

Class Justification for Other Than Full and Open Competition
COVID-19 Response

“Source Selection Information- see FAR 2.101 and 3.104”

1. Identification of the agency and contracting activity.

a. Federal agency and contracting activity.

Health & Human Services/ Office of the Secretary/Assistant Secretary for Financial Resources/Office of Acquisition. This class justification covers all HHS acquisition offices.

b. Sponsoring organization.

HHS/OS/ASFR/OA

2. Nature and/or description of the action being approved.

This is a class Justification & Approval (J&A) in accordance with FAR § 6.303-1(d) and 6.302-2, Unusual and Compelling Urgency, FAR § 8.405-6(a)(1)(A), Limiting Sources, and FAR § 16.505(b)(2)(i)(A), Exceptions to the Fair Opportunity Process for all contract actions to facilitate the recovery efforts necessary to address the 2019 Novel Coronavirus (COVID-19). Because COVID-19 is an emerging disease, and there are no vaccines or approved treatments, it is prudent to have adequate flexibility to address this public health emergency. This class J&A is essential to respond to urgent requests for immediate support to respond to the expanding outbreak of COVID-19 which was just declared a pandemic on March 11, 2020 and a national emergency via Presidential Proclamation on March 13, 2020. This class J&A supersedes all other class J&A’s executed and issued by HHS and negates the need for individual J&As for contract actions to facilitate the recovery efforts necessary to address COVID-19.

Requirements that arise and are executed by HHS contracts offices can be processed under the authority of the class J&A. A copy of the class J&A must go in the award file for all requirements processed under the authority of this class J&A and each contracting activity must maintain a log of all contract actions awarded under the authority of this class J&A.

a. Acquisition purposes and objectives.

The requirement is to purchase critically needed supplies and services to respond to the COVID-19 global outbreak. On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic, and on March 13, 2020, the United States issued a Presidential Proclamation declaring the COVID-19 outbreak to be a national emergency. Additionally, all fifty states and the District of Columbia have declared emergencies due to COVID-19.

The mission to respond to the community spread of COVID-19 throughout the United States and the mission to repatriate individuals who have been exposed to the virus are both ongoing and growing. The COVID-19 outbreak has evolved at a fast pace, resulting in an urgent and compelling need to rapidly procure supplies and services to support the containment and recovery of the outbreak throughout the country and world. This constitutes an unusual and compelling urgency that demands immediate attention. Immediate acquisition of services and supplies will help ensure that the United States of America remains prepared for and capable of responding to a public health emergency in the necessary and immediate manner that is required.

b. Project background.

This justification for unusual and compelling urgency is due to the public health emergency caused by COVID-19, which was declared a global pandemic by the WHO. The first confirmed case of COVID-19 in the United States was announced on January 21, 2020 and a national emergency was declared via Presidential Proclamation on March 13, 2020. The ultimate spread, length of time, and severity of the COVID-19 outbreak is unknown as this time and current data indicate that COVID-19 has begun to spread exponentially, in the typical pattern for an epidemic.. The goal of the ongoing U.S. public health response is to respond to and mitigate sustained spread of COVID-19 in this country.

The HHS has a requirement to provide medical and pharmaceutical related material and services to various locations across the US during this public health emergency and response effort. The Department anticipates receiving Mission Assignments generated from within and outside HHS to purchase and distribute required services, products and equipment. Any delay in providing critical medical supplies, services and equipment could cause irreparable harm and put American citizens at an increased risk of transmission and exposure. Every effort must be made to provide needed products and services in the most expedient manner.

3. Description of the supplies or services required to meet the agency's needs (including estimated value).

a. Project Title:

COVID-19 Response: Supplies and Services to support response and recovery to the national emergency created by the COVID-19 pandemic. Specific requirements and costs will be defined at the contract level and shall be documented as a part of the contract file.

Contract Performance for COVID-19 Supplies and Services

The exact length and breadth of this response cannot be determined at this time and therefore, the period of performance for COVID-19 supplies and services will vary from immediate to longer term support but is not to exceed 12 months.

b. Project Description:

The HHS is working in tandem with other Federal Agencies which, among others, are providing disaster medical assistance teams to provide medical relief and assistance to areas impacted by COVID-19. In support of these efforts, the HHS has an urgent need to obtain supplies and services to ensure the delivery of potentially lifesaving and preventative medical supplies and services in support of the response to the COVID-19 pandemic.

• **Requirement type.**

- ✓ Research & development (R&D)
- ✓ R & D support services
- ✓ Support services (non-R&D)
- ✓ Supplies/equipment
- ✓ Information technology (IT)

- ✓ Construction
- ✓ Architect-engineer (A & E) services
- ✓ Design-build
- ✓ Other (specify): Additional requirements as needed to support recovery efforts related to this national emergency

- **Type of action.**

- ✓ New requirement
- Follow-on
- Other (specify):

- **Proposed contract/order type.**

Contract type will be defined at the contract or task/delivery order level. All contract types available under FAR part 16 are authorized under this J&A and shall be documented as part of the contract file.

- **Acquisition identification number.**

To be identified at the individual contract and task/delivery order level. All contract actions made under this class J&A shall include a copy of this in the contract file.

c. Total estimated dollar value and performance/delivery period:

The estimated value of these supplies and services is \$30,000,000,000.00 based upon the supplemental funding provided by Congress and historical information from the first 6 weeks of the emergency COVID-19 response, and previous federal presidentially declared responses for similar public health emergencies such as Zika and H1N1. Supplemental appropriations were recently approved for immediate purchases to mitigate the further spread of COVID-19. The needs and extent of supplies and services will continue to evolve as the virus spreads across the nation. In the face of a potential public health disaster, the exact needs and locations can change rapidly and therefore the planned emergency acquisitions under this class J&A takes this into account in estimating the value. This class J &A is for all supplies and other related services described under Section 2- Nature and/or description of the actions. The exact length and breadth of this response cannot be determined at this time and therefore, the period of performance for COVID-19 supplies and services will vary from immediate to longer term support but is not to exceed 12 months. This is consistent with FAR 6.302-2(d)(ii).

4. Identification of the statutory authority permitting other than full and open competition

This acquisition is conducted under the authority of 41 United States Code (U.S.C.) 253(c)(1) as set forth in Federal Acquisition Regulation (FAR) 6.302- 2 Unusual and compelling urgency, FAR 8.405-6(a)(1)(A); and FAR 18.104. An urgent and compelling need exists, and following the procedures would result in unacceptable delays, and FAR 16.505(b)(2)(i)(A) The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.

This acquisition is conducted under the authority of section 4202 of the Clinger-Cohen Act of 1996.

- This acquisition is conducted under the authority of the Services Acquisition Reform Act of 2003 (41 U.S.C. 428a).**

5. Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited.

a. Name and address of the proposed contractor(s).

Actions taken under the authority of this class J&A shall include documentation of market research performed and prospective sources of supply and services. Additionally, actions taken under the authority of this class J&A shall include evidence of the urgent and compelling nature of the particular action, reviewed and approved at a level above the Contracting Officer.

b. Nature of the acquisition and proposed unique qualifications of the contractor(s)

Actions taken under the authority of this J&A shall include documentation of the contractor's qualifications and ability to perform the work as part of the Contracting Officer's responsibility determination.

6. Actions taken under the authority of this class J&A shall include documentation that the proposed contractor is found to be responsible to perform the work. Description of the efforts made to ensure that offers are solicited from as many potential sources as practicable. Indicate whether a Contract Opportunities notice was or will be publicized in beta.SAM.gov as required by FAR Subpart 5.2 and, if not, which exception under FAR 5.202 applies.

Due to the unusual and compelling urgency of this requirement, expedited procedures may be utilized. For commercial items, therefore in accordance with FAR Part 12 and 13, simplified procedures may be utilized for some actions, including informally requesting quotes via telephone or email, or other electronic means.

When the agency's need for the supplies or services is of such an unusual and compelling urgency that the Government would be seriously injured unless the agency is permitted to limit the number of sources from which it solicits bids or proposals, full and open competition need not be provided for.

Actions taken under the authority of this class justification shall include documentation of the extent of competition undertaken.

7. Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable.

The Contracting Officer will use appropriate and available information to review proposed prices and determine that they are fair and reasonable, and such documentation shall be included in the contract file. The contracting officer will review the offerors' published commercial price, including prices list on various government-wide acquisition vehicles and other sites, such as pricing data contained in the GSA Acquisition Gateway Pricing Portal. The Contracting Officer will also request other cost data, and explanations regarding market conditions, from the offeror, in the event that offerors submit prices that exceed published commercial prices. Other information that may be used includes Independent Government Cost Estimates (IGCE), historical information, contractor's invoice payments and commercial pricing that have been determined to be fair and reasonable.

Actions taken under the authority of this class justification shall include a documentation of the price/cost analysis conducted and that the proposed price is fair and reasonable.

8. Description of the market research conducted (see FAR Part 10) and the results, or a statement of the reasons market research was not conducted.

Actions taken under the authority of this class J&A shall include documentation of market research performed and prospective sources of supply and services.

Any other facts supporting the use of other than full and open competition.

Competing requirements taken under the authority of this class J&A would result in unacceptable time delays in fulfilling the agency's urgent needs in addressing a global pandemic and national public health emergency. It would jeopardize HHS' public health mission in a way that would result in unacceptable risks to the health of the general public in the United States. Delays in award of critical contracts would result in serious injury, financial or other, to the Government due to the unacceptable jeopardy that would be posed to the health of the general public.

9. Listing of sources, if any, that expressed, in writing, an interest in the acquisition.

None, sources and market research shall be defined at the contract or task/delivery order level, and shall be documented in the contract file.

10. Statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the required supplies or services.

None, this is an immediate, urgent requirement. This class J&A shall remain in place for the duration of the national emergency as declared by Presidential Proclamation on March 13, 2020 as described under Section 2 or until revoked by the HHS SPE.

David R. Dasher //s//
Deputy Assistant Secretary for Office of Acquisitions, ASFR
Senior Procurement Executive, Department of Health and Human Services



COVER PAGE FOR OFFICE OF ACQUISITIONS
OFFICE OF ACQUISITION POLICY

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Mary Coleman (Concurrence)	<u>MC</u> mc	Apr 18, 21 20
2. Tiffani Redding (Concurrence)	<u>TR</u> TR	Apr 18, 21 20
3. David R. Dasher, DAS	<u>DRD</u> DRD	Apr 21, 21 20

Name of Action: HRSA Acquisition Plan

The purpose of this document is to provide an acquisition plan for review. Supporting documents provided for informational purposes only.

For distribution to HRSA for issuance of a letter contract.

Return to: Mary Coleman

Review Comments:

FROM: (Name / Organization or Title) Mary Coleman	Contact Info: Enter your telework number
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**HHS Streamlined Acquisition Plan
Related to COVID-19 Acquisitions (IAW FAR Part 7)
This document must be placed in all contract files
OFFICIAL USE ONLY**

Program/Project Title: COVID-19 Claims Reimbursement for Testing and Treatment to Health Care Providers Serving the Uninsured

OPDIV/STAFFDIV/Division: Health Resources and Services Administration (HRSA)

Program Official: Robyn Ashton,
MSN, RN Senior Advisor
Healthcare Systems Bureau

Acquisition Year: FY 2020

Acquisition Plan # (if applicable): IOA181_C_3404

Type of Acquisition:

Commercial (if applicable FAR Part 12)

Service

Supply

IT

Other (describe) this acquisition will utilize a letter contract, to be definitized utilizing FAR 15 within 90 days of award.

Independent Government Cost Estimate:

This acquisition will result in a 12 month period of performance, no options or optional items are included.

Based on the current scope of this contract, the IGCE was developed by estimating the number of uninsured claims that will need to be process to support the COVID19 uninsured patients. The cost of diagnostic testing, cost of office/hospital visits, program management costs, call center activities, and costs for the implementation of the provider customer service center were developed by using market pricing charge by commercial entities. HRSA reviewed the reasonableness of costs by conducting internet research for administrative overheads, looking at data presented in a 2018 study of an academic health care system, "Administrative Costs Associated with Physician Billing and Insurance-Related Activities at an Academic Health Care System", and also reviewed the Medicare Administrative Contractor (MAC) Covid-19 Test Pricing, and the CMS Physician fee Schedule.

These are initial assumptions, which will be further defined upon definitization of this letter contract, within 90 days of effective date.

I. Acquisition Background (FAR 7.105(a)).

A. Brief Description of Requirement/Statement of Need:

HHS/HRSA is proposing to issue a contract to provide end-to-end claims processing services to physician practices, clinics, health care centers, hospitals, labs, and any health care entity that provides the Doctor Visits (screening), Testing and Treatment of Uninsured Patients. HHS/HRSA requires services for COVID-19 Claims Reimbursement for Testing and Treatment to Health Care Providers Serving the Uninsured. The scope of activity will include:

1. Project Management
2. Intake Electronic and Paper Claims
 - a. Electronic Data Interchange
 - b. Paper Claim Intake, Scanning, and Optical Character Recognition
3. Claim Adjudication
 - a. Paper Remittance Advice
 - b. General Claims Processing
 - c. Back-End Processing
 - d. Remittance Advice and Explanation of Benefits
4. Provider Customer Service Program
 - a. Education and Outreach
 - b. Call Center
5. Provider Payment and Integrity
6. Security

B. Conditions:

There are no conditions to consider.

C. Background and Contracting History (if applicable):

HRSA does not have any history with similar work performed, however, CMS provided HRSA guidance on the matter. .

D. Funding Source:

Public Health and Social Services Emergency Fund.

E. Delivery or Performance Period (Trade-offs/Risks/Streamlining):

The period of performance will be for 12 months.

Funding constraints – No funding risk as Congress has allocated funds for this project.
Programmatic constraints – New program under HRSA, to mitigate impact subject matter experts across HRSA will be contacting CMS subject matter experts and contracting for program management services.

Time/Schedule constraints – Must be awarded immediately to meet health emergency

needs to mitigate the risk to the nation's healthcare system infrastructure. To mitigate the schedule constraints; FAR Emergency and streamline procedures will be use.

HRSA will utilize FAR 13 and 12 procedures to negotiate the definitization of this letter contract and ensure that a fair and reasonable cost/price is obtained.

A Quality Assurance Surveillance Plan (QASP) will be utilized to monitor performance of the contract, meeting schedules and acceptability of deliverables.

II. Plan of Action.

A. Market Research Results/Interested Sources:

As part of its market research, internet researches were conducted to find vendors as well as review a list of the Medicare Administrative Contractors (MAC). HHS and HRSA held conversations with representatives from some of the MAC contractors, and other sources to gain a better understanding of the capability of vendors regarding their claim processing systems, staffing, and structure. Sources that express their interest: Celerian Group-Palmetto, Accenture, United HealthCare Group, Health Smart.

B. Types of Small Businesses Considered (check all that apply):

(No foreign contractors will be permitted to participate at the prime contractor level, as no awards were made to foreign contractors.)

Small Business

HUBZone

Small Disadvantage Business 8(a)

Service-Disabled Veteran-Owned Small Business

Women Owned Small Business

Other Disaster Response Registry Search (<https://www.sam.gov>, Search Records, Advanced Search, Disaster Response Registry Search was reviewed. However given the magnitude, specialization and the urgency of the services there were no small business capable to provide these services. Small Businesses will be considered at time of contract definitization as sub-contractors.

C. Acquisition Approach:

1. Solicitation method to be utilized

GWAC/Best-In-Class/Strategic Source

Competitive

Sole Source

Other (Describe) Letter Contract – Limited Competition

2. Contract Type:

- Fixed-Price
- Cost Plus Fixed Fee
- Cost Reimbursement
- Time and Material/Labor Hour
- Cost Plus Award Fee
- Other (Specify) Letter Contract

3. Brief rationale for selecting the contract type:

In December 2019, a novel (new) coronavirus known as SARS-CoV was first detected in Wuhan, Hubei Province, People’s Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Services (HHS) declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. The Federal Government, along with State and local governments, has taken preventive and proactive measures to slow the spread of the virus and treat those affected, including by instituting Federal quarantines for individuals evacuated from foreign nations, issuing a declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and releasing policies to accelerate the acquisition of personal protective equipment and streamline bringing new diagnostic capabilities to laboratories. On March 11, 2020, the World Health Organization announced that the COVID-19 outbreak can be characterized as a pandemic, as the rates of infection continue to rise in many locations around the world and across the United States. On March 13, 2020, President Donald J. Trump announced and proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

Due to the urgent nature of this pandemic, a Letter Contract will be issued to provide an immediate response to assist the Nation’s Health Care Infrastructure by processing and reimbursing claims for uninsured patients. The services are commercial in nature; therefore a Firm Fix Price contract which shift the risk from the Government to the contractor will be awarded.

The CARES Act specifies that eligible health care providers are to be reimbursed for testing and treatment health of uninsured patients attributable to coronavirus

D. Competition:

- Competitive – Results (abstract, summary, etc.) attached.
- Sole/Limited Source – FAR required justifications must be attached.
- FAR 6.
 - 6.302-2 Unusual & Compelling
 - 6.302-1 Only One Source
 - 6 Other (insert FAR reference)
- FAR 8.
 - 8.405-6 Urgent and Compelling
 - 8.405-6 Only One Source

- 8 Other (insert FAR reference)
- FAR 13.
- 13.106-1(b) Soliciting From a Single Source
- FAR 16.
- 16.505(b) (2) Exception to the fair opportunity process
- Micro-Purchase (< \$10,000) – FAR 13.203(a) (2)
- Other Sole or Limited Source Justification. (Must insert FAR ref/authority).

E. Government-Furnished Property/Information:

None.

F. Inherently Governmental Functions:

Yes (Explain).

No

G. Other Considerations (Security, Information Technology, Personnel/Organizational Conflicts of Interest, Price Reasonableness, Price Gauging/Hoarding, Steps taken to ensure vaccines, therapeutics, and diagnostics developed are affordable in the commercial market, PII, etc.):

- HHS IT Cyber Security and Privacy language has been added to the PWS. This language includes the contractor requirements for security of PII data; records management and system security. HHSAR Section 508 clauses will also be included in the letter contract. The PWS is reviewed by HRSA IT staff to ensure that the appropriate language and IT requirement were included.
- The [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#), Public Law 104-191, included Administrative Simplification provisions that required HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information in the contract.
- Organizational Conflict of Interest Clause will be added to contract.

H. Attachments:

- SOW/PWS/SOO
- IGCE
- D&F
- Class J&A (applicable):
- Yes

___No

III. Coordination/Approval.

___ I hereby certify that (a) this requirement represents a bona fide need of the fiscal year or years for which the appropriation was made and complies with the Anti-deficiency Act; and (b) funds are committed for the entire performance period of this acquisition.

X I hereby certify that (a) this requirement represents a bona fide need of the fiscal year or years for which the appropriation was made and complies with the Anti-deficiency Act; and (b) funds are committed for prescribed under FAR 52.216-24 for Letter Contract.

___ Funds are not currently committed for this acquisition.

Robyn S. Ashton -S Digitally signed by Robyn S. Ashton -S
Date: 2020.04.13 12:57:55 -04'00'
Robyn Ashton, MSN, RN
Senior Advisor
Healthcare Systems Bureau
Health Resources and Services Administration

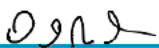
Date

Shirley Karver -S Digitally signed by Shirley Karver -S
Date: 2020.04.13 13:01:30 -04'00'
Shirley Karver
Senior Contracting Officer
Health Resources and Services Administration

Date

Alexandra B. Garcia -S Digitally signed by Alexandra B. Garcia -S
Date: 2020.04.13 13:11:12 -04'00'
Alexandra B. Garcia
Head Contracting Authority
Health Resources and Services Administration

Date


David R. Dasher (Apr 21, 2020)
David R. Dasher
Deputy Assistant Secretary, Office of Acquisitions
Senior Procurement Executive
U.S. Department of Health and Human Services

Apr 21, 2020
Date

*IAW Acquisition Alert 2020-04 SPE approval is required for actions exceeding \$150 million.

Signature: Mary Colman
Mary Colman (Apr 18, 2020)

Email: mary.coleman@hhs.gov

Signature: Tiffani Redding
Tiffani Redding (Apr 18, 2020)

Email: tiffani.redding@hhs.gov

Uninsured Claims Program IGCE

Assumptions	(b) (5), (b) (3) (A)	Estimated Number of uninsured	(b) (5), (b) (3) (A)
Estimated Number of uninsured		Project # of Treatment Claims	
Projected # of Testing Claims		Claims Program Budget	
Claims Program Budget			
Projected Uninsured Reimbursement Costs		Projected Uninsured Reimbursement Costs	
Cost of diagnostic test*		Treatment ****	
Cost of office visit**			
Total Estimated Reimbursement Amounts		Total Estimated Reimbursement Amounts	
Contractor Claim Processing Fee***		Contractor Claim Processing Fee***	
Program Management One Time		Program Management One Time	
Implementation Cost		Implementation Cost	
Telephone Calls Answered			
Total Estimated Contract Amount		Total Estimated Contract Amount	
Letter Contract 50% Requirement Amount		Letter Contract 50% Requirement Amount	

*<https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf>

**HCPCS 99214

<https://www.cms.gov/apps/physician-fee-schedule/search/search-results.aspx?Y=0&T=4&HT=0&CT=0&H1=99214&M=1>

***Based on Private Sector best in class benchmark from CMS

****Bases on projected amount from OPAE for expenditure of available fund

Market Research
COVID-19 Claims Reimbursement for Testing and Treatment
to Health Care Providers Serving the Uninsured
April 11, 2020

As part of its market research, HHS met with representatives from (b) (4), (b) (3) (A), (b) (4), (b) (3) (A) United Healthcare Services (UHC), and (b) (4), (b) (3) (A) to gain a better understanding of the capability of the vendors regarding their claim processing systems, staffing, and structure.

HHS research focused on five major topics:

1. Speed – How quickly can the solution be implemented?
2. Simplicity – Is the solution easily understood, and can it be quickly communicated?
3. Leverages existing capabilities – How can the vendor minimize new built up and use current technology as well to allow additional capacity?
4. Minimizes program risks (implementation risk, payment fraud) – How the proposed solution addresses benefits adjudication and what risk reviews are in place to avoid insurance fraud?
5. Adaptable if covered benefit is expanded to include ongoing treatment – Is the proposed solution able to grow with other required services?

(b) (4), (b) (3) (A)

UHC also has experience with CMS. In addition, as the largest insurer in the US, leveraging the strength of both United Healthcare and Optum, they are uniquely positioned to support this challenge. UHC extensive experience in payment validation and distribution includes processing (b) (4), (b) (3) (A)

(b) (4), (b) (3) (A)

(b) (4), (b) (3) (A)

HHS/HRSA reviewed past performance ratings for these contractors. The past performance ratings assess Quality, Schedule, Cost Control, Management, and Small Business subcontracting of each vendor. HHS evaluated two contracts rating cycles for each of the vendors.

(b) (4), (b) (3) (A)

(b) (4), (b) (3) (A)

United Healthcare Services had a rating of

(b) (4), (b) (3) (A)

(b) (4), (b) (3) (A)