment; and stabilization. This includes attention to services that address the needs of children, particularly in regard to school re-entry and related crises for children and adolescents. Children at risk for maltreatment or who have been maltreated should also be considered.

Developing a functioning crisis response system that works well for individuals in crisis involves engagement and often new ways of working with multiple components. These can include local community mental health centers and Certified Community Behavioral Health Clinics, substance use disorder treatment centers, other providers, emergency departments and inpatient psychiatric beds, local law enforcement, social services, and others. States are encouraged to use the recently developed SAMHSA Crisis Services: Meeting Needs, Saving Lives, which includes "National Guidelines for Behavioral Health Crisis Care: Best Practice Toolkit" as well as other related National Association of State Mental Health Programs Directors (NASMHPD) papers on crisis services to develop a comprehensive crisis service system.

SAMHSA requests that the following information is included when submitting the proposals:

- 1. Identify the needs and gaps of your state's mental health services in the context of COVID-19.
- 2. Describe how your state's spending plan proposal addresses the needs and gaps.
- 3. Describe how the state will advance the development of crisis services based on the *National Guidelines for Behavioral Health Crisis Care: Best Practice Toolkit.* The five percent crisis services set-aside applies to these funds.
- 4. Explain how your state plans to collaborate with other departments or agencies to address the identified needs.

5. If your state plans to utilize any of the waiver provisions or the recommendations listed in this guidance, please explain how your state will implement them with these funds. (These waivers are only applicable to these COVID-19 Relief supplemental funds and not to the regular or FY 2021 MHBG funds. States will be required to provide documentation ensuring these funds are tracked separately.)

Using the webBGAS revision request, upload the document (Microsoft Word or pdf) using the upload tab into State Information Page. Please title this document "COVID-19 Supplemental Funding Plan for FY 21." Upon submission, SAMHSA will review the proposal to ensure it is complete and responsive. Please complete the submission by April 5, 2021.

SAMHSA is ready and willing to assist you in addressing the needs of individuals with mental illness. Please feel free to contact your SAMHSA state project officers and grants management specialists with any questions that you may have.

Sincerely,

/Tom Coderre/

Tom Coderre
Acting Assistant Secretary for
Mental Health and Substance Use

Exhibit E



Substance Abuse and Mental Health Services Administration 5600 Fishers Lane • Rockville, MD 20857

www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

August 10, 2021

Dear Single State Authority Directors and State Mental Health Authority Commissioners:

People with mental illness and substance use disorder are more likely to have co-morbid physical health issues like diabetes, cardiovascular disease, and obesity. Such chronic illnesses are associated with higher instances of contracting coronavirus disease (COVID-19) as well as higher risk of death or a poor outcome from an episode of COVID-19. To address this concern, the U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), will invest \$100 million dollars to expand dedicated testing and mitigation resources for people with mental health and substance use disorders.

As COVID-19 cases rise among unvaccinated people and where the more transmissible Delta virus variant is surging, this funding will expand activities to detect, diagnose, trace, and monitor infections and mitigate the spread of COVID-19 in homeless shelters, treatment and recovery facilities, domestic violence shelters and federal, state and local correctional facilities-some of the most impacted and highest risk communities across the country. These funds will provide resources and flexibility for states to prevent, prepare for, and respond to the COVID-19 public health emergency and ensure the continuity of services to support individuals connected to the behavioral health system. This one-time funding for awards was authorized under the American Rescue Plan (ARP) Act of 2021 (P.L. 117-2) and Section 711 of the Social Security Act (42 U.S.C. 711(c)). SAMHSA will supplement the ARP funding for state grantees. The performance period for this funding is September 1, 2021 – September 30, 2025. Targeted support is necessary for mental health and substance use treatment providers to overcome barriers towards achieving and maintaining high COVID-19 testing rates. From the provider perspective, these barriers include limited financial and personnel resources to support ongoing testing efforts. Providers have limited staff and physical resources and COVID-19 testing activities must be balanced against COVID-19 vaccinations and other health care services. From the consumer perspective, these barriers include hesitancy in accepting vaccines and challenges with health care access. Recipients may allocate reasonable funds for the administrative management of these grants. SAMHSA envisions the maximum support possible for COVID-19 testing and mitigation; toward that goal, recipients are encouraged to expend a minimum of 85 percent of funding for allowable COVID-19 testing and mitigation activities.

The list below includes examples of allowable activities. While this list is not exhaustive, any activity not included on this list must be directly related to COVID-19 testing and mitigation. All recipients are strongly encouraged to work with state or local health departments to coordinate activities. The state must demonstrate that the related expense is directly and reasonably related to the provision of COVID-19 testing or COVID-19 mitigation activities. The related expense must be consistent with relevant clinical and public health guidance. For additional examples, you can visit the CDC Community Mitigation Framework website. Funding may not be used for any activity related to vaccine purchase or distribution.

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SAMHSA, through this supplemental funding, allocates \$50 million each for Mental Health Block Grant (MHBG) and Substance Abuse Prevention and Treatment Block grants (SABG) to the states. States have until September 30, 2025, to expend these funds. SAMHSA asks that states consider the following in developing a COVID-19 Mitigation Funding Plan:

- Coordinate and partner with state and local health departments/agencies on how to better align the state/provider mental health and substance use COVID-19 mitigation efforts and activities; develop guidance for partnering with state/local health departments; disseminating sample training curriculums.
- Testing education, establishment of alternate testing sites, test result processing, arranging for the processing of test results, and engaging in other activities within the CDC Community Mitigation Framework to address COVID-19 in rural communities.
- Rapid onsite COVID-19 testing and for facilitating access to testing services. Training and technical assistance on implementing rapid onsite COVID-19 testing and facilitating access to behavioral health services, including the development of onsite testing confidentiality policies; and implementing model program practices.
- Behavioral health services for those in short-term housing for people who are at high risk for COVID-19.
- Testing for staff and consumers in shelters, group homes, residential treatment facilities, day programs, and room and board programs. Purchase of resources for testing-related operating and administrative costs otherwise borne by these housing programs. Hire workers to coordinate resources, develop strategies and support existing community partners to prevent infectious disease transmission in these settings. States may use this funding to procure COVID-19 tests and other mitigation supplies such as handwashing stations, hand sanitizer and masks for people experiencing homelessness and for those living in congregate settings.
- Funds may be used to relieve the burden of financial costs for the administration of tests and the purchasing of supplies necessary for administration such as personal protective equipment (PPE); supporting mobile health units, particularly in medically underserved areas; and expanding local or tribal programs workforce to implement COVID-response services for those connected to the behavioral health system.
- Utilize networks and partners to promote awareness of the availability of funds, assist providers/programs with accessing funding, and assist with operationalizing the intent of said funding to ensure resources to mitigate the COVID-19 health impacts and reach the most under-served, under-resourced, and marginalized communities in need.
- Expanding local or tribal programs workforce to implement COVID-response services for those connected to the behavioral health system.
- Provide subawards to eligible entities for programs within the state that are designed to reduce the impact of substance abuse and mental illness; funding could be used for operating

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and administrative expenses of the facilities to provide onsite testing and mobile health services; and may be used to provide prevention services to prevent the spread of COVID-19.

- Develop and implement strategies to address consumer hesitancy around testing. Ensure
 access for specific community populations to address long-standing systemic health and
 social inequities that have put some consumers at increased risk of getting COVID-19 or
 having severe illness.
- Installing temporary structures, leasing of properties, and retrofitting facilities as necessary to support COVID-19 testing and COVID-19 mitigation.
- Education, rehabilitation, prevention, treatment, and support services for symptoms occurring after recovery from acute COVID-19 infection, including, but not limited to, support for activities of daily living.
- Other activities to support COVID-19 testing including planning for implementation of a COVID-19 testing program, hiring staff, procuring supplies to provide testing, training providers and staff on COVID-19 testing procedures, and reporting data to HHS on COVID-19 testing activities.
- Promote behaviors that prevent the spread of COVID-19 and other infectious diseases (healthy hygiene practices, stay at home when sick, practice physical distancing to lower the risk of disease spread, cloth face coverings, getting vaccinated).
- Maintain healthy environments (clean and disinfect, ensure ventilation systems operate properly, install physical barriers and guides to support social distancing if appropriate).
- Behavioral health services to staff working as contact tracers and other members of the COVID-related workforce. Maintain health operations for staff, including building measures to cope with employee stress and burnout.
- Investigate COVID-19 cases; the process of working with a consumer who has been diagnosed with COVID-19 and includes, but is not limited to:
 - o Discuss test result or diagnosis with consumers;
 - Assess patient symptom history and health status;
 - o Provide instructions and support for self-isolation and symptom monitoring; and
 - o Identify people (contacts) who may have been exposed to COVID-19.
- Conduct contact tracing: the process of notifying people (contacts) of their potential exposure to SARS-CoV-2, the virus that causes COVID-19 and includes, but is not limited to:
 - o Provide information about the virus;
 - o Discuss their symptom history and other relevant health information; and
 - o Provide instructions for self-quarantine and monitoring for symptoms.

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The following are ineligible costs for the purposes of this funding:

- Costs already paid for by other federal or state programs, other federal or state COVID-19 funds, or prior COVID-19 supplemental funding.
- Any activity related to purchasing, disseminating, or administering COVID-19 vaccines.
- Construction projects.
- Support of lobbying/advocacy efforts.
- Facility or land purchases.
- COVID-19 mitigation activities conducted prior to 9/1/2021.
- Financial assistance to an entity other than a public or nonprofit private entity.

Required Submission

1. COVID-19 Response Workplan and Overview

States must submit separate plans by October 1, 2021 for expending these funds for both MHBG and SABG. States must explain the types of activities, including expenditures. Provide a detailed plan by October 1, 2021 on how the state plans to implement COVID-19 testing and mitigation activities within the public mental health and or substance abuse system. (SAMHSA recommends that each state/jurisdiction's MH and SUD authorities work together in expending the MHBG and SABG funds in a coordinated way, if feasible.)

2. COVID-19 Response Budget and Budget Justification

States must submit a budget and a budget justification by October 1, 2021 capturing all expenses, including costs for administration at the state level and a plan to distribute it to providers, and subsequent reasons for the expenses in narrative format.

3. Annual Report

Annually, by December 31, until the funds expire, states must upload a narrative report including activities and expenditures.

Using the WebBGAS Revision Request for the FFY 2021 Block Grant Application, upload the document (Microsoft Word or pdf) using the tab into the State Information Section, Chief Executive Officer's Funding Agreement – Certifications and Assurances/Letter Designating Signatory Authority. SAMHSA will issue a revision request to states to submit the application. Please title this document "COVID Mitigation Funding Plan 2021(MH)" for MHBG and "COVID Mitigation Funding Plan 2021 (SA)" for SABG."

States must upload separate proposals based on Mental Health Block Grant and Substance Abuse Block Grant guidance into the WebBGAS system. Upon submission, SAMHSA will review the proposal to ensure it is complete and responsive. Proposals must be submitted to WebBGAS by Friday, October 1, 2021, 11:59 pm EDT. States can start utilizing the resources as soon as the states' plans are approved by SAMHSA.

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SAMHSA is ready and willing to assist you in addressing the needs of individuals with mental illness and substance use disorders. Please feel free to contact your SAMHSA state project officers and grants management specialists with any questions that you may have.

Sincerely,

Miriam E. Delphin-Rittmon, Ph.D. Assistant Secretary for Mental Health

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and Substance Use