

## Determination and Findings for HUBZone Sole Source Award to Element Solutions

### Conclusion:

CMS/CCSQ can use the authority under FAR 19.1306 to award a HubZone sole-source contract to Element Solutions llc. (see below for details)

### Federal Acquisition Regulation (FAR) Considerations:

#### **FAR 19.1306**

(a) A contracting officer **shall consider** a contract award to a HUBZone small business concern on a **sole-source basis** (see [6.302-5\(b\)\(5\)](#)) before considering a small business set-aside (see [19.203](#) and subpart [19.5](#)), **provided none of the exclusions at [19.1304](#) apply...**

#### **FAR19.1304**

(a) Requirements that can be satisfied through award to-

(1) Federal Prison Industries, Inc. (see [subpart 8.6](#)); or

(2) AbilityOne participating non-profit agencies for the blind or severely disabled (see [subpart 8.7](#));

(b) Orders under indefinite-delivery contracts (see subpart [16.5](#)). (But see [16.505\(b\)\(2\)\(i\)\(F\)](#) for discretionary set-asides of orders);

(c) Orders against Federal Supply Schedules (see subpart [8.4](#)). (But see [8.405-5](#) for discretionary set-asides of orders);

(d) Requirements currently being performed by an 8(a) participant or requirements SBA has accepted for performance under the authority of the 8(a) program, unless SBA has consented to release the requirements from the 8(a) program; or

(e) Requirements for commissary or exchange resale items.

### Analysis:

Requirement: This Determination and Findings (D&F) addresses the proposed sole source award to Element Solutions, LLC (Element), a certified Historically Underutilized Business Zone (HUBZone) small business concern, for a a FHIR-based bulk data client for large-scale data delivery service for healthcare.

1. Requirement Description: The requirement is for a FHIR-based bulk data client for large-scale healthcare data delivery service.
2. Market Research: Market research was conducted on 08/21/2025, using resources including video recorded vendor conferences originating from the CCSQ looking ahead event on 08/06/2025. Element provided a video submission detailing their point of view for a potential solution on 09/02/2025. The Government determined this to be a highly relevant and unique solution to their need to decrease the burden on healthcare providers in the submission of hospital quality data. The Government then researched Element through the Small business search dynamic tool and determined that they (Element) is a certified HubZone Small business with offices located at 14 Ridge Sq. NW, Suite 300 Washington, DC 20016.
3. HUBZone Capability: Market research indicates that Element has extensive FHIR experience on the Blue Button 2.0 & Beneficiary Claims Data (BCDA) application programming interfaces (API)s. Element has the capabilities, technical expertise, and experience to meet the Government's needs for a FHIR based solution to reduce clinician burdens. Specifically, the FHIR-based bulk data client for large-scale data delivery service for healthcare.
4. Lack of Reasonable Expectation of Two or More HUBZone Offers: Based on the market research, it is not reasonably expected that offers would be received from two or more responsible HUBZone small business concerns capable of meeting the Government's requirements at a fair and reasonable price given the extensive FHIR based experience situated with Element on the Blue Button 2.0 and BCDA contracts. Very few small businesses have this depth of experience and as of this writing CMS is not aware of any other HubZone certified small businesses with the same or similar capabilities with FHIR based APIs.
5. FAR 19.1304 Exclusions - Not Applicable: The proposed acquisition is not excluded from HUBZone sole source consideration under FAR 19.1304.
  - We searched for IT development and FHIR base API development on the list of offerings for the *Federal Prison Industries & AbilityOne*. These programs did not offer the required IT development services.
  - The IT development services cannot be satisfied and are not requirements for commissary or exchange resale items.
  - The Government plans to award a direct contract to Element under FAR 15 and the authorities under FAR 19. Accordingly, this is not an IDIQ

order using the procedures under FAR 16.5 neither is it a Federal Supply Schedule using the procedures under FAR 8.4

None of the exclusions under FAR 19.1304 apply.

6. Anticipated Contract Price: The estimated price of this contract, including options, is **TBD < \$4.5 million**, which does not exceed the FAR 19.1306(a)(2) threshold of \$7 million for manufacturing or \$4.5 million for other requirements].
7. Not an 8(a) Requirement: This requirement is not currently being performed by an 8(a) participant and has not been accepted as a requirement by the Small Business Administration (SBA) under Subpart 19.8 as it is a brand new requirement.
8. Responsibility: Element is a responsible contractor for this requirement. They are not on the list of parties excluded and they are up to date with an active System for Award Management (SAM) registration.
9. Fair and Reasonable Price: Award can be made at a fair and reasonable price, as confirmed by using the price analysis techniques at FAR 15.404.

#### Findings:

A potential HUBZone set-aside is unlikely to attract two or more qualified HUBZone offers due to the specialized nature of the requirement and the limited number of eligible HUBZone businesses possessing the required capabilities for FHIR based API development services. Considering the benefits of the HUBZone program, a sole source award to Element, a certified HUBZone concern, under the authority of FAR 19.1306 and in accordance with the policies in FAR 19.1305(b). Additionally, market research confirmed that the exclusions listed in FAR 19.1304 do not apply to this acquisition, further supporting the decision to consider a HUBZone sole source award. A responsible determination was made for Element, and a fair and reasonable price has been established and is expected. The decision to pursue a sole source award, in this instance, aligns with the objectives of the HUBZone program to foster economic growth and create employment opportunities within designated HUBZone areas.

#### Determination

Based on the findings and analysis, a sole source award to Element is justified under FAR 19.1306. This award will be made at a fair and reasonable price and is considered to be in the best interest of the Government.

## **FHIR Pilot Project**

### **Project Roadmap and Gate Reviews:**

#### **1. Sprint Team Gate 1 - Discovery and Prototype Development**

**Duration: Four (4) - Months**

##### **Deliverable Description:**

- Use Case Identification
- Wireframe Solution
- Proof of Concept

**General Tasks/Services:** Leading up to Gate Check 1 typical tasks & services include but are not limited to the following:

- Front-End Development
- Back-End Development
- Research & Analysis
- Stakeholder Interviews

Estimated Staffing Plan:

| Labor Category                             | Hourly Rate | Number of Hours | Total    |
|--|-------------|-----------------|----------|
| FHIR Subject Matter Expert (SME)           |             |                 |          |
| Senior Technical Lead / Solution Architect |             |                 |          |
| Full-Stack Developer                       |             |                 |          |
| Product Manager                            |             |                 |          |
|  |             |                 | 4-months |

#### **2. Sprint Team Gate 2 - FHIR Pilot Minimum Viable Product (MVP) Development**

**Duration: Six (6) - Months**

Deliverable Description:

- MVP

**General Tasks/Services:** Leading up to Gate Check 1 typical tasks & services include but are not limited to the following:

- Front-End Development
- Back-End Development
- Functionality & Feature Development
- Research & Analysis
- Stakeholder Interviews
- Product Features/Design
- Cybersecurity Patching and Hardening

Estimated Staffing/Pricing:

| Labor Category                             | Hourly Rate | Number of Hours | Total    |
|--|-------------|-----------------|----------|
| FHIR Subject Matter Expert (SME)           |             |                 |          |
| Senior Technical Lead / Solution Architect |             |                 |          |
| Full-Stack Developer                       |             |                 |          |
| Product Manager                            |             |                 |          |
| Data Engineer                              |             |                 |          |
| Full Stack Developer                       |             |                 |          |
| Security Engineer                          |             |                 |          |
|  |             |                 | 6-months |

**3. Sprint Team Gate 3 - FHIR Pilot Development Production Ready and Deployment**

**Duration: Twelve (12) - Months**

Deliverable Description:

- AI Process Automation Production Ready Solution

**General Tasks/Services:** Leading up to Gate Check 1 typical tasks & services include but are not limited to the following:

- Front-End Development
- Back-End Development
- Functionality & Feature Development
- Research & Analysis
- Stakeholder Interviews
- Product Design and use Refinement
- Authority to Operate (ATO) Support
- Application Programming Interface (API) Connection
- Data Compilation
- Cybersecurity Patching and Hardening

Estimated Staffing Plan:

| Labor Category                             | Hourly Rate | Number of Hours | Total |
|--|-------------|-----------------|-------|
| FHIR Subject Matter Expert (SME)           |             |                 |       |
| Senior Technical Lead / Solution Architect |             |                 |       |
| Full-Stack Developer                       |             |                 |       |
| Product Manager                            |             |                 |       |
| Data Engineer                              |             |                 |       |
| Full Stack Developer                       |             |                 |       |
| Full Stack Developer                       |             |                 |       |
| Security Engineer                          |             |                 |       |
| Scrum Master                               |             |                 |       |
| ML Engineer / Data Scientist               |             |                 |       |

|  |  |  |           |
|--|--|--|-----------|
|  |  |  | 12-months |
|--|--|--|-----------|