



REQUEST FOR QUOTE
Image Processing, Modeling and Simulation Software
RFQ-75F40126Q00136

Food and Drug Administration (FDA) Request for Quotation (RFQ)	
Reference #: RFQ-75F40126Q00136	
RFQ Title: <i>Image Processing, Modeling and Simulation Software</i> NAICS Code 541519	
RFQ Issue Date: 6/16/2026	RFQ Close Date: 6/23/2026 Required Submission Time: 3PM ET
F.O.B Point: Destination U.S. Food and Drug Administration White Oak Data Center (WODC) 10903 New Hampshire Avenue Silver Spring, Maryland 20993	Individual Receiving Shipment: Licenses shall be digitally provided. Point of Contact will be provided at award.
The Government anticipates awarding a firm fixed price (FFP) purchase order resulting from this solicitation for all items defined in the pricing table. The required delivery date for the items is on or before Sep 30, 2026.	
This is a combined synopsis/solicitation for commercial products or commercial services in accordance with the format in Federal Acquisition Regulation (FAR) Part 12, as supplemented with additional information included in this Request of Quotation. This announcement constitutes the only solicitation and quotes are being requested.	
NOTICE OF FAC This procurement is a total small business set aside. The applicable size standard is 150 employees. This solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2026-01, effective 13 March 2026. FAR and HHSAR provisions and clauses referenced in this RFQ can be found on the following website: https://www.acquisitions.gov	

Pricing Schedule Table

Item No.	Description	Line Item Type	Qty	Unit	Quoted Price
001	Image Processing Cloud-Based Platform	FFP	1	12 Months	
002	Delivery, Installation and On-Site Training	FFP	1	12 Months	

1. SALIENT CHARACTERISTICS OF REQUIRED SOFTWARE

The Food and Drug Administration (FDA); Division of Product Quality and Research (DPQR) requires an advanced image analysis platform that can provide the reviewers and regulatory researchers to assess the impact of process parameters and material attributes on product quality attributes, such as content uniformity, microstructural deformation, and release profile. A cloud-based powerful image analysis platform can meet these requirements. DPQR has its own high performance computing (HPC) environment. This HPC environment can provide few unique advantages as follows:

- Host the cloud-based platform
- Support the high storage requirement
- Provide faster image processing capability

The cloud-based image processing platform should provide a comprehensive workflow, data management, storage management, computing resource management capability. The platform needs to host unique analysis capability that can allow users to quickly analyze and correlate microstructural transformation due to process changes to assess the product's critical quality attributes. The platform needs to demonstrate a proven track record on solving pharmaceutical and regulatory science challenges involving imaging data. The platform needs to be deployed on FDA HCP clusters with a Linux based system that meets the required specifications.

As the system will be installed in FDA DPQR proprietary HPC cluster, there is no security risk. Technical risks on knowledge transfer are mitigated via training and support packages included. Administrative and financial risks are mitigated via annual renewal of the subscription contract.

2. SCOPE

The Contractor shall provide the image processing, modeling and simulation software as follows:

Item 001: Image Processing Cloud-Based Platform

The required technical features of cloud-based image processing software are:

- Provide a comprehensive workflow, data management, storage management, computing resource management capability.
- Manage and share large volumes of image and quantitative data.
- Create and manage complex image processing workflows.
- Segment complex imaging data from pharmaceutical samples through the use of traditional, machine learning and deep learning techniques.
- Extract quantitative information from complex data that can be used to make real world decisions.
- Predictively simulate critical quality attributes of various complex datasets.
- Browser based user interface, with multi-user support.
- The platform needs to be deployed on FDA HCP clusters with a Linux based system that meets the required system specifications.

- Quality control, FDA 21 CFR Part 11 Compliance and Audit Trail Support.
- Features a digital queue management system preventing users from overloading their computing resources. More or less resources can be allocated as need or lack of need arises.
- Cloud-based, fully integrated software platform with proven regulatory science application.
- The platform needs to demonstrate a proven track record on solving pharmaceutical and regulatory science challenges involving imaging data

The HPC system requirements are:

- Google Chrome browser
- CPU: 8 core or more
- Memory: 128G or more
- Instance Storage: 2T or more
- GPU
- Operating System: Ubuntu 20.04 (or latest version of Redhat if Ubuntu cannot be used)
- Software requirements: latest version of Docker and Docker compose should be installed.

DPQR HPC environments meet these requirements.

Item 002: Delivery, Installation, and On-site training

The vendor will cover all costs associated with the following:

- System software, shipping, and delivery.
- Full system installation in person or screen sharing support on FDA DPQR in house HPC cluster with the help of client's IT professional.
- User training.
- On-demand customer support.

3. DELIVERY REQUIREMENTS

The above items shall be delivered according to the defined required delivery date The vendor shall deliver all software as detailed in Sections 2 and 3 of this delivery order as follows:

SHIPPED TO:

ATTN: (To Be Determined) Food
and Drug Administration 10903
New Hampshire Ave Building 64,
Room 1068
Silver Spring, MD 20993

The Contractor shall deliver the required license deliverables via secure e-mail or via website download within thirty (30) calendar days after award to the Contracting Officer's Representative (COR)

4. REQUIRED DELIVERY DATE

The anticipated software license period shall consist of one (1) 12-month term, with active software coverage from September 30, 2025, through September 29, 2026.

5. CONTRACT TYPE

See pricing table within.

6. CONTRACT MANAGEMENT

Contracting Officer (CO):

Narissa Charles

Narissa.charles@fda.hhs.gov

Contracting Specialist (CS): Robert Waite

robert.waite@fda.hhs.gov

Contracting Officer's Representative (COR):

(To be entered at time of award)

7. CONTRACTING OFFICER'S AUTHORITY

The **Contracting Officer (CO)** is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the RFQ; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract. No statement, whether oral or written, by anyone other than the Contracting Officer, shall be

interpreted as modifying the terms and conditions of this award. It is the Contractor's responsibility to contact the CO immediately if there is even the appearance of any technical direction that is or may be outside the scope of the award. The Government will not reimburse the Contractor for any work not authorized by the Contracting Officer, including work outside the scope of the award.

The **Contracting Officer's Representative (COR)** is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the contract and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

8. IPP INVOICE REQUIREMENTS

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

- (a) All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).
<http://www.ipp.gov/vendors/index.html>
- (b) Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is:
<https://www.ipp.gov>.
- (c) The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
 - (1) Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov . or phone (866) 973-3131. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or

phone (866) 973-3131.

- (2) The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
 - (3) If your company is already registered to use IPP, you will not be required to re-register.
 - (4) If the Contractors unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.
- (d) Invoices that include time and materials, or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).
- (e) Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.
- (1) At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.
 - Direct Labor-include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
 - Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirect)-show rate, base and total amount;
 - Consultants (if applicable)-include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
 - Travel-include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
 - Subcontractors (if applicable)-include, for each subcontractor, the same data as required for the Prime Contractor;
 - Other Direct Costs-include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and-
 - Fee-amount as allowable in accordance with the Schedule and FAR52.216-8 if

applicable.

- (f) Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:
- (1) list of all invoices submitted to date under the subject award, including the following:
 - invoice number, amount, & date submitted
 - corresponding payment amount & date received
 - total amount of all payments received to date under the subject contractor order
 - and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.
- (g) Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.
- (h) If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.
- (i) Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.
- (j) The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.
- (k) Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

(END OF CLAUSE)

9. PAYMENT TERMS

Payment terms Net 30 days after government acceptance of the supply item / service. Payments shall not be made more frequently than monthly in arrears. Advance payments will not be made.

10. INSPECTION & ACCEPTANCE

Pursuant to FAR clause 52.212-4 (b), inspection and acceptance shall occur F.o.B destination. The Government has the right either to reject or to require correction of nonconforming supplies. Supplies are nonconforming when they are defective in material or workmanship or are otherwise not in conformity with contract requirements. The Government may reject nonconforming supplies with or without disposition instructions.

The COR will perform inspection and acceptance of all products and services. The performance criteria for these products shall be timely delivery and closure of all activities and deliverables listed above and within the established Period of Performance.

Inspection and acceptance will occur at the place of delivery. Inspection will include verifying all parts were received and warranties and services are in place. The Government will accept goods and services only if they conform to all terms and conditions of this order. The Government will provide written notification of acceptance or rejection within ten (10) business days of receiving the delivery.

The Government will reject non-conforming products and services. The Contractor shall correct any deficiencies within thirty (30) days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this time frame, the Contractor shall immediately notify the COR or technical POC of the reason for the delay and provide a proposed corrective action plan within ten (10) business days.

All quoter's shall be authorized reseller and/or servicing agent shall identify and/or provide documentation to confirm their claim as an authorized reseller and/or servicing agent.

All Offerors' quote shall clearly state license number, product description, quantity, price, and period of performance for each product. The quotation shall include and match license number, product description, quantity, and period of performance. Offerors are advised that should their quotation conflict with or does not clearly reflect the specified product and requirement of this solicitation, their quotation may be deemed as technically unacceptable and may not be considered for award.

Price: Provide a detailed quote for each item/component proposed to the schedule of items. Discounts are highly encouraged.

The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of macros. If the offeror or applicant submits documents that contain macros the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or

applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offerors or applicant's responsibility to ensure all electronic documents are submitted without the use of macros.

11. FAR / HHSAR CLAUSES**Provisions and Clauses****FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)**

This contract incorporates one or more clauses by reference, with the same force and effect as if they were

given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<https://www.acquisition.gov/far/52.252-2>

52.212-4 Terms and Conditions—Commercial Products and Commercial Services. (NOV 2025)

As prescribed in 12.205(b)(3), insert the following clause:

Terms and Conditions—Commercial Products and Commercial Services (Deviation Date)

(a) *Definitions*. The clause at Federal Acquisition Regulation (FAR) 52.202-1, Definitions, is incorporated by reference.

(b) *Inspection/Acceptance*. The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post acceptance rights—

(1) Within a reasonable time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(c) *Assignment*. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (*e.g.*, use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(d) *Changes*. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(e) *Disputes*. This contract is subject to 41 U.S.C. chapter 71, Contract Disputes. Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal, or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause FAR 52.233-1, Disputes, which is incorporated in this contract by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(f) *Excusable delays*. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence. Examples of occurrences include acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. When an excusable delay occurs, the Contractor shall—

(1) Notify the Contracting Officer in writing as soon as possible;

(2) Remedy the delay as quickly as possible; and

(3) Notify the Contracting Officer when the occurrence is over.

(g) *Invoice*. The Government will handle invoices according to the Prompt Payment Act (31 U.S.C. 3903) and 5 CFR part 1315. The Contractor shall submit invoices to the address designated in the contract to receive invoices. An invoice must include the information required by 5 CFR part 1315.9(b).

(h) *Patent indemnity*. The Contractor shall indemnify the Government and its officers, employees, and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark, or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) *Payment*—

(1) *Items accepted*. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) *Prompt payment*. The Government will make payment in accordance with the Prompt Payment Act ([31 U.S.C. 3903](#)) and prompt payment regulations at 5 CFR part 1315.

(3) *Discount*. In connection with any discount offered for early payment, time shall be computed from the date of

the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date that appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(4) *Overpayments.* If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall—

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the—

(A) Circumstances of the overpayment (*e.g.*, duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected line item or subline item, if applicable;

(D) Contractor point of contact; and

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(5) *Interest.*

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) *Final decisions.* The Contracting Officer will issue a final decision as required by FAR part 33 if—

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see FAR part 32).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a termination for cause.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on—

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures for interest credits prescribed in FAR part 32 in effect on the date of this contract.

(j) *Risk of loss.* Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon—

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) *Taxes.* The contract price includes all applicable Federal, State, and local taxes and duties.

(l) *Termination for the Government's convenience.* The Government reserves the right to terminate this

contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) *Termination for cause.* The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. The Government will send a cure notice to the Contractor, unless the reason for the termination is late delivery. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) *Title.* Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) *Warranty.* The Contractor warrants and implies that the items delivered under this contract are merchantable and fit for use for the particular purpose described in this contract.

(p) *Limitation of liability.* Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) *Compliance with laws unique to Government contracts.* The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 49 U.S.C. 40118, Government-financed air transportation; and 41 U.S.C. chapter 21 relating to procurement integrity.

(r) *Order of precedence.* Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

- (1) The schedule of supplies/services;
- (2) The Disputes, Payments, Invoice, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause;
- (3) Other contract clauses incorporated in the solicitation or contract;
- (4) Addenda to this solicitation or contract;
- (5) Solicitation provisions incorporated in the solicitation;
- (6) Other paragraphs of this clause;
- (7) Other documents, exhibits, and attachments; and
- (8) The specification.

(s) *Unauthorized obligations.*

(1) Except as stated in paragraph (s)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government-authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

- (iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.
- (2) Paragraph (s)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.
- (t) *Comptroller General examination of record.* This paragraph applies if this contract was awarded using other than sealed bid procedures and is in excess of the simplified acquisition threshold on the date of award of this contract.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
- (2) The Contractor shall make available at its offices, at all reasonable times, the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR part 4, longer period required by statute, or periods specified in other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.
- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This clause does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (u) *Incorporation by reference.* The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.
- (End of clause)

52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (SEP 2007)
52.203-18	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation (JAN 2017)
52.204-7	System for Award Management—Registration (NOC 2024)
52.204-90	Offeror Identification (APR 2026)
52.207-6	Solicitation of Offers from Small Business Concerns and Small Business Teaming Arrangements or Joint Ventures (Multiple-Award Contracts) (OCT 2023)
52.209-12	Certification Regarding Tax Matters (OCT 2020)
52.219-2	Equal Low Bids (OCT 1997)
52.219-6	Notice of Total Small Business Set-Aside (NOV 2020)
52.222-18	Certification Regarding Knowledge of Child Labor for Listed End Products (FEB 2024)
52.222-48	Exemption from Application of the Service Contract Labor Standards for Maintenance, Calibration, or Repair of Certain Equipment—Certification (MAY 2014)
52.222-50	Combating Trafficking in Persons (APR 2026)
52.222-56	Certification Regarding Trafficking in Persons Compliance Plan (MAR 2015)
52.222-90	Addressing DEI Discrimination by Federal Contractors (APR 2026)
52.223-4	Recovered Material Certification (MAY 2008)
52.225-2	Buy American Certificate (OCT 2022)
52.225-4	Buy American-Free Trade Agreements-Israeli Trade Act Certificate (NOV 2021)
52.225-6	Trade Agreements-Certificate (FEB 2021)
52.226-3	Disaster or Emergency Area Representation (NOV 2007)
52.226-8	Encouraging Contractor Policies to Ban Text Messaging While Driving. (MAY 2024)
52.229-11	Tax on Certain Foreign Procurements—Notice and Representation (FEB 2021)
52.240-90	Security Prohibitions and Exclusions Representations and Certifications (APR 2026)

HHSAR CLAUSES:

This contract incorporates one or more HHSAR clauses by reference, with the same force and effect as if they were given in full text. The full text of the HHSAR clauses may be accessed electronically at this address: <http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

HHSAR 352.222-70: Contractor Cooperation in Equal Employment Opportunity Investigations (Dec 2015)

HHSAR 352.232-71: Electronic Submission of Payment Requests (FEB 2022)

- (a) *Definitions.* As used in this clause –
Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.
- (b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.
- (c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.
- (d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

HHSAR 352.239-74: Electronic and Information Technology Accessibility (DEC 2015)

- (a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the “Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards” set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the “Access Board”) in 36 CFR part 1194. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.
- (b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- (c) The Section 508 accessibility standards applicable to this contract are:
- Must meet WCAG 2.0 A and AA
 - E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)

- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
 - E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
 - E205 Electronic Content (Appendix A, Application and Scoping Requirements)
 - 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
 - E207 Software
 - E208 Support Documentation Services
 - Chapter 5: Software
 - Chapter 6: Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)
- (d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS website: (<http://www.hhs.gov/web/508>). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- (e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://www.hhs.gov/web/508> . If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(END OF CLAUSE)

13. FAR / HHSAR PROVISIONS

FAR 52.252-1: Solicitation Provisions Incorporated by Reference (Feb 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The quoter is cautioned that the listed provisions may include blocks that must be completed by the quoter and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the quoter may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <https://www.acquisition.gov/browse/index/far>

FAR PROVISIONS:

FAR 52.204-7 System for Award Management (Nov 2024)

FAR 52.204-16 Commercial and Government Entity Code Reporting (Jul 2016)

HHSAR CLAUSES:

HHSAR Clauses By Full Text:

HHSAR 352.203-70 Anti-Lobbying (Dec 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:

- (a) Publicity or propaganda purposes;
- (b) 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; or
- (c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, 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.
- (d) The prohibitions in subsections (a), (b), and (c) above shall 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 for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

(End of clause)

HHSAR 352.204-72 Records Management (Feb 2024) (RFO DEVIATION)

As prescribed in 304.7004, insert the following clause:

RECORDS MANAGEMENT (FEB 2024) (DEVIATION)

(a) Applicability. This clause applies to contracts that include Federal records, as defined in paragraph (b).

(b) Definition. As used in this clause—

Federal record means all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them. See 44 U.S.C. 3301

(1) The term Federal record—

- (i) Includes HHS records;
- (ii) Does not include personal materials;
- (iii) Applies to records created, received, or maintained by Contractors pursuant to their contract; and
- (iv) May include deliverables and documentation associated with deliverables.

(2) Recorded information means all traditional forms of records, regardless of physical form or characteristics, including information created, manipulated, communicated, or stored in digital or electronic form. (See 44 U.S.C. 3301.)

(3) Personal materials means documentary materials belonging to an individual that are not used to conduct agency business. Personal files are excluded from the definition of Federal records and are not owned by the Government. (See 36 CFR 1220.18.)

(c) Requirements.

- (1) The Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chapters 21, 29, 31, 33), NARA regulations at 36 CFR chapter XII subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all Federal records, regardless of form or characteristics, mode of transmission, or state of completion.
- (2) In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), and the Privacy Act of 1974 (5 U.S.C. 552a), and must be managed and scheduled for disposition only as permitted by statute or regulation.
- (3) In accordance with 36 CFR 1222.32, the Contractor shall maintain all Federal records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.
- (4) The Contractor is responsible for preventing the alienation or unauthorized destruction of Federal records, including all forms of mutilation. Federal records may not be removed from the legal custody of HHS or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Contracting Officer. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. The Contractor shall report to the Contracting Officer any unlawful or accidental removal, defacing, alteration, or destruction of Federal records.
- (5) The Contractor shall immediately notify the Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the contract. The Contractor shall ensure that appropriate personnel are trained to adhere to these contract requirements, and that applicable, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of information, data, documentary material, Federal records and/or equipment is properly protected. The Contractor shall not remove Federal Records from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Contracting Officer. When information, data, documentary material, Federal records and/or equipment are no longer required, it shall be returned to HHS control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or as otherwise directed by the Contracting Officer. Destruction of Federal records is expressly prohibited unless in accordance with paragraph (c)(4).
- (6) The Contractor shall only use Government information technology equipment for purposes specifically authorized by the contract and in accordance with HHS policy.
- (7) The Contractor shall not create or maintain any Federal records containing any non-public HHS information that are not specifically authorized by the contract.
- (8) The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.
- (9) All Contractor employees assigned to this contract handle Federal records are required to take HHS-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.
- (d) Subcontract flowdown. The Contractor shall incorporate the substance of this clause, its terms and requirements including this paragraph, in all subcontracts under this contract.]

Health information technology (health IT) means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information. (42 U.S.C. 300jj)

Individually identifiable health information means information that is a subset of health information, including demographic information collected from an individual, and:

- (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i)

That identifies the individual; or

(ii)

With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (42 U.S.C. 300jj, 1320d)

ONC Health Information Technology Certification Program means the certification program administered by the HHS Office of the National Coordinator for Health Information Technology (ONC) using a third-party conformity assessment program for health IT. Certification criteria for the Program, which incorporate standards and implementation specifications in 45 CFR part 170 subpart B, are found in 45 CFR part 170, subpart C.

(b) Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), Pub. L. 111-5, Title XIII, sections 13111 and 13112, by submission of an offer and execution of a contract, the Contractor agrees that—

(1) For any work performed under the contract that involves implementing, acquiring, or upgrading health IT used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities, the Contractor will utilize health IT that—

- (i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support the work performed under the contract; and
- (ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support the work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the Contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act, or when the Contractor is implementing, acquiring or upgrading technology to be used by an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act.

(2) If the Contractor is a health care provider, health plan, or health insurance issuer, or is establishing an agreement with a health care provider, health plan, or health insurance issuer, for work performed under the contract that involves implementing, acquiring, or upgrading health IT, the Contractor will utilize health IT that—

- (i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support the work performed under the contract; and
- (ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support the work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the Contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act, or when the Contractor is implementing, acquiring or upgrading technology to be used by an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act.

(b)

If standards and implementation specifications adopted in 45 CFR part 170, subpart B, cannot support the work as specified in the contract, the Contractor is encouraged to use health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at <https://www.healthit.gov/isa/>.

(End of clause)

HHSAR 352.239-71 Security Requirements for Information Technology Resources (Feb 2024) Deviation
As prescribed in 339.106-70(a), insert the following clause:

SECURITY REQUIREMENTS FOR INFORMATION TECHNOLOGY RESOURCES (FEB 2024) (DEVIATION)

(a) Definitions. As used in this clause—

Information technology has the same meaning in FAR 2.101.

Information and communication technology (ICT) also means information technology (see FAR 2.101 for definitions).

Information system security plan means a formal document that provides an overview of the security requirements for an information system or an information security program and describes the security controls in place or planned for meeting those requirements.

(b) Responsibilities. The Contractor shall be responsible for information technology security for all systems connected to a Department of Health and Human Services (HHS) network or operated by the Contractor for HHS, regardless of location. This clause is applicable to all or any part of the contract that includes information technology resources or services in which the Contractor has physical or other system access to HHS information that directly supports the mission of HHS. Examples of tasks that require security provisions include—

(1) Hosting of HHS e-Government sites or other information technology operations;

(2) Acquisition, transmission, or analysis of data owned by HHS with significant replacement cost should the contractor's copy be corrupted; and

(3) Access to HHS general support systems/major applications at a level beyond that granted the general public, e.g., bypassing a firewall.

(c) Information system security plan. The Contractor shall develop, provide, implement, and maintain an Information System Security Plan. HHS information system and platform information technology systems must have a security plan that provides an overview of the security requirements for the system and describes the security controls in place or the plan for meeting those requirements. Generally, this plan shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of information system resources developed, processed, or used under this contract. The security plan should include implementation status, responsible entities, resources, and estimated completion dates. Security plans may also include, but are not limited to, a compiled list of system characteristics or qualities required for system registration, and key security-related documents such as a risk assessment, privacy impact assessment (PIA), system interconnection agreements, contingency plan, security configurations, configuration management plan, incident response plan, and the system privacy plan, as determined by the Contracting Officer's Representative. The plan shall address the specific contract requirements regarding information systems or related support or services included in the contract, to include the PWS or SOW. The Contractor's Information System Security Plan shall comply with applicable Federal Laws that include, but are not limited to, 40 U.S.C. 11331, the Federal Information Security Modernization Act (FISMA) of 2014 and the E-Government Act of 2002. The plan shall meet information technology security requirements in accordance with Federal and HHS policies and procedures, and as amended during the term of this contract, and include, but are not limited to the following:

(1) OMB Circular A-130, Managing Information as a Strategic Resource;

(2) National Institute of Standards and Technology (NIST) Guidelines;

(3) Federal Information Processing Standard (FIPS) 200; and

(4) HHS Cybersecurity Program related to HHS information (including HHS sensitive information and information systems security and privacy), as well as those set forth in the contract specifications, statement of work, or performance work statement. These include, but are not limited to, the Cyber Security Checklist and Cyber Security Infographic at <https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html>, which provides HHS procedures, responsibilities, and processes for complying with current Federal law, Executive Orders, policies, regulations, standards and guidance for protecting HHS information, information systems (see 302.101, Definitions), information technology, and ICT, security and privacy, and adhering to personnel security requirements when accessing

HHS information or information systems.

(d) Submittal of plan. Within 60 days after contract award, the Contractor shall submit the Information System Security Plan to the Contracting Officer for review and approval.

(e) Authority to Operate (ATO). As required by current HHS policy, the Contractor shall submit written proof of information technology security accreditation with a valid ATO to the Contracting Officer. Such written proof may be furnished either by the Contractor or by a third party. Accreditation shall be in accordance with HHS policy available from the Contracting Officer upon request. The Contractor shall submit for acceptance by the Contracting Officer along with this ATO a final security plan, risk assessment, security test and evaluation, privacy threshold analysis or privacy impact assessment, and a disaster recovery plan/continuity of operations plan.

(f) Annual validation. On an annual basis, the Contractor shall verify in writing to the Contracting Officer that the IT Security Plan remains valid.

(g) Banners. The Contractor shall ensure that the official HHS banners are displayed on all HHS systems (both public and private) operated by the Contractor that contain Privacy Act or other sensitive information before allowing anyone access to the system. The Office of Information Technology will make official HHS banners available to the Contractor.

(h) Screening and access. The Contractor shall screen all personnel requiring privileged access or limited privileged access to systems operated by the Contractor for HHS or interconnected to an HHS network in accordance with HHS policies referenced in paragraph (c).

(i) Training. The Contractor shall ensure that its employees performing services under this contract complete HHS security awareness and privacy training on an annual basis. This includes signing an acknowledgment on an annual basis that they have read, understand, and agree to abide by the HHS Rules of Behavior for the Use of HHS Information and IT Resources Policy as required; FAR 39.105, Privacy; clause 352.204-71, Information and Information Systems Security, and this clause.

(j) Government access. The Contractor shall provide the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, information systems, databases, and personnel used in performance of the contract. The Contractor shall provide access to enable a program of information technology inspection (to include vulnerability testing), investigation and audit (to safeguard against threats and hazards to the integrity, availability and confidentiality of HHS data or to the function of information technology systems operated on behalf of HHS), and to preserve evidence of computer crime.

(k) Notification of termination of employees. The Contractor shall immediately notify the Contracting Officer when an employee who has access to HHS information systems or data terminates employment.

(l) Subcontract flow down requirement. The Contractor shall incorporate and flow down the substance of this clause to all subcontracts that meet the conditions in paragraph (a) of this clause.

(End of clause)

HHSAR 352.232-71 Electronic Submission of Payment Requests (APR 2026) (RFO DEVIATION)

(a) Definitions. As used in this clause -

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request. (End of Clause)

HHSAR 352.239-73: Electronic and Information Technology Accessibility Notice (DEC 2015)

(a) As prescribed in HHSAR 339.203-70(a), the Contracting Officer shall insert the following provision:

Electronic and Information Technology Accessibility Notice (DEC 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document - in detail - whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://www.hhs.gov/web/508>. In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

HHSAR 352.239-74: Electronic and Information Technology Accessibility (Dec 2015)

The following Section 508 provisions apply:

- § 1194.21 - Software applications and operating systems.
- § 1194.22 - Web-based intranet and internet information and applications.
- § 1194.31 - Functional performance criteria.
- § 1194.41 - Information, documentation, and support.

HHSAR Provisions

HHSAR 352.239-72 Information Technology Security Plan and Accreditation (Apr 2026) (RFO Deviation)

(a) As prescribed in HHSAR 339.203-70(a), the Contracting Officer shall insert the following provision:

Electronic and Information Technology Accessibility Notice (DEC 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document - in detail - whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://www.hhs.gov/web/508>.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not

conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

18.0 Section 508 Compliance

The following standards are always required to be applied for contracts:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at <http://508.hhs.gov/>, or from the Section 508 Coordinator listed at <https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html>. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.
- E207 Software (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)

Appropriate Technical Performance and Technical Requirement from Appendix C

- Chapter 5 Software (Appendix C, Functional Performance Criteria and Technical Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)

Per 339.203-70 Contract Clauses for Electronic and Information Technology (EIT) Acquisitions

- (a) The contracting officer shall insert the provision at 352.239-73, Electronic and Information Technology Accessibility Notice, in all solicitations.
- (b) The contracting officer shall insert the clause at 353.239-74, Electronic and Information Technology Accessibility, in all contracts and orders.

14. SPECIAL NOTICE AND AGREEMENT REGARDING SOFTWARE EULA/TOS

Computer software and services are often subject to license agreements, referred to as End User License Agreements (EULA), Terms of Service (TOS), or other similar legal instruments or agreements. Many of these agreements contain indemnification clauses that are inconsistent with Federal law and unenforceable, but which could create a violation of the Anti-Deficiency Act (31 U.S.C. 1341) if agreed to by the Government.

Therefore, by submitting a quotation the quoter shall agree that the inclusions of any Limitation of Liability, Indemnification, and any clauses that conflict with Federal law or regulation in any EULA or TOS are NULL AND VOID. The quoter agrees that any EULA/TOS clauses conflicting with Federal law or regulation and are not agreed to by the Government if included with the submission of a quotation. Additionally, by submission of the quotation the quoter must agree to the inclusion of FAR 52.232-39: Unenforceability of Unauthorized Obligations in any resulting contract or order, if awarded.

15. AUTHORIZED RESELLER / SERVICING AGENTS

The Contractor shall be the software Original Equipment Manufacturer (OEM) or an authorized reseller/servicing agent of the software OEM. The Contractor shall not void any warranties, usage terms

and conditions of the FDA's perpetual licenses.

The Contractor shall notify the Contract Specialist / Contracting Officer immediately if this requirement is registered by a reseller with the OEM.

16. LANGUAGE FOR INSERTION IN ACQUISITION DOCUMENTATIONS BASED ON THE CHANGE TO DISABLE MACROS IN MICROSOFT OFFICE DOCUMENTS FROM OUTSIDE SOURCES

Be advised that FDA does not accept documents which contain the use of macros. Document submissions required throughout the award period(s) shall not have macro enabled functionality and any document delivered having that functionality will be deemed delinquent, if not corrected prior to the due date.

(END OF CLAUSE)

17. ORDER OF PRECEDENCE

The Contractor shall follow the terms and conditions of this contract. Should the Contractor include any additional terms and conditions resulting in conflicts between this document and the Contractor's document, the Order of Precedence shall be as specified in *FAR Clause 52.212-4*. The Contractor shall not auto-renew any subscriptions, licenses, maintenances and services not authorized under this contract. Any auto-renewals are at the risk of the Contractor, and the Government will not reimburse the Contractor.

18. INSTRUCTIONS

52.212-1 Instructions to Quoters

All questions in response to this solicitation shall be submitted on or before 06/22/2026, 3:00 pm Washington DC Local Time. All questions shall be submitted via email to Robert Waite, Contract Specialist, robert.waite@fda.hhs.gov.

Provided as addenda to FAR provision 52.212-1 Instructions to Offerors—Commercial Products and Commercial Services (RFO APR 2026) quoters are advised as follows:

(a) Submission of offers. Submit signed and dated offers to the office specified in this solicitation at or before the exact time specified in this solicitation. As a minimum, offers shall include—

- (1) The solicitation number; RFQ-75F40126Q00136
- (2) The name, address, telephone number of the Offeror;
- (3) The Offeror's Unique Entity Identifier (UEI) and, if applicable, Electronic Funds Transfer (EFT) indicator;
- (4) Information necessary to evaluate the factors contained in the provision at 52.212-2 or as described in the solicitation; Quoters are to input their pricing in table provided on page 2 of this solicitation.
- (5) Responses to provisions that require Offeror completion of information, representations, and certifications (other than those collected via the System for Award Management (SAM)); and
- (6) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and any solicitation amendments.

(b) Period for acceptance of offers. The Offeror agrees to hold the prices in its offer firm for 60 calendar days from the date specified for receipt of offers, unless another time period is specified in an addendum to the solicitation.

(c) Late submissions, modifications, revisions, and withdrawals of offers.

(1) Offerors are responsible for submitting offers and any modifications or revisions to the Government office designated in the solicitation by the time specified in the solicitation.

(2) Any offer, modification, or revision received after the time specified for receipt of offers is "late" and

will not be considered unless it is received before award is made and the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition. However, a late modification of an otherwise successful offer that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

(3) If an emergency or unanticipated event interrupts normal Government processes so that offers cannot be received at the Government office designated for receipt of offers by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation or other notice of an extension of the closing date, the time specified for receipt of offers will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(4) Offerors may withdraw their offers by written notice to the Government received at any time before award.

(d) Contract award (not applicable to Invitation for Bids). The Government intends to evaluate offers and award a contract without discussions with Offerors. Therefore, the Offeror's initial offer should contain the Offeror's best terms. However, the Government reserves the right to conduct discussions, if necessary. The Government may reject any or all offers if such action is in the public interest, accept other than the lowest offer, and waive informalities and minor irregularities in offers received.

(e) Debriefings. If a post-award debriefing is given to requesting Offerors, the Government will disclose the following information, if applicable:

(1) The agency's evaluation of the significant weak or deficient factors in the debriefed Offeror's offer.

(2) The overall evaluated cost or price and technical rating of the successful Offeror and the debriefed Offeror and past performance information on the debriefed Offeror.

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(3) The overall ranking of all Offerors when any ranking was developed by the agency during source selection.

(4) A summary of the rationale for award.

(5) For acquisitions of commercial products, the make and model of the product to be delivered by the successful Offeror. End of Provision.

(6) Reasonable responses to relevant questions posed by the debriefed Offeror as to whether the agency followed source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities. (End of provision)

19. EVALUATION

52.212-2 Evaluation Methodology

Provided as addenda to FAR provision 52.212-2 Evaluation—Commercial Products and Commercial Services (RFO APR 2026) quoters are advised as follows;

The Government will award a contract resulting from this solicitation to the responsible Quoter whose quotation conforming to the requirements of the solicitation, represents the best value to the Government. Best value is defined as Lowest Price Technically Acceptable (LPTA). The Food and Drug Administration intends to award this order without clarification or discussions with Quoters. Each Quoter is encouraged to submit its best and final quote. Federal discounts are highly encouraged.

Based on this solicitation's requirements, the Food and Drug Administration will evaluate quotations to ensure all technical requirements have been adequately met for the quantities required, and quoted prices are complete. Quotes not meeting the requirements of this RFQ will be considered technically unacceptable and therefore shall not be considered for award.

The Food and Drug Administration will evaluate total quoted price for each quotation and will verify the prices are accurate. The Government will verify the mathematical accuracy of the total price computation of all items quoted. The Government will award based on the lowest evaluated price quote meeting the acceptability standards as stated in this RFQ for technical & price factors.

Notice of award. A written notice of award or acceptance of an offer furnished to the successful Quoter within the time for acceptance specified in the offer, shall result in a binding contract without further action by either party. Before the offer's specified expiration time, the Government may accept an offer (or part of an offer), whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award. (End of provision)

(End of Solicitation)

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