DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Office of Minority Health

Funding Opportunity: Demonstration to Increase Hydroxyurea Prescribing for Children with Sickle Cell Disease Through Provider Incentives

Opportunity Number: MP-CPI-20-002

Application Due Date:

Thursday August 27, 2020 6:00 PM Eastern

OVERVIEW

FEDERAL AGENCY NAME

Office of the Assistant Secretary for Health and the Office of Minority Health

FUNDING OPPORTUNITY TITLE

Demonstration to Increase Hydroxyurea Prescribing for Children with Sickle Cell Disease Through Provider Incentives

ACTION

Notice

ANNOUNCEMENT TYPE

Initial Competitive Grant

FUNDING OPPORTUNITY NUMBER

MP-CPI-20-002

CFDA NUMBER AND PROGRAM:

93.137 Community Program to Improve Minority Health

DATES

Application Deadline: Thursday August 27, 2020 by 6:00 PM Eastern.

Technical Assistance: webinar, July 31, 2020 at 2:99 PM Eastern.

EXECUTIVE SUMMARY

The Office of Minority Health (OMH) announces the availability of funds for Fiscal Year (FY) 2020 grant awards under the authority of Section 1707 of the Public Health Service Act (42 U.S.C. § 300u-6).

This notice solicits applications to demonstrate the feasibility and effectiveness of providing financial incentives to providers to improve the quality of life of children with sickle

cell disease (SCD) through increased prescription rates of hydroxyurea. This initiative is not issued or funded by the Centers for Medicare and Medicaid Services (CMS).

OMH intends projects funded under this initiative to build the capacity of State Medicaid Offices and other partners to achieve three main goals: (1) develop performance measures for hydroxyurea prescribing for the three main provider types that care for children with SCD (i.e., hematologists, primary care providers, and emergency clinicians); (2) develop and implement an incentive payment system(s) for each provider type; and (3) evaluate the effectiveness of financial incentives for providers to increase hydroxyurea prescribing and decrease emergency department visits for children with SCD. OMH expects awarded projects to generate data and assess the impact of incentive payments on hydroxyurea prescribing behavior and the identification of best practices and lessons learned through the implementation of funded projects. OMH anticipates the availability of approximately $2,500,000 annually for this funding opportunity to support up to 2 awards ranging from $750,000 to $1,250,000 per year for up to 3 years, pending availability of funds and satisfactory performance.

This initiative is grounded in data demonstrating the effectiveness of hydroxyurea as a chronic, well-tolerated therapy that can reduce emergency visits, hospitalizations, and life-threatening complications in individuals living with SCD. Despite demonstrated efficacy, numerous studies have documented low rates of hydroxyurea utilization by children with SCD[1-3] due to multiple factors, including barriers at the provider, patient/family, and system levels.[4-6] To date, no published studies have assessed the effectiveness of providing financial incentives for providers to increase hydroxyurea prescribing in either children or adults living with SCD.

If the applicant is not a State Medicaid Office, the applicant is expected to secure a formal partnership with the State Medicaid Office as evidenced by a signed memorandum of agreement. If awarded, the applicant organization will be responsible for project implementation, project management and financial oversight for the federal grant. See Section E, Eligibility Information, for the organizations that are eligible to apply for this grant. HHS/OASH encourages applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that its application complies with all requirements and instructions.

FUNDING OPPORTUNITY DETAILS

A. DATES

1. Application Deadline

Your application is due August 27, 2020 by 6 p.m. Eastern Time. To receive consideration, you must submit your application electronically via Grants.gov no later than this due date and time. If you do not submit your application by the specified deadline, we will return it to you unread. You must submit electronically via Grants.gov unless you obtain a written exemption from this requirement 2 business days in advance of the deadline from the Director, HHS/Office of the Assistant Secretary for Health (OASH) Grants and Acquisitions Management (GAM) Division. To obtain an exemption, you must request one via email from the HHS/OASH/GAM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4 business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline. If you request an exemption, include the following in your e-mail request: the

HHS/OASH announcement number; your organization's DUNS number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (for example, GRANT####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to OASH_Grants@hhs.gov. Note: failure to have an active System for Account Management (SAM) registration prior to the application due date will not be grounds for receiving an exemption to the electronic submission requirement. As a result of the public health emergency for COVID-19, the requirement for an active SAM registration at the time of application submission has been waiveded (see Section F.4). However, if you do not have a DUNS number at this time, you should contact the Grants.gov to establish a temporary DUNS number. Your application will not be accepted through Grants.gov without this number. Failure to follow Grants.gov instructions to ensure software compatibility will not be grounds for receiving an exemption to the electronic submission requirement.

The HHS/OASH/GAM will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via email) from applicants obtaining prior written approval. If you receive an exemption, you must still submit your application by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via U.S. mail or other service or PDF via email) with an approved written exemption will be accepted. *See* Section F.8 ("Other Submission Requirements") for information on application submission mechanisms.

Executive Order 12372 comment due date: The State Single Point of Contact (SPOC) has 60 days from the application due date to submit any comments. For more information on the SPOC see section F.6 Intergovernmental Review.

To ensure adequate time to submit your application successfully, HHS/OASH recommends that you register as early as possible in Grants.gov since the registration process can take up to one month. You must register an authorizing official for your organization. HHS/OASH does not determine your organization's authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to http://www.grants.gov or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Your organization is strongly encouraged to register multiple authorized organization representatives in Grants.gov to ensure someone is available to submit your application.

2. Technical Assistance

A technical assistance webinar for potential applicants will be held on July 31, 2020. Please check the Office of Minority Health website, www.minorityhealth.hhs.gov, for more detailed information.

We recommend you review the entire announcement promptly so you can have any questions answered well in advance of the application due date. We also recommend you subscribe to this announcement in Grants.gov so you receive any amendments, question and answer documents, or other updates.

B. PROGRAM DESCRIPTION:

The Office of the Assistant Secretary for Health and the Office of Minority Health (OMH) announce the availability of funds for Fiscal Year (FY) 2020 grant awards under the authority of Section 1707 of the Public Health Service Act (42 U.S.C. § 300u-6). OMH is dedicated to improving the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. Through its demonstration grants,

OMH supports the identification of effective approaches for improving health outcomes with the ultimate goal of promoting dissemination and sustainability of these approaches. This particular grant aligns with the Assistant Secretary for Health's priority on SCD; HHS Strategic Goal 1: Reform, Strengthen, and Modernize the Nation's Health Care System; HHS Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play; and the HHS Secretary's Priority on Value-Based Care.[7]

This OMH initiative is intended to demonstrate the feasibility and effectiveness of providing financial incentives to providers to improve the quality of life of children living with SCD through increased prescription rates of hydroxyurea. OMH intends successful applicants to build the capacity of State Medicaid Offices and other partners to achieve three main goals: (1) develop quality measures for hydroxyurea prescribing for the three main provider types that care for Medicaid-eligible children with SCD (i.e., hematologists, primary care providers, and emergency clinicians); (2) develop and implement an incentive payment system(s) for each provider type; and (3) evaluate the effectiveness of provider incentives to increase hydroxyurea prescribing and decrease emergency department visits for children living with SCD. For the purposes of this FOA, the age range of children can be defined by the applicant but cannot exceed 21 years, consistent with the Medicaid definition of children in for Early and Periodic Screening, Diagnostic and Treatment Services.

1. Background

SCD, estimated to affect 100,000 Americans, is the most common inherited blood disorder in the United States and primarily affects African Americans and Hispanics.[8] SCD occurs among about 1 out of every 365 Black or African-American births and among about 1 out of every 16,300 Hispanic-American births.[8] About 40% of individuals with SCD in the United States are children and adolescents.[9] A majority of individuals with SCD are on Medicaid.[10] Federal statute and

regulations for the Early and Periodic Screening, Diagnostic and Treatment Services (EPSDT) benefit requires the provision of comprehensive and preventive health care services, including SCD services, to children under age 21 who are enrolled in Medicaid.[11] Over 47% of Medicaid beneficiaries with SCD are aged 18 and under.[12] There are significant differences in the geographic distribution of Medicaid beneficiaries by state. New York, Florida, Georgia, Texas, California, Illinois, Louisiana and North Carolina had the largest proportion of individuals with SCD among Medicaid beneficiaries.[12] Mississippi, the District of Columbia, Louisiana, South Carolina, Georgia, Alabama and Maryland had among the highest prevalence rates of SCD per 1,000 beneficiaries.[12] Over half of Medicaid beneficiaries with SCD in Nebraska, Texas, Maryland, Georgia, Arkansas, Mississippi, Tennessee, Kentucky, Louisiana, Delaware, Indiana, Florida and Oklahoma are aged 18 and under.[12]

SCD is characterized by debilitating pain crises, frequent hospitalizations, and decreased life expectancy compared to the general population and can lead to life-threatening complications such as stroke and infections.[13] Many severe complications of SCD, such as sepsis, stroke, and painful episodes requiring hospitalization, occur in childhood.[14] Medicaid-enrolled children with SCD were more likely to have inpatient admissions and emergency department visits than privately-insured children with SCD.[15] SCD is associated with high treatment costs, averaging $10,000 annually for children.[16]

These outcomes can be minimized with disease-modifying therapies, such as hydroxyurea. Initiation of hydroxyurea among pediatric patients has been found to reduce rates of hospitalizations, pain encounters, and emergency department visits.[17] Hydroxyurea treatment among children has been shown to be cost-effective and to reduce total health care costs.[18] Any physician can prescribe hydroxyurea, but it is usually prescribed in conjunction with a

hematologist to ensure appropriate monitoring.[19] Numerous studies, however, have documented low hydroxyurea prescriptions and/or utilization for pediatric patients with SCD.[1-3] A majority of individuals with SCD are on Medicaid, but only about 1 in 4 Medicaid-enrolled children with SCD received hydroxyurea.[20]

Increased reimbursement for providers is one intervention that can improve adherence to clinical guidelines, and thus increase access to treatment. Incentive payments provided to clinicians when performance benchmarks are met have been shown to improve care in oncology and might be effective for the SCD population. Because an estimated 50 to 60 percent of SCD patients who access care through state-based Medicaid plans, demonstration of the effectiveness of incentive payments to increase hydroxyurea prescribing in just one or a few states could serve as a powerful example for other states.

2. Expectations

OMH expects successful applicants to:

a. Develop hydroxyurea quality measures

- Convene key partners representing all three provider types (i.e., hematologists, primary care providers, and emergency clinicians) and major clinical care facilities within the state shortly after award to discuss and develop quality measure(s) to measure hydroxyurea prescribing among children with SCD. Define the candidate quality measure(s) for each provider type and develop algorithms for measuring them using administrative data, shortly after award. Algorithms should include methods for defining the SCD pediatric population eligible for

hydroxyurea consistent with the 2014 National Heart, Lung, and Blood Institute (NHLBI) guidelines.[21]

- Convene additional meetings with key partners to discuss pros and cons of each candidate quality measure and gain concurrence on which measures to include in the incentive payment system(s).
- Provide baseline data (OMH recommends at least 3-4 years using ICD-10 codes and pharmacy data) for all candidate quality measures for both the control and intervention groups as specified in the Awardee's application.

b. Develop and promote the incentive payment system(s) and develop evaluation plan

- Have Institutional Review Board (IRB) approval at or near the start of the project period and provide documentation to HHS/OASH/GAM.
- Within 6 months of the initial award, start developing incentive payment system(s) for all three provider types tailored to local contexts and priorities. Potential approaches include episode-based, shared savings, and population-based payment arrangements that incorporate meaningful quality measures. A state Medicaid agency can receive a federal grant from OMH so long as the state Medicaid agency uses the OMH funds for non-Medicaid, quality-based incentive payments to sickle cell providers, with no change to the otherwise applicable Medicaid service payments. The state Medicaid agency should abide by generally applicable cost allocation requirements and not use the OMH grant funds as the state share for Medicaid expenditures.

- The incentive plan system must include an appropriate oversight plan to ensure that hydroxyurea prescriptions are medically indicated for the patient. The plan should address patient safety concerns as well as potential fraud risks.
- Within 9 months of the initial award, demonstrate the ability to report high-quality quality measure data and define the anticipated start date of the implementation of the incentive payment system(s).
- Within 6 months prior to the anticipated start date of incentive payment system implementation, develop and disseminate informational materials (including notice of privacy practices) for clinicians, health-related service providers, and other prospective beneficiaries promoting the availability and time frame for the incentive payment system(s).
- Provide equitable opportunities for all provider types within the intervention group to participate in the proposed incentive payment system(s).
- Estimate potential uptake with the incentive payment system(s) and anticipated maximum and minimum payout costs during implementation.
- Finalize agreed processes and authorization/consent forms for incentive payment system participation. Awardees must adhere to all applicable Federal, state, and local laws and ordinances, and should work with their counsel to determine what patient authorizations, if any, may be required to implement the incentive payment system(s) as designed,

including with respect to information sharing required to support the incentive payment system(s).

- Within 15 months of the initial award, demonstrate an ability to operationalize and implement quality measure(s) and related incentive payment system(s).
- Within 15 months of the initial award, develop an evaluation plan that, at a minimum, will assess the impact of the incentive payment system(s) on hydroxyurea prescribing and emergency department utilization among children with SCD. Applicants are encouraged consider data for other downstream outcomes measures (e.g., hospitalizations, overall healthcare costs) in addition to emergency department visits.
- Identify and document best practices and lessons learned with input from key stakeholders before implementation of the incentive payment system(s).
- Meet OMH expectations for attendance and participation in scheduled Project Officer calls, timely and complete submissions for quarterly progress reports, annual performance reports, and attendance at all required learning events.

c. Implement and evaluate incentive payment system(s)

- Before the end of the second year, implement the incentive payment system(s) for at least 12 months, including maintaining the infrastructure, processes, and programs established before implementation of the incentive payment system(s).

- Collect, analyze and report on quality measures quarterly and develop tools for sharing data with administrators, healthcare providers, and practice managers, in compliance with all applicable laws regarding information sharing.
- Provide incentive payments at the end of the period of performance to providers as outlined in the incentive payment system specifications.
- Work with the State Medicaid Office to collect, analyze, and summarize data as required for evaluation of the incentive payment system(s) hydroxyurea prescribing rates and emergency department visits for both control and intervention populations.
- Identify and document best practices and lessons learned

d. Disseminate project findings and results

- Document project findings and results and disseminate to State Medicaid Offices, the population served, the general public, and other parties who might be interested in using the results of the project. OMH expects that nationwide dissemination of products and knowledge will occur.

e. Develop a sustainability plan

- Develop a sustainability plan that addresses financial, staff and supervisory, and material resources needed to sustain successful intervention of the incentive payment system(s) after the project period ends.

OMH expects successful applicants to partner with State Medicaid Offices to:

- Collect and provide data (individual- and population-level) for both the intervention and control groups
- Support the development of information sharing agreements and related infrastructure
- Align support for the incentive payment system across child-focused state agencies and organizations
- Assist in designing and implementing the incentive payment system(s)
- Establish and execute any necessary formal legal agreements between the awardee and State Medicaid Office within 12 months of the initial project start date outlining roles and responsibilities of the of each party for system implementation and evaluation
- Meet any applicable laws and requirements for implementing the incentive payment system(s)), including but not limited to requirements for information sharing in support of such incentive payment system(s),and including but not limited to requirements under statutes and regulations administered by CMS.
- As appropriate, communicate regularly with the CMS POC for the State Medicaid Office on the progress of the incentive payment system(s).
- Implement the incentive payment system(s).
- Provide required evaluation data, including complete and timely claims and encounter data for the incentive payment systems' intervention and

control groups, in compliance with all applicable laws regarding information sharing

OMH expects successful applicants to work with Partners to:

- Enter into written data-sharing agreements, as appropriate, that comport with all applicable laws regarding information sharing
- Work cooperatively and in good faith for the overall achievement of incentive payment system goals
- Continue to support the incentive payment system and ensure representation from all previously listed stakeholder entities
- Meet on a quarterly basis to review responsibilities related to this grant

C. AUTHORITY

Section 1707 of the Public Health Service Act (42 U.S.C. § 300u-6)

D. FEDERAL AWARD INFORMATION

The Office of Minority Health intends to make funds available for competing grant.

We will fund awards in annual increments (budget periods) and generally for a project period up to 3 years, although we may approve shorter project periods. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors. Funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, adequate stewardship of Federal funds, and the best interests of the Government.

Award Information

Estimated Federal Funds Available: $2,500,000.00

Anticipated Number of Awards: 2

Award Ceiling (Federal Funds including indirect costs): $1.25 million per budget period

Award Floor (Federal Funds including indirect costs): $750,000 per budget period

Anticipated Start Date: September 30, 2020

Estimated Project Period: 2 years with possible 3rd year

Anticipated Initial Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted: Electronic via Grants.gov ONLY unless an exemption is granted

E. ELIGIBILITY INFORMATION

1. Eligible Applicants.

- State Governments
- County Governments
- City or township governments
- Special district governments
- Independent school districts
- Public and State controlled institutions of higher education

- Native American tribal governments (Federally recognized)
- Public Housing authorities/Indian housing authorities
- Native American tribal organizations (other than federally recognized tribal governments)
- Nonprofits having 501(c)(3) status with the IRS, other than institutions of higher education
- Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
- Private non-profit institutions of higher education
- U.S. Territories

2. Cost Sharing or Matching

You are not required to provide cost sharing or matching in your proposed budget.

3. Application Disqualification Criteria

(a) If you successfully submit an application, we will screen it to ensure it meets the below requirements. If we determine your application fails to meet the criteria described below we will disqualify it, that is, we will not review it and will give it no further consideration.

(b) You must submit your application electronically via *www.grants.gov* (unless an exemption was granted 2 business days prior to the deadline) by the date and time indicated in the DATES section (Section A.1) of this announcement.

(c) If you successfully submit multiple applications from the same organization for the same project, we will only review the last application received by the deadline.

(d) HHS/OASH/GAM deems your application eligible according to Section E.1 Eligible Applicants.

(e) You must complete the required forms in the application package: SF-424, SF-424A, SF-424B, SF-LLL, and Project Abstract Summary.

(f) Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ " x 11" inch page size, with 1" margins on all sides (top, bottom, left and right) and font size not less than 12 points.

(g) Your Project Narrative must not exceed *50* pages. NOTE: The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables).

(h) Your total application, including the Project Narrative plus Appendices, must not exceed *100* pages. NOTE: items listed in "(f)" immediately above do not count toward total page limit.

(i) Your Federal funds request including indirect costs must not exceed the maximum indicated in Award Ceiling.

(j) Your Federal funds request including indirect costs must not be below the minimum indicated in Award Floor.

(k) Your application must meet the Application Responsiveness Criteria outlined above.

F. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at http://www.grants.gov/. You can find it by searching on the CFDA number shown on page 2 of this funding opportunity announcement. If you have problems accessing the application or difficulty downloading, contact:

Grants and Acquisitions Management

Phone: 240-453-8822

Email: OASH_Grants@hhs.gov

2. Content and Form of Application Submission

a. Application Format

Your application must be prepared using the forms and information provided in the online application package.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section C. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria. Please do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete. If your application exceeds the specified page limits for the Project Narrative or Project Narrative plus Appendices when printed on 8.5" X 11" paper by HHS/OASH/GAM, we will not review it. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

You must double-space the Project Narrative pages.

You should use an easily readable typeface, such as Times New Roman or Arial. You *must* use 12-point font. You may single-space tables or use alternate fonts but you must ensure the tables are easy to read.

b. Appendices Format

Your Appendices should include any specific documents outlined in Section D.2.iii., under the heading "Appendices" in the Application Content section of this funding opportunity announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/CVs, organizational charts, tables, or letters of commitment may use formatting common to those documents, but the pages must be easy to read. All of your appendices must be uploaded as a single, consolidated file in the Attachments section of your Grants.gov application.

c. Project Abstract Summary Format

You must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application and will form the basis for the application summary in grants management and program summary documents. If your project is funded, HHS may publish information from your form; therefore, do not include sensitive or proprietary information.

d. Budget Narrative Format

The Budget Narrative should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

3. Application Content

Successful applications will contain the following information:

a. Project Narrative Content

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether your project meets the minimum requirements for an award under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following components identified by these headings: 1) problem statement and background; 2) project plan; 3) evaluation plan; 4) dissemination plan; 5) sustainability plan; and 6) organizational capability and readiness.

1) Problem Statement and Background

You should describe in this section, in both quantitative and qualitative terms, the nature and scope of the specific and particular problem or issue, and the proposed intervention it is designed to address. You should detail how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified. We recommend that you focus your problem statement on the specific aspects of the history, existing literature, current status, and policy considerations bearing on the program area, and the roles of the national, state, and local agencies responsible for their operation, rather than providing a broad or sweeping historical overview that is not directly related to the proposed interventions and activities.

Include a description of the burden of SCD disease in your state in both quantitative and qualitative terms. Key data include, but are not limited to, estimated number of SCD patients (children and adults), incidence based on newborn screening data, patient demographics (e.g., race,

gender, income, education, immigrant populations), geography (e.g., urban/rural ratio, large urban centers), estimated percentage of patients (in particular, children) who are Medicaid-eligible, and names and locations of major academic medical centers. Describe the availability of pediatric hematologists at each center, including the number. If available, also include data on estimated hydroxyurea usage rates among children with SCD at the state level and estimate the potential impact that this project may have on increasing hydroxyurea prescription rates.

2) Project Plan

Provide a detailed Work Plan outlining specific activities to be undertaken (based on the needs of the project proposed and project timeline. Your Work Plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of the project period. However, each year's activities should be fully attainable in one budget year. You may propose multi-year activities, as well as activities that build upon each other, but each phase of the project must be discreet and attainable within a single budget year. Your Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. Describe the approach that will be used to monitor and track progress on the project's tasks and objectives. Describe the processes for identifying and convening key partners; developing and providing baseline data for candidate quality measures for each provider type; and developing, promoting, and implementing the final incentive payment system(s). Describe how you will use the National Standards for Culturally and Linguistically Appropriate

Services in Health and Health Care (National CLAS Standards) to ensure the project will be implemented in a culturally appropriate manner.

Include in your narrative a description of your oversight plan or your approach to developing an oversight plan to ensure that incentivized hydroxyurea prescriptions are medically indicated for the patient. The plan should address patient safety concerns as well as potential fraud risks.

3) Evaluation Plan:

Describe your evaluation design and how your evaluation design will clearly establish whether hydroxyurea quality measure-based incentive payments result in statistically significant increases in hydroxyurea prescriptions. A power analysis, or other technique to establish/demonstrate statistical significance, should also be included. Describe the expected outcomes for your project and how you will measure and report the outcomes. Describe how you will identify best practices and lessons learned in implementing this project. Indicate whether the quantitative data you collect will include pre- and post-intervention hydroxyurea prescribing data for all provider types and emergency department visits data for both control and intervention groups. Applicants are encouraged to consider data for other downstream outcomes measures (e.g., hospitalizations, overall healthcare costs) in addition to emergency department visits. Describe how you will evaluate the quality of the implementation of the National CLAS Standards through process and outcome measures. Describe the relationship between your evaluator and your organization and the degree of independence the evaluator will have.

4) Dissemination Plan

Describe how the project's results and findings will be documented and disseminated in a timely manner and in easily understandable formats to State Medicaid Offices, the population served, the general public, and other parties who might be interested in using the results of the project. HHS/OASH may publish (including on a website), all appropriate findings and products. Also, please describe other, innovative approaches to informing parties who might be interested in using the results of your project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project. HHS expects that nationwide dissemination of products and knowledge will occur.

5) Sustainability Plan

Applications should include a summary for a feasible, time-phased sustainability plan that addresses financial, staff and supervisory, and material resources needed to sustain a successful intervention after the project period ends. Applications also should describe the experience and expertise of the applicant, the State Medicaid Office, and other partner(s) in establishing or supporting the sustainability of health-related projects.

6) Organizational Capability and Readiness:

Please describe in detailed terms your organization's capabilities to implement this project successfully, including any previous efforts to measure prescription adherence rates for orphan diseases, develop quality measures, and/or implement interventions to improve SCD clinical care. You should describe how your agency (or the particular division of a larger agency which will

have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses.

Describe any data currently available on hydroxyurea usage and emergency department utilization rates within the state or among children with SCD. Outline the data sources you will use to determine hydroxyurea usage rates and emergency room utilization rates and indicate how you would gain access to such data sources. Outline the data sources you will access for other outcomes you propose to measure.

In this section, please also delineate the roles, responsibilities, and qualifications of key project staff and subrecipients, if any, and how they will contribute to achieving the project's objectives and outcomes. At a minimum, key project staff should include the Principal Investigator/Project Director and evaluator. OMH expects that, throughout the award period, the Principal Investigator/Project Director will have day-to-day oversight of, and substantial knowledge about, all aspects of the project.

b. Budget Narrative Content

You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application. You must enter the project budget on the Budget Information Non-construction Programs standard form (SF 424A) according to the directions provided with this standard form. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by "object class categories" identified on the SF-424A and justification of the costs. You must indicate the method you are selecting for your indirect cost rate. See Indirect Costs below for further information.

Project budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. If matching or cost sharing is

required, you must include a detailed listing of any funding sources identified in box 18 of the SF-424 (Application for Federal Assistance).

Please be sure to carefully review section Funding Restrictions for specific information regarding allowable, unallowable, and restricted costs.

You must provide an object class category budget using Section B, box 6 of the SF 424A for the first year of the proposed project. Provide a budget justification, which includes explanatory text and line-item detail, for the first year of the proposed project. The budget narrative should describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

For subsequent budget years, provide a summary narrative and line item budget. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes. Note, **do not** include costs beyond the first budget year in the object class budget in box 6 of the SF- 424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget year.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. For example, if you are proposing to provide services to clients, you should describe how many clients are you expecting to serve, the unit cost of serving each client, and how this is cost effective.

Use the following guidelines for preparing the detailed object class budget required by box 6 of the SF-424A. The object class budget organizes your proposed costs into a set of defined categories outlined below. Both federal and non-federal resources (when required) must be

detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

Sample Budget Table

Object Class	Federal Funds Requested	Non-federal Resources	Total Budget
Personnel	$100,000	$25,000	$125,000

Note, subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items, i.e., subrecipient travel should be included in the Contractual line item not in Travel.

1) Object Class Descriptions and Required Justifications

(a) Personnel Description

Costs of staff salaries and wages, excluding benefits.

(b) Personnel Justification

Clearly identify the project director or principal investigator, if known at the time of application. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent: annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary. No salary rate may exceed the statutory limitation in effect at the time you submit your application (see D.6 Funding Restrictions, *Salary Rate Limitation* for details). Do not include the costs of consultants, personnel costs of

delegate agencies, or of specific project(s) and/or businesses to be financed by the applicant. Contractors and consultants should not be placed under this category.

Sample Personnel Table

Position Title and Full Name	Percent Time	Annual Salary	Federally-funded Salary	Non-federal Salary	Total Project Salary
Project Director, John K. Doe	50%	$100,000	$50,000	$0	$50,000
Data Assistant, Susan R. Smith	10%	$30,000		$3,000	$3,000

(c) Fringe Benefits Description

Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

(d) Fringe Benefits Justification:

Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

(e) Travel Description

Costs of travel by staff of the applicant organization only.

(f) Travel Justification

For each trip proposed for applicant organization staff only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances. **Do not** include travel costs for subrecipients or contractors.

(g) Equipment Description

Equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000. (Note: Acquisition cost means the cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non- Federal entity's regular accounting practices.) See 45 C.F.R. § 75.2 for additional information.

(h) Equipment Justification

For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; as well as a plan for the use, and/or disposal of, the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy, or section of its policy, that includes the equipment definition; include this with your Budget Narrative file. Reference the policy in this justification and include the policy copy in your Budget Narrative file (not your appendices).

(i) Supplies Description

Costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a per-unit cost of less than $5,000.

(j) Supplies Justification

Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

(k) Contractual Description

Costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant. This line item is not for individual consultants.

(l) Contractual Justification

Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 45 CFR § 75.329 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by 41 U.S.C. § 134 and currently set at $250,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available to HHS/OASH.

Note: Whenever you intend to delegate part of the project to another agency, you must provide a detailed budget and budget narrative for each subrecipient/contractor, by agency title, along with the same supporting information referred to in these instructions. If you plan to select

the subrecipients/contractors post-award and a detailed budget is not available at the time of application, you must provide information on the nature of the work to be delegated, the estimated costs, and the process for selecting the delegate agency.

(m) Other Description

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: consultants; insurance; professional services (including audit charges); space and equipment rent; printing and publication; training, such as tuition and stipends; participant support costs including incentives, staff development costs; and any other costs not addressed elsewhere in the budget.

(n) Other Justification

Provide computations, a narrative description, and a justification for each cost under this category.

(o) Indirect Costs Description

Total amount of indirect costs. This category has one of two methods that you may select. You may only select one.

- Your organization currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant federal agency. You should enclose a copy of the current approved rate agreement in your Budget Narrative file. If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that the organization is accepting a lower rate than allowed.
- Per 45 CFR § 75.414(f) Indirect (F&A) costs, "any non-Federal entity [.,i.e., applicant] that has never received a negotiated indirect cost rate,

> … may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in § 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time."
>
> This method only applies if you have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. If you are waiting for approval of an indirect cost rate, you may request the 10% de minimis rate. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

(p) Indirect Costs Justification

Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved agreement is being applied and why that rate is being used. For example, if you have both on-campus and off-campus rates, identify which is being used and why.

(q) Program Income Description

Program income means gross income earned by your organization that is directly generated by this project if funded except as provided in 45 CFR § 75.307(f). Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal

property acquired under the award. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 CFR §§ 75.307, 75.407 and 35 U.S.C. §§ 200-212 (applies to inventions made under Federal awards).

(r) Program Income Justification

Describe and estimate the sources and amounts of program income that this project may generate if funded. Unless being used for cost sharing, if applicable, these funds should not be added to your budget. This amount should be reflected in box 7 of the SF-424A.

(s) Non-Federal Resources Description

Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the criteria listed in 45 CFR § 75.306. For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period or by project period for fully-funded awards, even if the justification by budget period, or by project period for fully-funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. For awards that do not require matching or cost sharing by statute or regulation, where "cost sharing" refers to costs of a project in addition to Federal funds requested that you voluntarily propose in your budget, if your application is successful, we will include this non-federal cost sharing in the approved project budget and you will be held accountable for the non-federal cost-

sharing funds as shown in the Notice of Award (NOA). Your failure to provide voluntary cost sharing of non-federal resources that have been accepted by HHS/OASH as part of the approved project costs and that are shown as part of the approved project budget in the NOA may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. Note, you will not receive any preference, priority, or special consideration in the funding process for voluntarily including non-Federal cost sharing in your proposed budget.

(t) Non-federal Resources Justification

You must provide detailed budget information for every funding source identified in box 18. "Estimated Funding ($)" on the SF-424. Provide this documentation as part of your Budget Narrative file, not your Appendices.

You must fully identify and document in your application the specific costs or contributions you propose in order to meet a matching requirement. You must provide documentation in your application on the sources of funding or contribution(s). In-kind contributions must be accompanied by a justification of how the stated valuation was determined. Matching or cost sharing must be documented by budget period (or by project period for fully-funded awards). If your application does not include the required supporting documentation for a matching requirement, it will not be disqualified from competitive review; however, it may impact your score under the evaluation criteria in Section of this announcement.

2) Plan for Oversight of Federal Award Funds

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to

your project as proposed and how your oversight plan addresses these risks.

- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.
- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.
- organizational controls that will ensure timely and accurate submission of Federal Financial Reports to the OASH Office of Grants Management and Payment Management Services as well as timely and appropriate withdrawal of cash from the Payment Management System.

c. Appendices

All items described in this section will count toward the total page limit of your application. You must submit them as **a single electronic file** uploaded to the Attachments section of your Grants.gov application.

1) **Supplemental Information/Supporting Documentation for Work Plan.**

If needed, include any additional information or documentation related to the Work Plan.

2) **Memorandums of Agreement from partner agencies.**

Applicants should include a signed memorandum of agreement (MOA) with all partners who will contribute substantially to this project. If the applicant is not a State Medicaid Office, the applicant is expected to secure a formal partnership with the State Medicaid Office as evidenced by a signed MOA. The MOA(s) submitted in your application must be signed by all partners and include specific roles, responsibilities, resources, and contributions of partner(s) to the project. If the applicant is unable to submit a signed MOA, the applicant should submit an unsigned MOA and signed letters of commitment (LOCs) with all partners.

3) Letters of Commitment from Subrecipient Organizations and Agencies.

Your application should include signed Letters of Commitment for all organizations and entities that have been specifically named as a subrecipient in the application to carry out any aspect of the project. The signed letters of commitment must detail the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the letter of commitment.

Letters of commitment are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. You should NOT provide letters of support as these will not be considered during the review.

4) Organizational Documents/Items.

(a) Applicant's organizational chart

(b) State Medicaid Office's organizational chart

(c) An organizational chart for key partners and subrecipient(s) including office locations

5) Curriculum Vitae/Resume for Key Project Personnel.

You must submit with your application curricula vitae or resumes of the Principal Investigator/Project Director and all other key personnel. Key personnel include those individuals who will oversee the technical, professional, managerial, and support functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum the Principal Investigator/Project Director. We encourage individuals to use their full name (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records.

6) **Just-in-Time Institutional Review Board Agreement**

You should submit letter signed by the authorized official assuring that, if funded, the applicant will submit an application to an Institutional Review Board for approval.

4. Unique Entity Identifier and System for Award Management (SAM)

You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal awards through Grants.gov. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is free and easy to obtain. If you do not currently have a DUNS number, please contact Grants.gov to create a temporary DUNS number if you are unable to complete the SAM registration process prior to submitting your application.

You will find instructions on the Grants.Gov web site as part of the organization registration process at http://www.grants.gov/web/grants/applicants/organization-registration.html.

Your organization must register online in the System for Award Management (SAM). Under normal operating procedures Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. Because of the public health emergency with COVID-19, the requirement for SAM registration at the time of submission has been waived. Grants.gov will temporarily allow submissions without a current SAM registration. A completed registration in SAM may be required prior to receiving any award based on your application.

If you are registering a new entity or renewing your registration, you must submit a notarized letter formally appointing an Entity Administrator to SAM.GOV For detailed instructions on the content of the letter and process for domestic entities see: https://www.fsd.gov/fsd-gov/answer.do?sysparm_kbid=d2e67885db0d5f00b3257d321f96194b&sysparm_search=kb0013183

A quick start guide for registrants is available at https://www.sam.gov/sam/transcript/Quick_Guide_for_Grants_Registrations.pdf. You should allow a minimum of five days to complete an initial SAM registration. Allow up to 10 business days after you submit your registration for it to be active in SAM. This timeframe may be longer if SAM flags the information you provide for manual validation. You will receive an email alerting you when your registration is active.

If your organization is already registered in SAM, you must renew your SAM registration each year. Organizations registered to apply for Federal awards through http://www.grants.gov will need to renew their registration in SAM. SAM has extended the expiration dates for registration renewals that may be delayed because of the public health emergency. Please review your status in SAM.

You should make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4. Should you successfully compete and receive an award, this information must be included on a Notice of Award. For instructions on updating this information see https://gsafsd.service-now.com/fsd-gov/answer.do?sysparm_kbid=c3d982af6fb8d5006f348d412e3ee47e

It may take 24 hours or more for SAM updates to take effect in Grants.gov, so if you plan to apply for this funding opportunity or think you might apply, you should ensure your organization's registration is active in SAM well before the application deadline and will be active through the competitive review period.

If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during which your organization has an active award or an application or plan under consideration by an HHS agency.

HHS/OASH cannot make an award until you have complied with these requirements as modified under the public health emergency. If you have not complied with these requirements, HHS/OASH:

- May determine that you are not qualified to receive an award; and
- May use that determination as a basis for making an award to another applicant.

Should you successfully compete and receive an award, all first-tier sub-award recipients must have a DUNS number (permanent or temporary) at the time you, the recipient, make a sub-award.

5. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated in Section A.1 of this announcement.** Your submission time will be determined by the date and time stamp provided by Grants.gov when you **complete** your submission.

If you fail to submit your application by the due date and time, we will not review it, and it will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with http://www.grants.gov . Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may consider your application if you provide verification from Grants.gov indicating system problems existed at the time of your submission **and that time was before the submission deadline**. A "system problem" does not include known issues for which Grants.gov has posted instructions regarding how to successfully submit an application such as compatible Adobe versions or file naming conventions. **As the applicant, it is your responsibility to review all instructions available on Grants.gov regarding successfully submitting an application.**

6. Intergovernmental Review

Applications under this announcement are subject to the requirements of Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' as implemented by 45 CFR part 100, ''Intergovernmental Review of Department of Health and Human Services Programs and Activities.'' As soon as possible, you should discuss the project with the State Single Point of

Contact (SPOC) for the State in which your organization is located. The current listing of the SPOCs is available at https://www.whitehouse.gov/wp-content/uploads/2017/11/SPOC-Feb.-2018.pdf. The SPOC should forward any comments to the Department of Health and Human Services 1101 Wootton Parkway, Suite 100, Rockville, MD 20852. The SPOC has 60 days from the due date listed in this announcement to submit any comments. For further information, contact the HHS/OASH/GAM at 240–453–8822.

7. Funding Restrictions

Direct and Indirect Costs proposed and, if successful, charged to the HHS/OASH award must meet the cost requirements of 45 CFR part 75 "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards," Subpart E—Cost Principles. These requirements apply to you, the applicant, and any subrecipients. You should thoroughly review these regulations before developing your proposed budget.

Indirect costs may be included per 45 CFR § 75.414. See the Budget Narrative section of this announcement for more information. To obtain a negotiated indirect cost rate with the Federal Government you may contact the U.S. Department of Health and Human Services Cost Allocation Services (CAS) regional office that is applicable to your State. CAS regional contact information is available at https://rates.psc.gov/fms/dca/map1.html.

1) Pre-Award Costs

Pre-award costs (per 45 CFR § 75.458) are those incurred prior to the effective date of the Federal award directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work. Such costs are allowable only to the extent that they would have been allowable if incurred after the date of the Federal award and only with the written approval of the HHS awarding agency.

Pre-award costs are not allowed.

2) Salary Rate Limitation:

Each year's appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II. As of January 2020, the Executive Level II salary is $197,300. This amount reflects an individual's base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award.

An example of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Individual's *actual* base full time salary: $350,000 50% of time devoted to project, i.e. .5 FTE	
Direct salary ($350,000 x .5)	$175,000
Fringe (25% of salary)	$43,750
Total	$218,750
Amount that may be claimed on the application budget due to the legislative salary rate limitation: Individual's base full time salary *adjusted* to Executive Level II: $197,300 with 50% of time devoted to the project	
Direct salary ($197,300 x .5)	$98,650
Fringe (25% of salary)	$24,663
Total amount allowed	$123,313

Appropriate salary rate limits will apply as required by law.

8. Other Submission Requirements

a. Electronic Submission

HHS/OASH requires that all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. If you submit an application via any other means of electronic communication, including facsimile or electronic mail, it *will not* be accepted for review unless you receive an exemption as described in the DATES section of this announcement.

You may access the Grants.gov website portal at http://www.grants.gov.

Applications, excluding required standard forms, must be submitted as three (3) files (see acceptable file types below). One file must contain the entire Project Narrative, another the

entire Budget Narrative including supporting documentation described in the Budget Narrative content section; and the third file must contain all documents in the Appendices. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process.

Any files uploaded or attached to the Grants.gov application must be Adobe PDF, Microsoft Word, or image formats (JPG, GIF, TIFF, or BMP only) and must contain a valid file format extension in the filename. HHS/OASH strongly recommends that electronic applications be uploaded as Adobe PDF. If you convert to PDF prior to submission you may prevent any unintentional formatting that might occur with submission of an editable document. Please note, even though Grants.gov allows you to attach any file format as part of your application, HHS/OASH restricts this practice and only accepts the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format listed above will not be accepted for processing and will be excluded from the application during the review process.

Any file submitted as part of the Grants.gov application that contains password protection will not be accepted for processing and will be excluded from the application during the review process. We will not contact you for passwords or resubmission of unprotected files. Unprotected information in the application will be forwarded for consideration but password protected portions will not. You should avoid submitting personally identifiable information such as personal contact information on résumés.

In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. We will not contact you for resubmission of uncompressed versions of files. Compressed information in the application will not be forwarded for consideration.

You must submit your application in a format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. If you submit documents that do not conform to these instructions, we will exclude them from your application during the review process.

b. Important Grants.gov Information

You may access the electronic application for this program on http://www.grants.gov. You must search the downloadable application page by the Funding Opportunity Number or CFDA number, both of which can be found on page 1 of this funding opportunity announcement.

To ensure successful submission of your application, you should carefully follow the step-by-step instructions provided at http://www.grants.gov/web/grants/applicants/apply-for-grants.html . These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information. **You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.**

You should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov. See Contacts below. See Section D.3 for requirements related to DUNS numbers and SAM registration.

G. APPLICATION REVIEW INFORMATION

1. Criteria

Federal staff and an independent review panel will assess all eligible applications according to the following criteria. Disqualified applications will not be reviewed against these criteria

a. Problem Statement/Background (15 points)

- How strong is the demonstrated need for project, based on a quantitative description of burden of SCD (particularly among children) at the state level, proportion of Medicaid-eligible patients, and estimated number of patients to be impacted by project?
- How well does the applicant describe health disparities experienced by children with SCD in the proposed service area?
- Does the applicant demonstrate adequate hematologist workforce capacity to support the project?

b. Project Work Plan (30 points)

- How appropriate and coherent is the proposed approach, including:
    - Strength and feasibility of the work plan and timeline
        - How detailed, thoughtful, and comprehensive is the project Work Plan? To what extent does the work plan reflect and is consistent with the Project Narrative and Budget?
        - How clearly and comprehensively does the Work Plan describe a clear and logical statement of the project's overall result-based goals, anticipated outcomes, key objectives, and the major tasks/action steps that will be pursued to achieve the goal and outcome(s)?

- How practical, feasible, and measureable are the components to evaluate progress toward achieving the applicant's stated goals and outcomes?
- How well does the Work Plan identify feasible timeframes involved (including start- and end-dates) to meet project goals and objectives and the lead person (including partners/consultants) responsible for completing each task?
- How well does the proposed approach include securing partnerships with and collecting input from partners representing the three main provider types (hematologists, primary care providers, emergency clinicians) and clinical care facilities?
- To what extent does the applicant's approach allow for the development and promotion of appropriate quality measure(s) and incentive payment system(s) within 15 months of award?
- To what extent will the applicant's proposed approach allow for the implementation of incentive payment system(s) by the end of the second year?

- How well does the applicant's plan use the National CLAS Standards to ensure project activities are culturally and linguistically appropriate?

- How well does the oversight plan (or the approach to developing an oversight plan) ensure that incentivized hydroxyurea prescriptions are medically indicated for the patient? Does the plan address patient safety concerns as well as potential fraud risks?

c. Evaluation Plan (20 points)

- How rigorous is the evaluation design?
- How clearly and unambiguously will the proposed evaluation clearly establish whether hydroxyurea quality measure-based incentive payments result in statistically significant increases in hydroxyurea prescriptions among the target population?
- How well does the applicant identify the measurable outcomes that will result from the project, and to what extent do these outcomes directly address the goals of the funding opportunity?
- To what extent are the proposed outcomes quantifiable, measurable, and likely to be achieved during the project period?
- How will the evaluation identify best practices and lessons learned in implementing this project?
- To what extent does the quantitative data collection include pre- and post-intervention hydroxyurea prescribing data for all provider types and emergency department visits data for both control and intervention groups?

- To what degree does the evaluation plan include data for other downstream outcomes measures (e.g., hospitalizations, overall healthcare costs) in addition to emergency department visits?

d. Dissemination Plan (5 points)

- How achievable is the applicant's proposed method for documenting and disseminating the project's results and findings in a timely manner to State Medicaid offices and others who might be interested in using the results of the project to inform practice, service delivery, program development, and/or policy-making?

e. Sustainability Plan (5 points)

- How feasible is the applicant's plans for developing strategies to support the program(s) beyond the grant period?
- To what extent does the applicant note the following:
    - Who their sustainability partners are?
    - Any strategies, contracts, and/or other means to secure and/or expand sustainable financing?
    - How they will secure funding for the proposed program(s) beyond the end of the grant period and/or embed the program(s) within the routine operations of collaborating organizations?
- What experience do the applicant, the State Medicaid Office, and other partner(s) have in establishing or supporting the sustainability of health-related projects?

f. Organizational Capability and Readiness (20 points)

- To what extent does the applicant demonstrate adequate capacity, infrastructure, competencies, and expertise to successfully meet the goals and objectives of this project?
- To what extent does the applicant demonstrate capability and readiness through relevant prior experience in measuring prescription adherence rates for orphan diseases, developing quality measures, and/or implementing interventions to improve SCD clinical care?
- How clearly and comprehensively does the applicant outline the data sources that will be used to determine hydroxyurea usage rates and emergency room utilization rates (and other outcomes as identified by the applicant), and demonstrate adequate access to such data sources to support monitoring and project evaluation?
- To what extent does the applicant demonstrate adequate expertise and capability of key personnel and other staff and partners to successfully meet the goals and objectives of the project?
- To what extent does the applicant demonstrate a strong partnership with a State Medicaid office to support meeting project goals and objectives?

g. Budget (5 points)

- How well justified are the budget and requested resources with respect to the adequacy of resources requested?
- How clearly are budget line items delineated and consistent with Work Plan objectives?

- How well are relevant activities from the Project Narrative and Work Plan reflected in the budget as appropriate?

2. Review and Selection Process

Each HHS/OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that meet the responsiveness criteria, if applicable, and are not disqualified. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section E.1, the reviewers will comment on and score the applications, focusing their comments and scoring decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance.

The Deputy Assistant Secretary for Minority Health will provide recommendations for funding to the Grants Management Officer to conduct risk analysis.

In providing these recommendations, the Deputy Assistant Secretary for Minority Health will take into consideration the following additional factor(s):

- equitable geographic distribution of projects.

2. Review of Risk Posed by Applicant

The HHS/OASH will evaluate, in accordance with 45 CFR § 75.205, each application recommended for funding by the program official indicated in Review and Selection Process for risks before issuing an award. This evaluation may incorporate results of the evaluation of

eligibility or the quality of an application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a reimbursable rather than cash advance basis. OASH will use a risk-based approach and may consider any items such as the following:

1) Your financial stability;

2) Quality of management systems and ability to meet the management standards prescribed in 45 CFR part 75;

3) History of performance. Your record in managing Federal awards, if you are 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; and

5) Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently $250,000), we are required to review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)).You may, at your option, review information in SAM and comment

on any information about yourself that a Federal awarding agency previously entered and is currently available through SAM. We will consider any comments by you, in addition to the other information in the designated system, in making a judgment about your integrity, business ethics, and record of performance under Federal awards when completing the review of risk.

If an we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 CFR §75.205(a)(2), we must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are 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." 45 CFR § 75.205(a)(2); see also 45 CFR §75.212 for additional information.

3. Final Award Decisions, Anticipated Announcement, and Federal Award Dates

Upon completion of risk analysis and concurrence of the Grants Management Officer, HHS/OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued. All award decisions, including level of funding if an award is made, are final and you may not appeal.

HHS/OASH seeks to award funds as much in advance of the anticipated project start date shown in Section B "Federal Award Information," as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later project period start date.

H. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

HHS/ OASH does not release information about individual applications during the review process. If you would like to track your application, please see instructions at http://www.grants.gov/web/grants/applicants/track-my-application.html. The official document notifying you that an application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH/GAM. If you are successful, you will receive this document via system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the project period, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization's information is correct and that you understand all terms and conditions. You should pay specific attention to the terms and conditions, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the award for assistance and monitoring.

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by HHS/OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. On occasion, you may receive a letter indicating that an application was approved but unfunded. These applications may be kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

2. Administrative and National Policy Requirements

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, or other Department regulations and policies in effect at the time of the award.

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf Please note HHS plans to revise the HHS GPS to reflect changes to the regulations; 45 CFR parts 74 and 92 have been superseded by 45 CFR part 75.

You may only use award funds to support activities outlined in the approved project plan. If your application is funded, your organization will be responsible for the overall management of activities within the scope of the approved project plan. Please consult the HHS GPS Section II and 45 CFR § 75.308 for aspects of your funded project that will require prior approval from the Grants Management Officer for any changes. Modifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); significant budget revisions, including changes in the approved cost-sharing or matching; a change in a key person specified in your application; reduction in time devoted to the project by the approved project director or principal investigator,

either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or the subawarding, transferring or contracting out of any work that was not described in the approved proposal.

3. Closeout of Award

Upon expiration of your project period, if we do not receive acceptable final performance, financial, and/or cash reports in a timely fashion within the closeout period, and we determine that closeout cannot be completed with your cooperation or that of the Principal Investigator/ Project Director, we may elect to complete a unilateral closeout. (See F.3 Reporting below for closeout reporting requirements.) As a result, we may determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

4. Lobbying Prohibitions

You shall not use any funds from an award made under this announcement for other than normal and recognized executive legislative relationships. You shall not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You shall not use any funds from an award made under this announcement to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

The above prohibitions include any activity to advocate or promote any proposed, pending, or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

5. Non-Discrimination Requirements

Pursuant to Federal civil rights laws, if you receive an award under this announcement you must not discriminate on the basis of race, color, national origin, disability, age, and in some cases sex and religion. The HHS Office for Civil Rights provides guidance for complying with civil rights laws that prohibit discrimination. https://www.hhs.gov/civil-rights/index.html.

HHS provides guidance to recipients of federal financial assistance on meeting the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency. See *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, 68 Fed. Reg. 47311, 47313 (HHS Office for Civil Rights, 2003, www.gpo.gov/fdsys/pkg/FR-

2003-08-08/pdf/03-20179.pdf) You must ensure your contractors and subrecipients also comply with federal civil rights laws.

The *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf), provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency. Compliance with the National CLAS Standards meets the legal obligation to take reasonable steps to provide meaningful access to persons with limited English proficiency.

6. Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS/OASH mission to protect and advance the physical and mental health of the American people.

7. Acknowledgement of Funding and HHS Rights to Materials and Data

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3)

percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

> This publication (journal article, etc.) was supported by Award No. _____ from the Office of the Assistant Secretary of Health (OASH). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of OASH.

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 CFR § 75.322(b), HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

8. Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104). For the full text of the award term, go to http://www.hhs.gov/opa/grants/trafficking_in_persons_award_condition.html. If you are unable

to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

9. Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at http://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/.

10. Whistleblower Protection

If you receive an award, you will be subject to a term and condition that applies the terms of 48 CFR § 3.908 to the award, and requires that you inform your employees in writing of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the predominant native language of the workforce.

11. Human Subjects Protection

Federal regulations (45 CFR Part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 CFR part 46. You may find it online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Applicants that plan to engage in research involving human subjects are encouraged to provide information regarding participation in research in their recruitment efforts and provide a link to www.hhs.gov/about-research-participation.

12. Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of part 93. More information is available at ori.hhs.gov/assurance-program.

13. Reporting

a. Performance Reports

You must submit performance reports on a quarterly basis. Your performance reports must address content required by 45 CFR § 75.342(b)(2). The awarding program office may provide additional guidance on the content of the progress report. You must submit your performance reports by the due date indicated in the terms and conditions of your award via upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

You will also be required to submit a final performance report covering the entire project period 90 days after the end of the project period. You must submit the final report by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

b. Performance Measures

In addition to the submission of quarterly reports in our grants management system, OMH expects awardees to report program process and outcome data electronically to OMH on a quarterly basis. Performance process and outcome data allow OMH to evaluate the performance of its initiatives across awardees. All OMH awardees under this initiative are required to report project performance process and outcome data on a quarterly basis through Grant Solutions. No performance measure reporting will be required without OMB approval. Training will be provided to all new grantees on the collection and reporting of performance data during the Technical Assistance and Training grantee meeting. Note: Successful applicants may be required to report project-related data in the Office of Minority Health's Performance Data System (PDS) (OMB No. 0990-0275, Expiration date 8/31/2022).

c. Financial Reports

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire project period 90 days after the end of the project period. You must submit FFRs via our grants management system (GrantSolutions.gov) FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note, at this time, these FFR reports are separate submissions via the Payment Management System. At this time, data is not transferable between the two systems and you will report twice on certain data elements.

d. Audits

If your organization receives $750,000 or greater in Federal funds, it must undergo an independent audit in accordance with 45 CFR part 75, subpart F.

e. Non-competing Continuation Applications and

Each year of the approved project period, you will be required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well in advance of the application due date. HHS/OASH will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Additionally, failure to provide final progress or financial reports on other awards from HHS may affect continuation funding.

f. FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (http://www.FSRS.gov) for all sub-awards and sub-contracts issued for $25,000 or more as well as addressing executive compensation for both recipient and sub-award organizations.

g. Reporting of Matters Relating to Recipient Integrity and Performance

Applications under this announcement are subject to the requirements of Executive Order 12372, ‘‘Intergovernmental Review of Federal Programs,’’ as implemented by 45 CFR part 100, ‘‘Intergovernmental Review of Department of Health and Human Services Programs and Activities.’’ As soon as possible, you should discuss the project with the State Single Point of Contact (SPOC) for the State in which your organization is located. The current listing of the SPOCs is available at https://www.whitehouse.gov/wp-content/uploads/2017/11/SPOC-Feb.-

2018.pdf. The SPOC should forward any comments to the Department of Health and Human Services 1101 Wootton Parkway, Suite 550, Rockville, MD 20852. The SPOC has 60 days from the due date listed in this announcement to submit any comments. For further information, contact the HHS/OASH Office of Grants Management at 240–453–8822.

h. Other Required Notifications

Before you enter into a covered transaction at the primary tier, in accordance with 2 CFR § 180.335, you as the participant must notify HHS/OASH, if you know that you or any of the principals for that covered transaction:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 CFR § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 CFR § 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 CFR § 180.350, you must give immediate written notice to HHS/OASH if you learn either that—

- You failed to disclose information earlier, as required by 2 CFR § 180.335; or
- Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 CFR § 180.335.

I. CONTACTS

1. Administrative and Budgetary Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH grants management specialist listed below.

Roscoe Brunson

Senior Grant Management SpecialistOffice of Grants Management

1101 Wootton Parkway, Suite 100

Rockville, MD 20852

Phone: 240-453-8822

Email: roscoe.brunson@hhs.gov

2. Program Requirements

For information on program requirements, please contact the program office representative listed below.

Enrique Fernández

Office of Minority Health

1101 Wootton Parkway, Suite 100

Rockville, MD, 20852

Phone: 240-453-6153

Email:Enrique.fernandez@hhs.gov

3. Electronic Submission Requirements

For information or assistance on submitting your application electronically via Grants.gov, please contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

GRANTS.GOV Applicant Support

Website: www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

J. OTHER INFORMATION

1. Awards under this Announcement

We are not obligated to make any Federal award as a result of this announcement. If awards are made, they may be issued for periods shorter than indicated. Only the grants officer can bind the Federal government to the expenditure of funds. If you receive communications to negotiate an award or request additional or clarifying information, this does not mean you will receive an award; it only means that your application is still under consideration.

2. Application Elements

The below is a summary listing of all the application elements required for this funding opportunity.

- Application for Federal Assistance (SF-424)
- Budget Information for Non-construction Programs (SF-424A)
- Assurances for Non-construction Programs (SF-424B)
- Disclosure of Lobbying Activities (SF-LLL)

- Project Abstract Summary
- Project Narrative – Submit all Project Narrative content as a single acceptable file, specified above.
- Budget Narrative – Submit all Budget Narrative content as a single acceptable file, specified above.
- Appendices – Submit all appendix content as a single acceptable file, specified above **in the Attachments section of your Grants.gov application**.
    - Supplemental Information/Supporting Documentation for Work Plan
    - Memorandums of Agreement
    - Letters of Commitment
    - Organizational Documents/Items
    - Curriculum Vitae/Resumes for Key Personnel
    - Just-in-Time Institutional Review Board Agreement

RADM Felicia Collins Date
Deputy Assistance Secretary for Minority Health

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