Opioid Crisis Innovation and Research Program (OCIRP) Program: Harnessing Evidence and Innovation to Solve the Opioid Epidemic

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Summary

Addressing the opioid epidemic in the United States today will require not only additional resources, as recognized by the last Congress, but also stronger evidence about effective treatments and new field-generated innovations in service delivery. To catalyze evidence-building and innovation at the state and local levels, the federal government should launch an Opioid Crisis Innovation and Research Program (OCIRP) within the Substance Abuse and Mental Health Services Administration (SAMHSA). OCIRP's design would encourage the scale-up of proven treatments while also encouraging the development and testing of new, innovative approaches. Innovative approaches are especially critical now in that there a wide variety of opioid products with differing formulations that may make a single (or previously established) treatment approach less effective.

The Scope of the Problem

The United States today faces an opioid crisis. In fact, there are several urgent, related challenges:

- **Increased misuse, overdose and deaths.** Opioid misuse has risen dramatically in the United States in recent years, overwhelming treatment resources and resulting in a 200% increase in the rate of deaths from opioid overdoses since 2000[i]. Tragically, by 2015, there were 33,091 such deaths.[ii] Moreover, aside from the risk of overdose, people with opioid use disorders (OUDs) are also at high risk of contact with the criminal justice system, child welfare agencies, and emergency health care services.

- **Low treatment usage.** Despite the risks just discussed, many people with substance use disorders never receive treatment.[iii] In 2014, an estimated 2.5 million Americans aged 12 or more were opioid dependent, but only 1.4 million were in treatment programs for the disorder.[iv]

- **The need for stronger evidence about effective treatment options.** The treatment that may offer the most promising solution for mitigating the crisis, given the existing evidence, is known as Medication-Assisted Treatment or MAT (also called Medication-Assisted Recovery). MAT involves a complement of treatments that combine medication with behavioral therapies. However, MAT is currently not widely implemented and the quality of evidence supporting it varies by the treatment type and population served. The appendix provides more information about the specific treatments involved in MAT.

Current challenges with MAT

Several important challenges and barriers exist that highlight the need for additional evidence about how it can be most effective as well as new strategies to overcome barriers to access.

- **Gaps in the evidence base.** Since MAT refers to several different treatments administered in different settings using different modes of administration, it is understandable that the level of evidence varies across these different modalities. Methadone maintenance therapy, the longest established treatment, has well-supported experimental evidence of safety and effectiveness in improving outcomes for individuals with opioid use disorders.[v] However, because methadone is often only available on a daily basis at approved OTPs until patients are stabilized, treatment slots are limited and geographic access barriers exist in many areas. Since it can be prescribed and dispensed in non- OTP settings, buprenorphine is more accessible than methadone though still requires daily administration. A Cochrane review of available evidence suggests that while buprenorphine is superior to a placebo in producing positive outcomes, only higher, fixed doses (as opposed to typically administered flexible doses) of buprenorphine produce treatment retention and opioid use outcomes comparable to established methadone protocols.[vi] Oral naltrexone has limited effectiveness for OUD treatment,[vii] though some recent studies have demonstrated positive outcomes for the extended release injectable form, which eliminates the possibility of diversion and reduces risks of overdose while patients remain in treatment.[viii ix,x, xi] No form of MAT has been demonstrated to be effective if patients are treated for fewer than 90 days.[xii]

- **Barriers to access.** Despite the promising evidence for certain types of MAT, the promising MAT approach has not yet been widely implemented. In 2013, most people in treatment for OUDs were in programs that did not administer medications (often referred to as drug-free programs). Only 30% of those in treatment for OUDs were in MAT, the majority of which (86%) were receiving methadone.[xiii] Inadequate coverage from public and private insurers, authorization requirements, limits on medications used to treat opioid use disorders (OUDs), and in some cases high upfront costs have all limited adoption of MAT. On average, monthly buprenorphine treatments in 2011 cost $300 per patient, compared to $200 for methadone. Extended-release injectable naltrexone costs about $1100 for each monthly shot, and is not covered by Medicaid in most states. There is also stigma associated with the use of medications by many treatment providers that use a "12-step" treatment model, which emphasizes complete abstinence and view medications as substituting one drug for another.[xiv, xv] In addition, research and scans of the MAT landscape have found that successful implementation of MAT programming relies on stable political support and collaboration across systems of care.[xvi]

Overview of proposed OCIRP

The OCIRP program would use a so-called "tiered evidence" design that allows for scaling up of programs with strong evidence of effectiveness while simultaneously supporting field-generated innovations that can lead to even more effective approaches.[xvii] Based on the need to encourage the use of evidence-based approaches to the opioid epidemic and continue to learn what works in terms of treatment, this design would be ideal. Moreover, the tiered evidence approach has bipartisan support, including from Speaker of the House Paul Ryan and House Republicans who called on Congress to require social programs to use a tiered evidence model.[xviii]

Over the last decade, five agencies have launched tiered evidence competitive grant programs, also known as innovation funds. They include the Department of Education, Department of Labor, the

Department of Health and Human Services, and the Corporation for National and Community Service (CNCS).[xix] The most common version has three tiers to which applicants can apply, including a:

- *Development tier*, providing small grants for innovative but less tested approaches.
- *Validation tier*, providing medium-sized grants for approaches backed by moderate evidence.
- *Scale up tier*, providing large grants for approaches backed by strong evidence.

Moreover, grants also come with requirements for rigorous program evaluation so that interventions found effective can move up tiers and qualify for expanded funding, while funding for interventions that do not produce the hoped-for effects can be redirected to other, more promising efforts.

In particular, we propose that the OCIRP be modeled on the Education Innovation and Research (EIR) program, a tiered evidence grant program at the Department of Education. It includes a matching requirement that can be fulfilled by states and localities using their formula dollars, creating incentives for states to use those larger dollars to fund evidence-based approaches.

Specifics of OCIRP's design

Under this OCIRP, the appropriate agency leader (within SAMHSA or the National Institute of Drug Abuse) would make grants to eligible entities to create, develop, implement, replicate, or take to scale entrepreneurial and field-initiated evidence-based innovations at the federal, state, or local level to reduce the prevalence of and/or improve the treatment of opioid disorders in the U.S. The grants would be implemented by eligible organizations under the following tiered approach:

- **Early-phase grants (*e.g.*, $50,000 to $300,000) to fund the development and feasibility testing of an intervention which has promising prior research**, for the purpose of determining whether the intervention can be successfully implemented in real-world settings (*e.g.*, hospitals, jails, community health clinics).

- **Mid-phase grants (*e.g.*, $500,000 to $3 million) to fund implementation and a rigorous evaluation of an intervention that has been successfully implemented under an early-phase grant** (or other effort meeting similar criteria), for the purpose of measuring the intervention's impact on important outcomes, such as opioid use and criminal arrests.

- **Expansion grants (*e.g.*, $3 million to $7 million) to fund implementation and a rigorous replication evaluation of an intervention found to produce sizable, important impacts under a mid-phase grant** (or other effort meeting similar criteria), for the purposes of delivering the intervention on a larger scale and determining whether its sizable impacts can be successfully reproduced and sustained over time.

The appropriate federal agency(ies) would solicit applications from organizations seeking to propose innovative and field-based interventions to significantly reduce the opioid epidemic by proposing interventions that vary on the:

- Type of medication (Methadone, Buprenorphine, naltrexone)
- Behavioral therapies used in combination with medication
- Characteristics of the treatment (e.g., dosage frequency, length, etc.)
- Treatment setting

- Interaction of patient characteristics and treatment effectiveness

The agency could also solicit applications to test any drug-free interventions that show strong promise of effectiveness and will be rigorously evaluated.

Applicants would need to:

- Ensure appropriate coverage (reimbursement) is provided for patients to receive services Propose rigorous program evaluations (in partnership with trained evaluation partners) thereby increasing our understanding of "what works"
- Propose matching funds, in cash or through in-kind contributions from federal, state, local, or private sources, of *at least* 10 percent of the funds provided. Preference could be given to applicants that will match at a higher rate using block grant, formula, or Medicaid funding, thereby increasing the share of resources in large federal funding streams that support evidence-based practices and knowledge-building.

Congress or the Administration could implement an Opioid Crisis Innovation and Research Program through several means:

- Congress could develop legislation through its authorizing or appropriations process that directs HHS to award competitive grants using a tiered framework similar to the Education Innovation and Research program included in the Every Student Succeeds Act. (See appendix for EIR provisions.)

- HHS could modify its solicitations for substance use disorder grants to incorporate tiered evidence criteria modeled on the EIR program.

Ideally, Congress and HHS would work together to ensure adequate resources are provided to implement the program effectively. The HHS offices involved in the initiative should participate in the interagency working group on tiered evidence grants that was recently launched by OMB in response to GAO's recommendations.[xx]

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APPENDIX

I. Specific treatments involved in MAT

MAT comprises several different FDA-approved treatments for OUDs. The oldest and most widely known, methadone, was approved by the FDA in 1947. It is only available from federally approved OTPs for the treatment of opioid addiction with daily or near daily direct observation to ensure compliance and reduce diversion, though some OTPs offer take-home doses for stabilized patients[xxi]. Buprenorphine (Suboxone®, Subutex®) was approved in 2000 for prescription by physicians who have received a Controlled Substances Act waiver and have completed special training or certification in addiction treatment. Physicians using the waiver are limited in the number of patients they can treat. New legislation temporarily grants eligibility to nurse practitioners and physician assistants to prescribe buprenorphine for MAT through October2021. Buprenorphine can be dispensed by physicians in their office, rather than in a treatment center. It is available as a sublingual tablet, a sublingual or buccal film and an implantable formulation. Naltrexone, which blocks opioid receptors but is not itself a controlled substance was approved by the FDA for opioid therapies in 2010 and available in tablets and monthly extended release injectable form (brand name Vivitrol®) for individuals who are already in recovery to prevent relapse.[xxii]

II. Language authorizing the Education Innovation and Research Program in the U.S. Department of Education, enacted as part of the Every Student Succeeds Act

SEC. 4611. GRANTS FOR EDUCATION INNOVATION AND RESEARCH

(a) PROGRAM AUTHORIZED—

(1) IN GENERAL: From funds reserved under section 4601(b)(2)(A),[1] the Secretary shall make grants to eligible entities to enable the eligible entities to—

(A) create, develop, implement, replicate, or take to scale entrepreneurial, evidence-based, field- initiated innovations to improve student achievement and attainment for high-need students; and

(B) rigorously evaluate such innovations, in accordance with subsection (di).

(2) DESCRIPTION OF GRANTS: The grants described in paragraph (1) shall include—

(A) *early-phase grants* to fund the development, implementation, and feasibility testing of a program, which prior research suggests has promise, for the purpose of determining whether the program can successfully improve student achievement or attainment for high-need students;

(B) *mid-phase grants* to fund implementation and a rigorous evaluation of a program that has been successfully implemented under an early-phase grant described in subparagraph (A) or other effort meeting similar criteria, for the purpose of

measuring the program's impact and cost effectiveness, if possible using existing administrative data; and

(C) *expansion grants* to fund implementation and a rigorous replication evaluation of a program that has been found to produce sizable, important impacts under a mid-phase grant described in subparagraph (B) or other effort meeting similar criteria, for the purposes of—

(i) determining whether such impacts can be successfully reproduced and sustained over time; and

(ii) identifying the conditions in which the program is most effective.

(b) ELIGIBLE ENTITY—In this subpart, the term "eligible entity" means any of the following:

(1) a local educational agency;
(2) a State educational agency;
(3) the Bureau of Indian Education;
(4) a consortium of State educational agencies or local educational agencies;
(5) a nonprofit organization;
(6) a State educational agency, a local educational agency, a consortium described in paragraph (4), or the Bureau of Indian Education, in partnership with—
(A) a nonprofit organization;
(B) a business;
(C) an educational service agency; or
(D) an institution of higher education.

(c) RURAL AREAS—

(1) IN GENERAL: In awarding grants under subsection (a), the Secretary shall ensure that not less than 25 percent of the funds made available for any fiscal year are awarded for programs that meet both of the following requirements:

(A) The grantee is—

(i) a local educational agency with an urban-centric district locale code of 32, 33, 41, 42, or 43, as determined by the Secretary;

(ii) a consortium of such local educational agencies;

(iii) an educational service agency or a nonprofit organization in partnership with such a local educational agency; or

(iv) a grantee described in clause (i) or (ii) in partnership with a State educational agency.

(B) A majority of the schools to be served by the program are designated with a locale code of 32, 33, 41, 42, or 43, or a combination of such codes, as determined by the Secretary.

(2) EXCEPTION: Notwithstanding paragraph (1), the Secretary shall reduce the amount of funds made available under such paragraph if the Secretary does not receive a sufficient number of applications of sufficient quality.

(d) MATCHING FUNDS—In order to receive a grant under subsection (a), an eligible entity shall demonstrate that the eligible entity will provide matching funds, in cash or through in-kind contributions, from Federal, State, local, or private sources in an amount equal to 10 percent of the funds provided under such grant, except that the Secretary may waive the matching funds requirement, on a case-by-case basis, upon a showing of exceptional circumstances, such as:

(1) the difficulty of raising matching funds for a program to serve a rural area;

(2) the difficulty of raising matching funds in areas with a concentration of local educational agencies or schools with a high percentage of students aged 5 through 17—

(A) who are in poverty, as counted in the most recent census data approved by the Secretary;

(B) who are eligible for a free or reduced price lunch under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.);

(C) whose families receive assistance under the State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 et seq.); or

(D) who are eligible to receive medical assistance under the Medicaid program; and

(3) the difficulty of raising funds on tribal land.

(di) EVALUATION—Each recipient of a grant under this section shall conduct an independent evaluation of the effectiveness of the program carried out under such grant.

(dii) TECHNICAL ASSISTANCE—The Secretary may reserve not more than 5 percent of the funds appropriated under section 4601(b)(2)(A) for each fiscal year to:

(1) provide technical assistance for eligibility entities, which may include pre-application workshops, web- based seminars, and evaluation support; and

(2) to disseminate best practices.

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